Drug Development & Delivery

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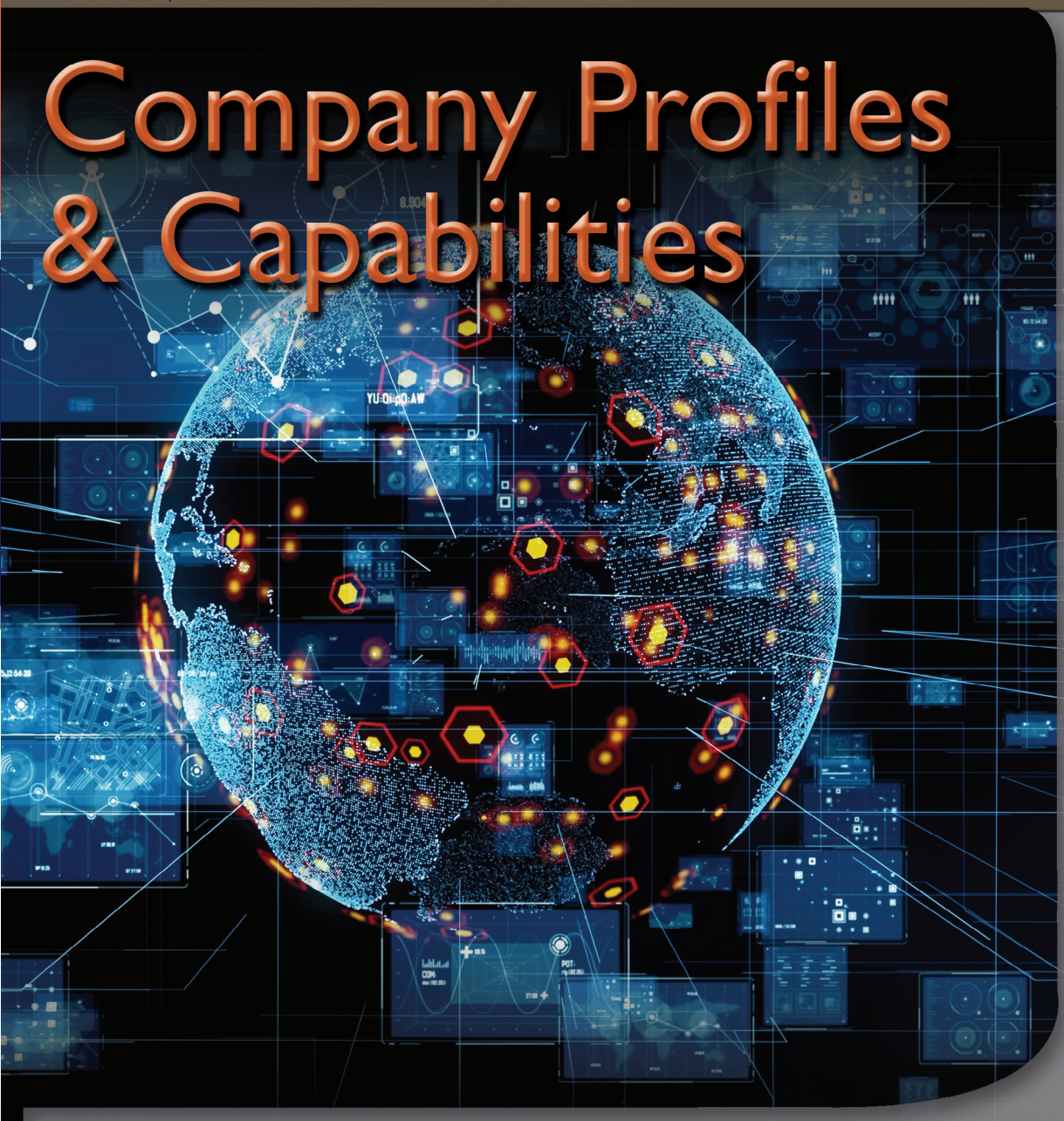

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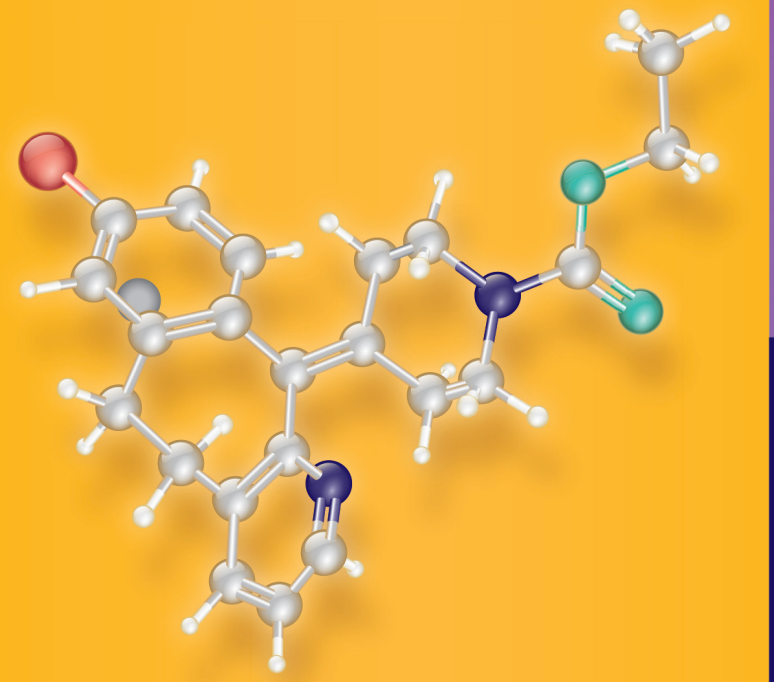

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Corporate/Editorial Office
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CERo Therapeutics Appoints Chris Ehrlich CEO

CERo Therapeutics Holdings, Inc. recently announced its Board of Directors has appointed Chris Ehrlich as CEO. Previously he held the position of Interim CEO.

Mr. Ehrlich commented, "I believe that CERo presents multiple, significant opportunities to make an impact on the market and benefit a significant patient population with both sound science and an experienced team of professionals to drive successful execution. As we draw closer to introducing CER-1236 into the clinic, we continue to make additional pre-clinical progress with CER-1236 and presently intend to file an additional Investigational New Drug Application for CER-1236 in solid tumors, including ovarian and non-small cell lung cancers, in the first half of 2025. We also anticipate having a robust program of publications and presentations throughout 2025. In the meantime, I'm looking forward to continued collaboration with our talented team to potentially drive this unique compound and the underlying science to patients and providers alike. I thank the Board of Directors for their confidence and look forward to providing updates on our successes."

Chris brings significant biotechnology industry, business development, venture capital, and investment banking experience. In addition to his role at CERo, he currently serves as CEO of Launch One Acquisition Corporation. Prior to these appointments he was involved in multiple leadership and transactional roles, including as CEO of Phoenix Biotech Acquisition Corporation, which merged with CERo, CEO of Locust Walk Acquisition Corporation which merged with eFFECTOR Therapeutics and as Senior Managing Director and Head of Biotechnology at Locust Walk. Prior to Locust Walk, he was a Managing Director at Inter-West Partners, a venture capital firm where he served on the boards of KAI Pharmaceuticals, a privately held pharmaceutical company, which was acquired by Amgen, Biomimetic Therapeutics, Inc., which was acquired by Wright Medical Technologies, Invuity, Inc., which was acquired by Stryker and Xenon Pharmaceuticals, a NASDAQ -listed biopharmaceutical company.

In addition to his roles at CERo and LPAA, Mr. Ehrlich currently serves on the Healthcare at Kellogg Advisory Board at Northwestern University. He is the Principal of Ehrlich Bioventures, LLC, an advisory firm which assists emerging biopharmaceutical companies. He has a B.A. in Government from Dartmouth College and an M.B.A. from the Kellogg Graduate School of Management at Northwestern University.

CERo is an innovative immunotherapy company advancing the development of next generation engineered T cell therapeutics for the treatment of cancer. Its proprietary approach to T cell engineering, which enables it to integrate certain desirable characteristics of both innate and adaptive immunity into a single therapeutic construct, is designed to engage the body's full immune repertoire to achieve optimized cancer therapy. This novel cellular immunotherapy platform is expected to redirect patient-derived T cells to eliminate tumors by building in engulfment pathways that employ phagocytic mechanisms to destroy cancer cells, creating what CERo refers to as Chimeric Engulfment Receptor T cells (CER-T).

World's First Zero-Off-Target Base-Edited NK Cell Therapy Receives IND Approval in Both China & US

Base Therapeutics recently announced its NK510 cell injection, the world's first zero-off-target base-edited NK cell product, has received IND approvals from both the US FDA and China's NMPA for clinical trials on advanced solid tumors. This dual approval marks a significant milestone in cancer immunotherapy, leveraging Base Therapeutics' pioneering base-editing technology.

NK cells hold great promise for cancer therapy owing to their innate logic gating performance to recognize cancer cells. However, NK cell-based therapeutics face significant challenges: limited expansion, genetic modification resistance, and immune escape of cancer cells. Base Therapeutics utilizes the proprietary AccuBase base-editing technology to precisely modify genes in human primary NK cells. With an editing efficiency of over 90%, this technology offers a safer and more effective approach to NK cell-based therapies. NK510s are specifically engineered to reprogram their logic gating performance, which enables them to respond to tumor-associated antigens (TAA) and resist immune checkpoint signals. Preclinical and clinical studies have shown robust anti-tumor activity against solid tumors.

Additionally, Base Therapeutics has optimized the ex vivo expansion process for NK510. Through meticulous refining of dozens of processes and hundreds of parameters, the NK510s have been successfully expanded up to millions of times in Base Therapeutics' GMP-compliant facilities, overcoming global challenges such as low expansion rates and low transfection efficiency in allogeneic NK cell products.

AccuBase is a zero-off-target base editing technology developed by Base Therapeutics. Unlike traditional CRISPR technologies, AccuBase directly modifies target DNA bases without inducing double-strand breaks, offering a safer, more precise alternative for gene editing. With proven applications across various cell types and species, AccuBase has garnered international recognition, including non-exclusive licensing to a leading CAR-T cell therapy company.

Advantages of AccuBase inclide, Zero-Off-Target achieved by precise design, Clinical validated performance, High efficiency without compromising cell viability, even in multiplex gene editing, The world's only GMP grade base editor with superior stability in high quality and quantity, The world's only base editor that could be delivered in the form of RNP, and Global FTO.

Founded in 2021, Base Therapeutics is a leading innovator in cell therapy and in vivo gene editing therapies. The company has developed multiple base-edited therapies, including NK510 and several in vivo gene editing projects. By leveraging the proprietary base editing technology, Base Therapeutics

Exclusive UniSafe Distribution Agreement Between Owen Mumford & NIPRO Exceeds Expectations in Japan With New Biosimilar Launch

Owen Mumford, a global leader in medical devices, recently announce its exclusive agreement with Osaka-based NIPRO CORPORATION (NIPRO) to distribute drug delivery device UniSafe® has achieved rapid early growth in combination product sales in Japan.

The agreement has been in place since 2019 and has scored a major new product launch success in delivering a biosimilar product into the Japanese market. This biosimilar is used with cancer medicines.

Since the launch of the product in late 2023, it has already acquired considerable share of its market in Japan, including the original biologic combination product. This success within just the first three months of commercial availability has exceeded expectations at NIPRO and Owen Mumford. Anecdotal feedback indicates this acceptance rate has been accelerated by the existing good reputation of UniSafe on the Japanese market, based on its ease of use and concealed needle.

The biosimilar product is delivered through Owen Mumford's UniSafe safety syringe. UniSafe is a unique springless, passive safety device for 1mL pre-filled syringes which has been designed to overcome some of the challenges of traditional spring-based safety systems. The absence of a spring means UniSafe is reliable, intuitive and easy to use. The design of the secure plunger helps to prevent re-use and accidental removal. UniSafe is also designed to prevent needlestick injury.

Masanobu Iwasa, Director PharmaPackaging Division at NIPRO, said "Japan has a particularly stringent regulatory environment, and so that makes our rapid and early success with the product all the more gratifying. Our careful development process, in tandem with our Owen Mumford partnership, has clearly appealed to clinicians and their patients alike. The product's rapid take-up shows that we are meeting a true market demand."

Tim Holden, Commercial Head, Pharmaceutical Services at Owen Mumford adds: "We are very committed to the Japanese market, with an established presence that has recently been greatly enhanced through our partnership with NIPRO over UniSafe. Healthcare in Japan is growing strongly, with healthcare spending rising by over a fifth between 2018 and 2025. In partnership with NIPRO, we intend to continue bringing innovative therapies to Japanese patients."

Groundbreaking Cretostimogene Grenadenorepvec Monotherapy Data Demonstrates Sustained, Durable Complete Responses in High-Risk BCG-Unresponsive Non-Muscle Invasive Bladder Cancer

CG Oncology, Inc. recently announced topline data from the Phase 3 BOND-003 trial in patients with high-risk Non-Muscle Invasive Bladder Cancer (NMIBC) unresponsive to Bacillus Calmette Guerin (BCG) demonstrating 74.5% of patients (82 out of 110, 95% CI, 65.4% – 82.4%) achieved a complete response (CR) at any time, after receiving treatment with cretostimogene as a single agent. The median duration of response (DOR) has not been reached but exceeds 27 months as of the data cutoff of September 30, 2024. These data will be presented today as a Late-Breaking Abstract at the Society of Urologic Oncology (SUO) 25th Annual Meeting. Additionally, the company is hosting a virtual investor event today at 8 am EST and details to join are included below.

"There continues to be a significant need for new treatment options for patients with bladder cancer," said Gary D. Steinberg, MD, Professor, Department of Urology at Rush University Medical Center. "Therefore, I am very encouraged by the latest data from the BOND-003 study, which demonstrates cretostimogene's compelling efficacy as well as its potential to induce a best-in-class durable response in NMIBC patients, with 63.5% of patients remaining in response at 12 months or greater and 56.6% of patients remaining in response at 24 months or greater, by K-M estimate. Additionally, 97.3% of patients were free from progression to Muscle Invasive Bladder Cancer (MIBC) at 12 months. If approved by the FDA, cretostimogene may represent an important, bladder-sparing, advancement in the bladder cancer treatment paradigm, and meaningfully improve patient outcomes."

There were no Grade 3 or greater treatment-related adverse events (TRAEs) or deaths reported. No treatment-related discontinuation of cretostimogene was observed. 97.3% of patients completed all expected treatments, demonstrating favorable patient adherence and compliance. The most common TRAEs (≥10%) were bladder spasm, pollakiuria, micturition urgency, dysuria, and hematuria.

"The BOND-003 monotherapy data underscores our novel investigational oncolytic immunotherapy's unique product profile, including its dual mechanism of action, which we believe differentiates it from current and investigational NMIBC treatments," said Ambaw Bellete, President & Chief Operating Officer, CG Oncology. "Based upon the latest data, we are confident that cretostimogene is well positioned to address an unmet need for patients as a potential backbone bladder-sparing therapeutic if approved by the FDA."

BOND-003 (NCT04452591) is a single-arm, Phase 3, monotherapy clinical trial for the treatment of patients with high-risk BCG-unresponsive NMIBC with carcinoma in-situ (CIS) with or without Ta or T1 papillary tumors. The fully enrolled global trial with a total of 112 patients is currently ongoing in North America and the Asia-Pacific region. The primary endpoint of the trial is CR at any time, with DOR measured as a secondary endpoint. The highly pre-treated trial population includes patients with prior intravesical chemotherapy and systemic immunotherapy.

Denali Therapeutics Announces First Participant Dosed in Phase 2a Study of LRRK2 Inhibitor, BIIB122, in LRRK2-Associated Parkinson's Disease

Denali Therapeutics Inc. recently announced initiation of dosing in a global Phase 2a clinical study, BEACON, of the investigational drug leucine-rich repeat kinase 2 (LRRK2) inhibitor BIIB122 (DNL151) in participants with LRRK2-associated Parkinson's disease (LRRK2-PD). LRRK2 inhibition is a potential therapeutic approach that may slow progression of Parkinson's disease by targeting underlying lysosomal dysfunction implicated in this disease.

The Phase 2a study is intended to evaluate safety and biomarkers associated with oral daily dosing of BIIB122 in approximately 50 participants with Parkinson's disease and LRRK2 pathogenic mutations confirmed by genetic testing. The study is designed to enroll participants into a double-blind treatment period of three months followed by an open label extension. Denali holds the Investigational New Drug application for this Phase 2a study and is leading its design and execution. This study is being funded under a Collaboration and Development Funding Agreement between Denali and a third party. BIIB122 is also being investigated in the ongoing global Phase 2b LUMA study in participants with early-stage Parkinson's disease with or without a LRRK2 mutation, in collaboration with Biogen.

"We are thrilled to initiate this study and broaden our efforts in evaluating BIIB122 as a potential treatment for people living with Parkinson's disease related to LRRK2 mutations," said Carole Ho, MD, Chief Medical Officer at Denali. "We look forward to continued collaboration with the Parkinson's community as we aim to generate biomarker and safety data to inform how LRRK2 inhibition may have an impact on the course of this disease."

"LRRK2 continues to be a prominent target in Parkinson's research, and a priority area of focus for disease-modifying therapies," added Todd Sherer, PhD, Chief Mission Officer of The Michael J. Fox Foundation. "The Phase 2a study of BIIB122 is a meaningful milestone in advancing the potential of LRRK2 as a therapeutic approach for people with Parkinson's disease."

Following discovery of the LRRK2 mutation as a pathogenic genetic factor for Parkinson's disease, further research has uncovered that it has the potential to be a novel therapeutic target for Parkinson's disease. Pathogenic mutations in LRRK2 account for 4-5% of familial and 1-2% of sporadic Parkinson's disease.

BIIB122 (DNL151) is a selective, central nervous system-penetrant small molecule inhibitor of LRRK2 that is hypothesized to improve lysosomal dysfunction.

Denali's strategic partner Biogen is conducting the global Phase 2b LUMA study of BIIB122, which is expected to enroll approximately 640 participants with early-stage Parkinson's disease, including eligible participants with LRRK2 mutations.

The Phase 2a BEACON study is a multicenter, randomized, 12-week double-blind, placebo-controlled, parallel-group study, followed by an open label extension in participants with LRRK2-PD, which is defined as Parkinson's disease in individuals who are heterozygous or homozygous carriers of a pathogenic LRRK2 variant that increases LRRK2 kinase activity. This study's purpose is to evaluate the safety, tolerability, and pharmacodynamic effects of BIIB122.

BIIB122 is an investigational drug that is not approved by any regulatory authority, and its safety and efficacy have not been established.

8 Years Survival With Complete Cure for a Patient With Advanced Liver Cancer Being Treated With Namodenoson Drug

Can-Fite BioPharma Ltd. recently announced a patient currently treated with Namodenoson in a compassionate use program in Can-Fite's Phase 2 Liver Cancer Study has an overall survival time of 8 years with a complete response.

The patient, who suffered from advanced liver cancer was enrolled in the former Can-Fite Phase 2 study, continue to be treated with Namodenoson, and has now an overall survival of 8 years, with disappearance of ascites, normal liver function, good quality of life and is defined as a long term complete response.

Can-Fite is currently enrolling patients in Israel, Europe and the US for a pivotal Phase 3 clinical study for patients with advanced HCC as a 2nd or 3rd line treatment and Namodenoson is administered twice daily orally. The study protocol has been agreed upon with US FDA and European Medicines Agency (EMA).

Namodenoson has Orphan Drug status with both the FDA and EMA, as well as Fast Track Status with the FDA for the treatment of HCC. A compassionate use program has been ongoing in Israel and Romania.

"With a very favorable safety profile and anti-cancer effect of Namodenoson, we are now enrolling patients for the pivotal Phase 3 clinical study where we expect to prolong patients' overall survival, and see a response similar to that of the patient who has now been treated with Namodenoson for 8 years. The uniqueness of Namodenoson which specifically acts against the tumor cells and protects the normal liver cells, is the rationale for the conductance of the current trial," said Prof. Salomon Stemmer, a leading key opinion leader, at the Institute of Oncology, Rabin Medical Center, Israel.

According to the American Cancer Society, liver cancer accounts for more than 700,000 deaths globally each year. HCC is commonly aggressive with poor survival rates. As new drugs that effectively and safely treat HCC are developed and approved, the market for HCC treatments is estimated by Delveinsight to reach $6.1 billion by 2027 for the G8 countries.

Namodenoson is a small orally bioavailable drug that binds with high affinity and selectivity to the A3 adenosine receptor (A3AR). Namodenoson was evaluated in Phase II trials for two indications, as a second line treatment for hepatocellular carcinoma, and as a treatment for non-alcoholic fatty liver disease (NAFLD) and non-alcoholic steatohepatitis (NASH). A3AR is highly expressed in diseased cells whereas low expression is found in normal cells. This differential effect accounts for the excellent safety profile of the drug.

Lonza Launches Tailored Offering for Smart Capsules Companies Developing Oral Delivery Solutions for Biologic Drugs

Lonza, a global manufacturing partner to the pharmaceutical, biotech and nutraceutical markets, recently announced an expansion of its service offering for orally delivered biologic therapies to support the unique development and manufacturing needs of smart capsules companies.

Oral delivery of active pharmaceutical ingredients (APIs) is the preferred route of administration by patients worldwide, leading to improved patient compliance and adherence, and drug accessibility. In addition, delivering biologics through an oral administration route represents a growing market that is expected to exhibit 35% CAGR from 2023-2028. Since most new drug entities face bioavailability challenges, exploring innovative delivery solutions to mitigate these challenges is of great value to drug developers and their patients.

Smart capsules, designed to enhance precision, efficacy, and control by using electronic or mechanical elements to deliver drugs to the stomach or intestine, have the potential to revolutionize the oral biologics market. They have promising applications in areas such as diabetes, obesity, and other therapeutic fields. To meet the needs of this innovative field, Lonza has expanded its offering for orally delivered biologics with a bespoke development and manufacturing service focusing on the specific needs of smart capsules companies. The offering leverages Lonza's expertise in highly customized capsule solutions tailored to specific requirements, including size, design, and lock mechanisms. It also offers a variety of functionalities, such as targeted release using a bi-layer manufacturing technology, adjustable to the needs of the respective API.

Bart Pelgrims, Vice President, R&D, Capsules & Health Ingredients, Lonza, said "The strong market interest in this bespoke offering for smart capsules, marked by the first customer already on board and additional discussions in progress, reinforces the value of our approach. By ensuring every detail of development, which goes beyond formulation, we are confident in our ability to support smart capsule innovators to help shape the future of healthcare."

The expanded service offering for orally delivered biologic therapies is being offered at Lonza's recently launched Innovaform Accelerator in Colmar (FR). The Innovaform Accelerator is a Center of Excellence for developing and innovating capsule-based manufacturing and delivery solutions for oral and pulmonary administration.

PTC Therapeutics Enters Global License & Collaboration Agreement With Novartis

PTC Therapeutics, Inc. recently announced the signing of an exclusive global license and collaboration agreement with Novartis Pharmaceuticals Corporation, a subsidiary of Novartis AG (NYSE: NVS), for its PTC518 Huntington's disease program, which includes related molecules. Under the agreement, PTC will receive an upfront payment of $1.0 billion, up to $1.9 billion in development, regulatory and sales milestones, a profit share in the U.S., and double-digit tiered royalties on ex-US sales.

"PTC518 is the leading oral disease-modifying therapy in development for Huntington's disease and the economics of this agreement are consistent with the promise of this treatment," said Matthew B. Klein, MD, Chief Executive Officer, PTC Therapeutics. "This collaboration combines PTC's expertise in developing small molecule splicing therapies with Novartis's expertise in global development and commercialization of neuroscience therapies. We are excited to collaborate with Novartis to accelerate the potential of PTC518 for the hundreds of thousands of HD patients worldwide in need of a therapy designed to be well-tolerated and an effective disease-modifying therapy. PTC will use the proceeds of this transaction to expand our splicing platform as well as to support commercial and development portfolio activities."

"Huntington's Disease is a devastating, fatal, familial disease. This agreement with PTC is intended to bolster our neuroscience pipeline and reflects our strategic focus and commitment to explore new and potentially transformative approaches for neurodegenerative diseases with high unmet needs," said Vas Narasimhan, CEO of Novartis. "We look forward to building on our expertise in neurodegenerative diseases and experience in HD with the intention to advance this potential first in class oral therapy for the HD community."

PTC518 was discovered from PTC's validated splicing platform and is currently being studied in the ongoing Phase 2 PIVOT-HD trial. Interim results reported in June 2024 demonstrated that PTC518 treatment resulted in durable, dose-dependent reduction in blood and cerebrospinal fluid (CSF) mutant Huntingtin protein (HTT) levels as well as early signals of dose-dependent benefit on key clinical measurements at 12 months. Importantly, PTC518 continues to demonstrate a favorable safety and tolerability profile.

Novartis will assume responsibility for PTC518's development, manufacturing and commercialization, following the completion of the on-going placebo-controlled portion of PIVOT-HD, which is expected to occur in H1 2025.

The companies will share U.S. profits and losses, on a 40/60 basis (40% PTC and 60% Novartis).

The closing of the transaction is subject to customary closing conditions, including regulatory clearance. The parties anticipate that the agreement will close in the first quarter of 2025.

XOMA Royalty Acquires Pulmokine for $20 Million Adding the Royalty & Milestone Interest in Seralutinib, a Phase 3 Asset, to Its Portfolio

XOMA Royalty Corporation recently announced it now owns an economic interest in seralutinib, a Phase 3 asset being studied in pulmonary arterial hypertension (PAH), through its acquisition of Pulmokine Inc., a privately held company. In 2017, Pulmokine licensed seralutinib to Gossamer Bio, Inc., and in 2024, Gossamer Bio signed a global collaboration and license agreement with Chiesi Farmaceutici S.p.A.

"We acquired Pulmokine to add seralutinib, a Phase 3 asset with strong mechanistic rationale in PAH, to our growing royalty and milestone portfolio while creating a favorable outcome for Pulmokine's founders and stockholders. In addition, we believe seralutinib has the potential to address several cardio-respiratory conditions beyond PAH in the future," stated Brad Sitko, Chief Investment Officer of XOMA Royalty. "This transaction marks the second whole-company acquisition we have completed in 2024. We continue to offer creative royalty capital solutions to access assets with the potential to deliver attractive returns to XOMA Royalty's diverse portfolio."

XOMA Royalty acquired all outstanding shares of Pulmokine for a $20 million cash payment at closing. In addition, XOMA Royalty will pay success-based consideration contingent on future development and commercial events to Pulmokine stockholders. XOMA Royalty's net royalties will range from the low to mid-single digits on commercial sales; additionally, the Company will retain up to $25 million of the milestone payments.

XOMA Royalty was represented by Gibson, Dunn & Crutcher LLP.

XOMA Royalty is a biotechnology royalty aggregator playing a distinctive role in helping biotech companies achieve their goal of improving human health. XOMA Royalty acquires the potential future economics associated with pre-commercial therapeutic candidates that have been licensed to pharmaceutical or biotechnology companies. When XOMA Royalty acquires the future economics, the seller receives non-dilutive, non-recourse funding they can use to advance their internal drug candidate(s) or for general corporate purposes. The Company has an extensive and growing portfolio of assets (asset defined as the right to receive potential future economics associated with the advancement of an underlying therapeutic candidate). For more information, visit www.xoma.com.

Formulation Forum

Nanoparticle Technology for Nose-to-Brain Drug Delivery

By: Shaukat Ali, PhD, Sr. Director, Scientific Affairs & Technical Marketing, and Jim Huang, PhD, Founder & CEO, Ascendia Pharmaceuticals Inc.

Shaukat Ali, PhD
shaukat.ali@ascendiapharma.com

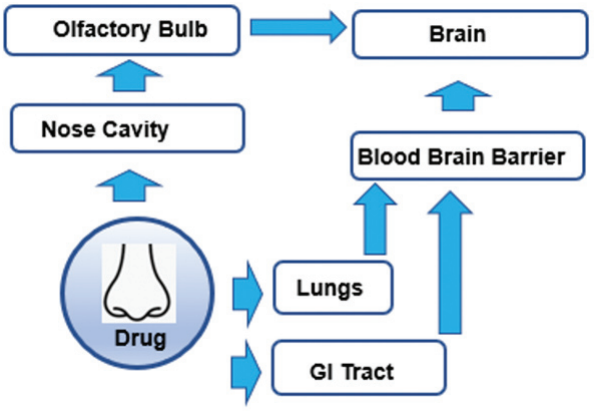
Jim Huang, PhD
j.huang@ascendiapharma.com

INTRODUCTION

Central nervous system (CNS) disorders affect millions globally. Many of those life ailments are not treatable due to restricted passage through the blood brain barrier (BBB), making the drug impassable through the tight junctions. As a result, it creates challenges for treatment of diseases like Alzheimer's disease, Parkinson's epilepsy, schizophrenia, and brain tumors like glioblastoma.[1] Oral administration of drugs could have low bioavailability in the brain due to poor GI absorption and/or first-pass hepatic metabolism, requiring frequent dosing to maintain the concentration of drugs in plasma passing through the BBB. All these factors thus diminish the efficacy of drugs via the oral (po) route. Therefore, a more efficient method is highly desirable to deliver drugs to the brain through the BBB without compromising its efficacy. Though the BBB plays an important role in protecting the CNS from toxins, pathogens, inflammation, and other diseases, the BBB with extensive tight junctions also severely restricts cell permeability.[2]

Nasal delivery is one of the most ideal routes of administration for delivery of drugs through the BBB, which first bypass the hepatic clearance, and second yield better efficacy by directly penetrating the membranes in the nasal cavity to brain.[3] The nasal cavity with its relatively low volume of 25 cm^3 allows only limited liquid volume (ca. 100-200 µl). The nasal cavity is composed of a vestibular area, respiratory area, and olfactory area. The drugs are mainly absorbed through epithelial cells as they contain a large number of pharyngeal cells, cilia cells, intermediate cells, and basal cells.[4] Thus, absorption through epithelia cells allows drug to enter the systemic circulation.[5] Whereas the olfactory region, composed of sustentacular cells, basal cells, and sensory neurons, helps penetrate drug molecules to the brain through membrane permeation.[6] Taken collectively, there are two key mechanisms by which the drugs enter the brain; one through systemic circulation and via lungs or GI tract by overcoming the BBB, and the other through the olfactory system, as shown in Figure 1.[7]

FIGURE 1



Transport Mechanism of Drug Through Nose to Brain (N2B).

LIPID NANOPARTICLES FOR NOSE-TO-BRAIN (N2B) DELIVERY

Intranasal (IN) is a non-invasive route of administration to overcome the BBB. Hydrophilic drugs with higher molecular weight have lesser tendency to penetrate the BBB, but when formulated and protected in polymeric and lipid nanoparticles, their permeation increases significantly due, in part, to enhanced permeability, better stability, and longer resident time. These nanoparticles armed with surface-modified specific ligands and antibodies can further enhance longer resident time by interacting with the specific transporters or receptors.

Lipid-based carriers are considered safe for intranasal delivery of

TABLE 1

Nanoparticle	Drug	Disease	Observation	Reference
Liposomes	Imatinib mesylate	Alzheimer's	150 nm PSD, controlled release over 96 hrs, 7-fold AUC increase in liposomes vs oral and IN solution	8
Liposomes	Lomustine & propyl gallate	Glioblastoma	PSD 127 nm, zeta potential, -34 mV; 64%-74% drug loading, increased solubility, permeation, reduced antiproliferative effects on all cell types	9
Nanoemulsions (NEs)	Tetrabenazine	Huntington's	107 nm PSD, zeta potential -9.63 mV; 1.68-fold increase permeation in NE vs aq. Solution	10
Solid lipid nanoparticles (SLNs)	Risperidone	Schizophrenia	Higher AUC in IN vs IV route, reduced systemic side effect due to half conc. of IV dosing	11
Nanostructured lipid nanocarriers (NLCs)	Buspirone	Anxiety Disorder	AUC 3-fold higher BA vs IV and 2-fold vs IN solution	12

Nanoparticle Carriers for IN Drug Delivery

drug because of their low toxicity, improved stability, and higher drug encapsulation efficiency. Designed as liposomes, nanoemulsions, solid lipid nanoparticles (SLNs), and nanostructured lipid carriers (NCLs) among others, they have been investigated in IN drug delivery. In fact, these lipid nanocarriers help protect drug molecules from degradation by nasal mucosa in the nasal cavity while targeting the brain. Table 1 cites a few examples of drugs in lipid carriers composed of different assemblies.

As indicated in the Table 1, there are a number of drugs investigated via the IN route of administration to overcome the BBB. Lipid nanoparticles are comprosed of lipids and often stabilized with surfactants or Pegylated lipids for yielding longer circulation and stability. LNPs are prepared by several methods, including reverse phase evaporation, extrusion, microfluidics, sonication, and high pressure homogenization depending upon lipid components and drugs.[7]

PLGA-BASED DRUG DELIVERY

Polymeric nanoparticles are another dosage form that have widely been investigated in nasal delivery of molecules. For example, PLGA, which is a biocompatible polymer composed of lactic acid and glycolic acid, has been investigated extensively via the IN route. PLGA nanoparticles containing olanzapine have shown a 10-fold increase in C_{max} versus solution.[13] Likewise, oxcarbazepine containing PLGA nanoparticles showed significantly higher pharmacokinetic behavior versus solution.[3] Table 2 lists a few of the selected studies with polymeric nanocarriers aimed at improving the bioavailability of drugs via intranasal routes to brain.[14]

NANOCRYSTALS FOR N2B DRUG DELIVERY

Nanocrystal (NC) drugs are often used to improve the solubility of drugs. Essentially stabilized with polymers, lipids, and surfactants, the NC can be used as liquid suspensions and administered via the IM or subcutaneous and oral routes. When administered intranasally to target the brain, NC can potentially pose challenges like local irritation due to high concentration, lower absorption, and lack of *in vivo* fate about undissolved molecules. Given the low volume of drug in the nasal cavity, NC can help to increase drug loading, dissolve slowly, and promote drug permeation across the mucosal barrier leading to prolonged residence time with the help of mucus adhesive polymer, and hence, enhanced targeting to brain. Table 3 lists a number of NC-based drugs investigated for targeting the brain via intranasal route.

Table 3 highlights some of the recent advances in nasal drug delivery targeting the brain for a variety of ailments by using NCs. Most of them have been targeted for CNS diseases and marketed also by the parenteral or oral route of administration. N2B delivery; however, offers advantages for accumulating the drug in the brain by direct administration

TABLE 2

Polymer	Drug	Disease	PSD, nm	PDI	Functionality	Reference
PLGA	Diazepam	Epilepsy	148-337	0.04-0.45	Mucopenetration	15
Lf-PEG-PCL	Octapeptide	Alzheimer	88	0.22	Lf active targeting	16
Lf-PEG-PLGA	Rotigotine	Parkinson's	122	0.194	Lf active targeting	17
WGA-PEG-PLGA	miR132	Alzheimer	191	0.250	WGA active targeting	18
TAT-PEG-PCL	Anti-TNF-a	Cerebral Ischemia	62	n/a	Tat cell permeation	19

List of Selected Polymers for IN Delivery of Drugs to the Brain

TABLE 3

Drug	Disease	PSD (nm)	PDI	Stabilizer	Preparation Method	Result	Reference
Resveratrol	Model drug	241	0.234	Gellan gum	Precipitation	Increased absorption to brain vs IV	20
Zotepine	Antipsychotic	330	n/a	Poloxamer 407, HPMC and phospholipid	High pressure homogenizer	Enhanced accumulation in brain	21
Paeoniflorin	Parkinson's	156	0.102	Vitamin E-TPGS	Precipitation	Transmucosal permeation to brain	22
Clozapine	Antipsychotic	281	n/a	Vitamin E-TPGS/PVP	High pressure homogenization	Accumulation in brain via transmucosal permeation	23

List of Nanocrystals for IN Delivery to the Brain

through the nasal cavity and absorption via olfactory lobes. The physiochemical properties, such as molecular weight and lipophilicity, influence the diffusion of drugs from nose to brain. For example, molecules like proteins, peptides, or nucleic acids with a size of 300 D or highly hydrophilic drugs, have a tendency to lower permeability compared to more lipophilic molecules.[24] These molecules hence are likely to be transported through receptor mediator receptors like insulin and oxytocin.[25, 26]

ROLE OF PENETRATION OR PERMEATION ENHANCERS

Biomolecules in combination with permeation enhancers can lead to N2B transport more effectively. For example, nanoparticles linked with permeation enhancers, such as trans-activator of transcription (TAT) protein composed of 13 amino acids, can lead to efficient delivery of insulin over 6-fold through PLGA NPs when administered intranasally.[27] Other example includes siRNA delivery via PEG-PCL micelles, which is more effective, attributed primarily due to smaller particle size (20-35 nm) when modified with TAT protein.[19] There are other examples of permeation enhancers, such as surfactants, which enable the transport of drugs from N2B by nanoparticles. Inclusion of the enhancers in NPs should be limited to alleviate any long-term adverse effects or prevent any immunological issues.[28] Bioavailability of simvastatin in polymeric micelles via the intranasal route was dependent upon the particle size. In fact, the particles ranging between 100-700 nm showed significantly higher transportation through the nasal cavity to the brain. Other factors, such as surface properties and composition of NPs, are equally important in influencing the penetration of drug to the brain. For instance, polysorbate 80 (PS80) used in polycaprolactone (PCL) nanoparticles influenced the permeability of drugs through mucus via diffusion.[29]

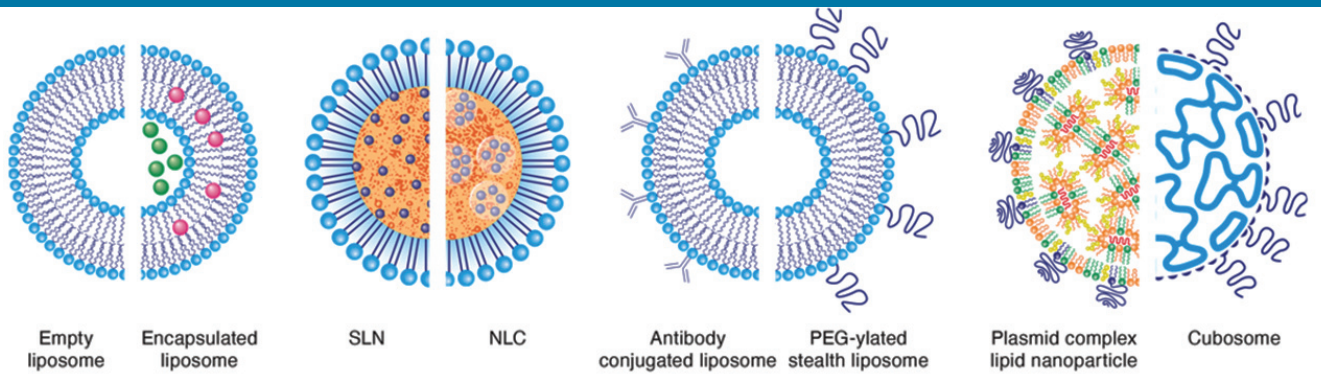
CONCLUSION & FUTURE PERSPECTIVE

In the past, nanotechnology has gained considerable attention in drug delivery, especially in N2B delivery. The challenges, however, remain in finding the right lipid components to penetrate the BBB and also in designing and scaling up of LNPs. Multiple nanocarriers now well-designed and characterized, such as liposomes, NEs, SLNs, NLCs, and others like polymeric nanocarriers, micelles, nanogels, have yielded a much better understanding of drug delivery and targeting to the brain. A majority of nanocarriers range in particle size 50-200 nm; however, the smaller ones have a greater chance to succeed in transporting the drug to the brain via the IN route. The nanoparticles bearing negative or neutral surface charge might have a greater impact on N2B transport. Use of permeation enhancers and pegylated compounds will also aid in transport of drugs via N2B.

Many other obstacles remain with high molecular weight peptides and proteins, lower membrane permeability, mucociliary clearance, and enzymatic degradation in the nasal cavity. Using innovative formulation strategies, novel excipients, and devices could help improve the bioavailability of drugs via the IN route. With the emergence of microfluidics, membrane emulsion technology among others, scale up is possible, which could help expedite the manufacturing of nasal NP product formulations to the clinic faster. As we continue our investigation of innovative delivery routes for drug molecules besides the parenteral and oral routes, the IN route remains the future method for drug delivery to the brain. Several biomolecules, including proteins, peptides, and biologics, are currently in clinical studies awaiting successful outcomes. Only a limited number of trials are listed on the clinicaltrials.gov site for nasal delivery of drug through the BBB.[30]

Ascendia's LipidSol™, a lipid-based enabling platform technology offers an opportunity for exploring small and larger molecules in nanoparticles.[31] Designed with FDA approved lipids, polymers, and surfactants, LipidSol (Figure 2) can help create a variety of nanoparticles to improve the permeability and

FIGURE 2



LipidSol Assemblies for Delivery of Small & Large Molecules

enhance bioavailability of molecules for absorption through olfactory systems. Other enabling technologies, such as EmulSol® and NanoSol®, could also be applicable for small and large molecules destined to be delivered intranasally. ◆

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Drug Development
EXECUTIVE

Josh Marsh

Bioavailability Enhancement & PBPK Lead Scientist

Lonza

Lonza

Lonza: Utilizing Analytical Tools & Predictive Models to De-Risk Drug Development

The high risk of failure, combined with the significant investment of time, labor, and financial resources in each new drug candidate, presents a constant challenge for drug developers. To maximize development efficiency and ensure safe, effective, and reliable products for patients, drug developers seek a strategic partner to help de-risk the process at every stage. Overcoming these challenges often requires the expertise of a contract drug manufacturing organization (CDMO), who can provide support from the earliest stages of development through commercialization. With advanced technologies, predictive tools like PBPK modeling, and deep experience, CDMOs can improve dissolution rates, solubility, and overall bioavailability, helping guide drug developers from candidate compound to clinical success.

Drug Development & Delivery recently interviewed Josh Marsh, Bioavailability Enhancement and PBPK Lead Scientist at Lonza, to discuss the benefits of predictive tools and Lonza's approach.

Q: What challenges do drug developers face in early development?

A: Drug development continues to advance our understanding about causes of disease, as well as to innovate therapeutic modalities. Yet, the process remains time intensive, costly, and high risk. The average drug takes over 10 years and $1 billion-$2 billion to be approved for clinical use — yet 90% of new drugs reaching Phase 1 clinical trials ultimately fail to reach approval.[1]

This high risk of failure, along with the substantial investment of time, labor, and financial resources allocated to every new drug candidate, poses a persistent challenge for drug developers. For example, when a problem with the shelf stability of a drug product is discovered while clinical trials are already underway,

development progress stops, and all batches of the drug product must be reworked. Ultimately, these delays impact patients getting access to innovative treatments.

To ensure the efficient use of development resources and the creation of safe, effective, and reliable products for patients, it is essential for drugmakers to find a strategic partner, such as a CDMO, with expertise to help to de-risk development at every step.

Q: Poorly soluble molecules are becoming more prevalent in early phase development. What tools and strategies can be used to enhance formulation?

A: The earliest phases of clinical development are critical and within the past 5 years, we have seen an increase in poorly soluble molecules. CDMOs also are faced with the challenge to develop new and innovative approaches that help the drug developers' journey from clinical to scale-up.

To tackle this issue, one effective strategy involves the use of PBPK modeling. This tool can simulate the dissolution, absorption, distribution, and clearance rates of a drug in the body, helping to identify potential solubility-related issues early in the development process. By providing insights into the underlying mechanisms of drug absorption, distribution metabolism, and clearance, PBPK models help enhance formulation in early phase development.

To build on the insights gained from PBPK modeling, combining it with biorelevant *in vitro* dissolution testing offers additional advantages to the formulation and API form (salt, co-crystal, etc) screening process. In instances of a molecule being flagged for a particular absorption risk *in silico*, the risk can be further assessed *in vitro* to understand the relative impact on solubilization, dissolution, and precipitation. Additionally, an understanding of the potential for an enabled formulation or API form to overcome the identified risk relative to the free form can be developed. The *in vitro* data can then be incorporated into the in silico model, further refining the understanding of the molecule and potential strategies of progressing a molecule into preclinical and clinical studies.

In addition to PBPK modeling, high-throughput experimentation (HTE) for drug substance is another valuable tool. HTE facilitates the miniaturization and parallelization of chemical reactions, allowing for the rapid testing of a broad spectrum of reagents, solvents, catalysts, and conditions. It enables the assessment of various routes, thereby increasing the likelihood of identifying optimal conditions early in the project's timeline.

Q: Drug development is notoriously high risk and expensive. How can the integration of tools like PBPK modeling, solid form screening, and retrosynthetic analysis significantly improve the odds of success for a drug candidate?

A: Drug development is a complex and high-risk endeavor, fraught with challenges in the earliest stages of development that can lead to costly hurdles. Key sources of risk include toxicity, drug-drug or food-drug interactions, poor solubility, low bioavailability, and insufficient potency. Additionally, intellectual property constraints, regulatory hurdles, and supply chain disruptions can pose significant challenges.

To increase the likelihood of success, developers must proactively address risks related to safety, efficacy, and manufacturability. One approach is utilizing advanced computational tools, such as PBPK modeling. PBPK modeling helps predict a drug's ADME (absorption, distribution, metabolism, excretion) profile, enabling more informed decision-making in preclinical and clinical development. Another approach is solid form screening to ensure drug stability and bioavailability by optimizing the physical properties of the drug for formulation. Lastly, retrosynthetic analysis can enhance synthetic route design, leading to more efficient, scalable, and cost-effective production.

By integrating these tools, developers can de-risk critical steps in the drug development lifecycle, increasing the chances of bringing safe, effective therapies to market. Lonza's Small Molecules division offers a comprehensive suite of tools and expertise to support clients throughout the entire drug development

Q: Solid form screening is often overlooked in early drug development. Why is it crucial to invest in this process early on, and what impact can it have on the overall development timeline and cost?

A: Solid form screening involves the search, preparation, and characterization of different solid forms of an active pharmaceutical ingredient (API). This process includes selecting a preferred form, designing methods to isolate that form, and ensuring the lead form's stability and performance. Researchers must also identify a compound's possible polymorphs, which are different molecular arrangements in the crystalline lattice.

Investing in solid form screening early in the development process is crucial for several reasons. Firstly, it helps identify the lead form of an API, which is essential for the drug's stability,

solubility, dissolution rate, and overall manufacturability. By selecting an optimal solid form early on, developers can significantly shorten the development timeline and reduce costs.

Moreover, solid form screening provides valuable insights that extend beyond selecting a lead form. It aids in de-risking and optimizing every stage of drug development, from lead form identification to intellectual property (IP) protection. This comprehensive approach ensures the chosen solid form will perform well throughout the drug's lifecycle, ultimately leading to a more efficient and cost-effective development process.

Q: How does retrosynthetic analysis contribute to the overall efficiency of drug development? Can you share examples of how this tool has helped accelerate the discovery and development of new drug candidates?

A: The emergence of sophisticated therapeutic modalities, such as induced proximity technologies and synthetic nucleic acid therapeutics, bring more complexity to the drug development process. Consequently, process chemists frequently encounter new molecular entities (NMEs) whose preparation demands over 20 synthetic steps — a sharp contrast from the roughly 8-step average observed nearly 2 decades ago. This added synthetic complexity becomes a major challenge for small and emerging biotechnology companies in the earliest stages of development, as each synthetic step requires extensive development and optimization before scale-up.

To address this, pharmaceutical and cheminformatics innovators developed advanced computer-aided synthesis planning tools (CSPTs) to defray the impacts of finding first-generation process routes to complex targets. For instance, when chemists provide a molecule target to a CSPT, the software estimates the shortest — from the target back to available starting materials — with the highest probability of success, thus improving efficiency.

At Lonza, we combine our extensive proprietary commercial data in a leading computer-aided synthesis planning technology. Using this technology, which is enabled by artificial intelligence, process research and development experts can deliver synthetic pathways in full consideration of real-world raw material costs and availability, along with actionable supply chain information. This results in direct synthetic pathways to their drug candidates, have more resilient raw material supply chains, and experience accelerated process R&D start-up times.

Q: Given the increasing complexity of drug molecules, how do you see the role of these predictive tools evolving in the future? What new capabilities or applications might we expect to see?

A: In terms of industry impact, we expect PBPK modeling to continue to grow in popularity with sponsors, CDMOs, and regulatory agencies. The mechanistic approach required to develop a PBPK model allows us to have a deeper understanding of the critical properties of a molecule or formulation. This provides perspective on whether an API is likely to make it to clinical or commercial stages.

Regarding new capabilities for analysis, we can foresee retro-synthesis becoming more sophisticated in the coming years, especially given the current prevalence of AI-enabled technology. AI may help retrosynthetic analysis tools handle large data sets more efficiently, resulting in more unique solutions to client needs.

Lastly, as the structural complexity of molecules in development increases, predictive methods relying upon structure-activity relationship may fall short in terms of predicting critical ADME properties. Alternative screening methods will be needed to understand parameters such as permeability, clearance, and first-pass metabolism. For example, organ on a chip (OoC) assay, which have existed for over 20 years, can measure ADME properties that can be used as inputs for an in silico model, enabling the development and refinement of a predictive PBPK model. As OoC systems advance, their data is further integrated into PBPK modeling. This will provide greater opportunity to decrease unnecessary animal and human testing while increasing confidence in predictive models. ◆

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MULTILAYER PLASTIC VIALS

OXYCAPT™: Contributing to Stability of Cell & Gene Therapy Products

By: Shota Arakawa, MSc, and Tomohiro Suzuki

INTRODUCTION

Mitsubishi Gas Chemical (MGC) is a leading company in the field of special polymers with oxygen-absorbing and barrier functions. In 2019, MGC launched new products named OXYCAPT™ Multilayer Plastic Vials, featuring a high oxygen, carbon dioxide, and ultraviolet barrier. Since then, a lot of biologics and cell and gene therapy companies have started their evaluations, and we have received positive results from them.

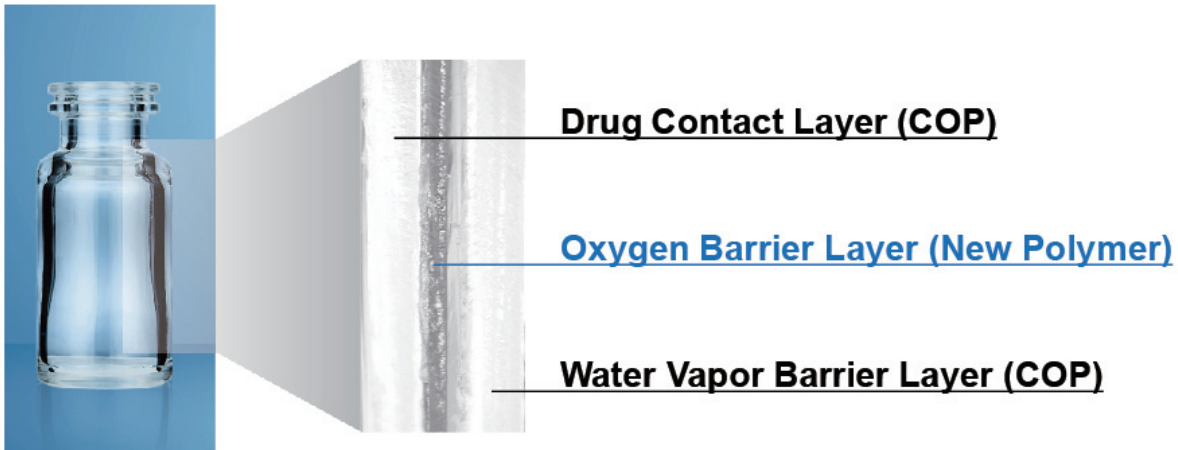
As cell and gene therapy products are usually stored under harsh conditions, such as deep-cold or cryogenic temperatures, the property of containers has been more focused recently. Glass vials have been used for injectable drugs for many years, but they have issues of breakage and container closure integrity (CCI) when stored at deep-cold or cryogenic temperatures. Alternatively, polymer vials are often used for cell and gene therapy products, but some issues, such as breakage at -180°C and CCIT during the thawing process, have been found. Under these situations, we developed OXYCAPT Multilayer Plastic Vials that can overcome such drawbacks.

OVERVIEW OF OXYCAPT™

OXYCAPT is a multilayer plastic vial developed by MGC, offering several advantageous properties as a primary drug container, such as excellent oxygen, carbon dioxide, and ultraviolet (UV) light barrier, strong water vapor barrier, very low extractables, high pH stability, low protein adsorption and aggregation, high transparency, high break resistance, easy disposability, and light weight, etc.

OXYCAPT consists of three layers: the drug contact layer and the outer layer are made of COP, and the oxygen barrier layer is made of MGC's novel polyester.

As stated previously, OXYCAPT provides an excellent oxygen and carbon dioxide barrier. For example, the oxygen and carbon dioxide barrier of an OXYCAPT vial is about 20 times better than that of a COP monolayer vial. OXYCAPT also provides an excellent UV barrier. While about 70% of 300 nm UV light transmits through glass and COP, only 1.7% transmits through OXYCAPT. We have confirmed this feature contributes to the stability of biologics. The water vapor barrier of OXYCAPT is similar to those of COP, which has been used for injectable drugs for many years.



Number of Broken and Leaked Vials

	OXYCAPT™ Vial	COP Monolayer Vial
Breakage	0/20	8/20
Leakage	0/20	8/20

Broken COP Monolayer Vial

This means OXYCAPT easily meets the requirements of a water vapor barrier proposed by the ICH guideline.

Studies have shown an extremely low level of extractables from OXYCAPT. One study was conducted to confirm the levels of volatile, semi-volatile, and non-volatile impurities from OXYCAPT. Water and four solutions (50% ethanol, NaCl, NaOH, and H3PO4) were selected, and impurities were measured by gas chromatography mass spectrometry (GC-MS) and liquid chromatography-UV spectroscopy-mass spectrometry (LC-UV-MS) after 70 days at 40°C. Compared with the control, impurities were not detected in the OXYCAPT containers. The other study confirmed inorganic extractables levels from OXYCAPT were similar to those from COP, which is well known as an extremely pure polymer with a better extractables profile than Type 1 glass. Lower levels of inorganic extractables are known to contribute to the stability of pH in drug products.

OXYCAPT vials are produced by co-injection blow-molding technology. We have also developed inspection methods to test the oxygen barrier layer. All of the containers are fully inspected by state-of-the-art inspection machinery. We can offer ready-to-use (RTU) vials in standard nest and tub or tray formats. These formats are mainly sterilized using gamma rays. There are 2-, 6-, 10-, and 20-mL variants for the vials.

Each polymer meets the requirements of United States Pharmacopeia (USP) 661, 87, and 88, as well as those of the European Pharmacopeia, and has been filed in the US FDA's drug master file (DMF). OXYCAPT vials are also compliant with each pharmacopoeia and have been filed in the DMF.

BREAK RESISTANCE AT CRYOGENIC TEMPERATURE

Break resistance is one of the important factors for vials for cell and gene therapy products stored at deep-cold or cryogenic temperature. Because cell and gene therapy products are very expensive and valuable for patients, break resistance is an essential property to prevent unexpected losses. To confirm the efficacy of OXYCAPT, we conducted some dropping tests using OXYCAPT and COP vials. As glass is always broken after these tests, we didn't add it to the sample list.

First, we prepared OXYCAPT 10R vials filled with 5 mL of water and stored them at -80°C for 1 week, 6 months, and 2 years. All the vials were dropped from 150-cm height after each storage period and inspected by naked eyes. No breakage and water leakage were observed in the vials after the dropping test.

Second, we prepared OXYCAPT and monolayer COP 10R vials filled with 10 mL of water and stored them in liquid nitrogen gas phase (around -180°C) for 1 month. All the vials were dropped from 150-cm height and inspected by naked eyes. No breakage and water leakage were observed in OXYCAPT, but some of monolayer COP vials were broken after the dropping test. We assume there is a risk that medical workers, such as doctors and nurses, drop the expensive and precious drugs by mistake, so the break resistance is an essential property for such high value products.

CONTAINER CLOSURE INTEGRITY AT -80°C WITH DRY ICE

All pharmaceutical containers must maintain integrity against microbial contamination and have a gas barrier when a drug is sensitive to oxygen or carbon dioxide (CO_2). Gene therapy drugs are usually stored at deep-cold temperature and transported with dry ices. During storage and transportation, packages, including vials, are exposed to temperatures of around -80°C in a deep freezer or dry ice, which is a potential risk to container closure integrity (CCI) due to differences in the coefficient of thermal expansion (CTE) of the vial and rubber closure materials.

The CCI of Type I glass vials is particularly at risk from very low temperatures compared with plastic vials because the CTE of typical Type I glass is a factor of 10 smaller than that of rubbers. On the other

CO2 Partial Pressure in Vial Headspace at -65, -45, -27 with Dry Ice

Fig 1. **T2** (after 7+7 day storage under -65°C)

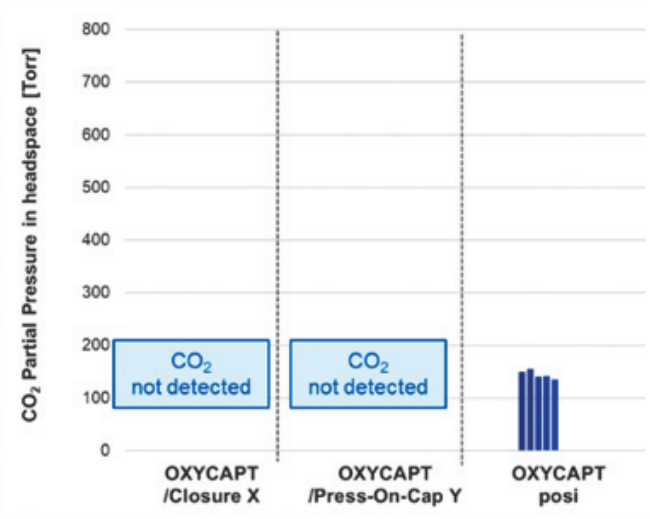


Fig 2. **T3** (at -45°C)

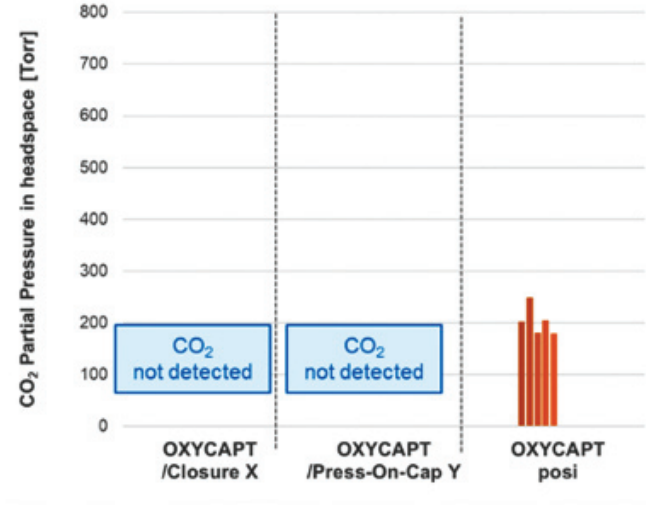
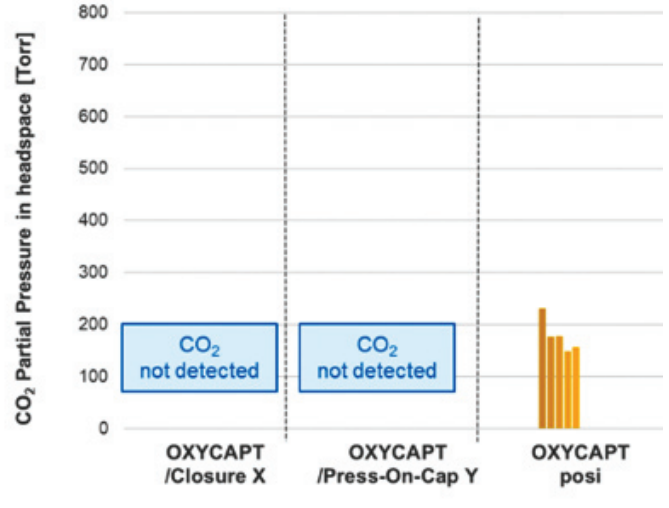


Fig 3. **T4** (at -27°C)



hand, standard plastic vials have a potential risk of CO_2 transmission when stored with dry ice. To examine the benefits of OXYCAPT, MGC conducted a CCI test with dry ice.

We prepared OXYCAPT vial and general rubber closures. The rubber closure is a typical bromo butyl rubber with -65°C Tg. We also prepared press-on-cap closures and OXYCAPT's positive control with a fine hole of a 5-µm nominal diameter.

First, all the vials, closures, and aluminum seals were inserted into a chamber where the air was replaced with nitrogen, then they were assembled and crimped by hand in the chamber. After preparing the samples, we measured the partial pressureof CO_2 in the vials' headspace (T0). The samples were then stored in a deep freezer at -80°C for 7 days. After storage in the freezer, the CO_2 pressure in the headspace was measured (T1). Next, the remaining samples were immediately inserted into an insulation box with 30 kg of dry ice. After storage in the CO_2-rich environment for 7 days, CO_2 pressure in the headspace was measured (T2). Lastly, the remaining vials were stored at room temperature for 4 days to sublimate the dry ice, and CO_2 pressure in the headspace was measured (T3 & T4).

Headspace pressure of CO_2 was measured with an FMS-Carbon Dioxide, manufactured by LIGHTHOUSE Instruments (VA, US). The instrument is based on frequency modulation spectroscopy (FMS), which is a non-destructive method.

At temperatures lower than -65°C, bromo butyl rubber loses its elastic properties, which may lead to loss of airtightness at the interface between vial and rubber closure. Therefore, maintaining a temperature inside the insulation box under -65°C is crucial for measuring the leakage precisely in this test.

The test result shows the headspace CO_2 pressure of OXYCAPT with traditional rubber closure (Entry 1), OXYCAPT with press-on-cap (Entry 2), and OXYCAPT positive control sample (Entry 1'). Although much CO_2 partial pressure was detected in Entry 1', no CO_2 partial pressure was observed in Entry 1 and 2. This study has demonstrated OXYCAPT has an excellent CCI even under a CO_2-rich environment.

CARBON DIOXIDE BARRIER AT ROOM TEMPERATURE

CO_2 molecules permeates through polymers and get into a vial's headspace, affecting drug stability. As the rate of CO_2 transmission is different among polymer materials, we performed related studies using OXYCAPT and COP vials.

OXYCAPT and commercially available COP 10R vials were prepared with bromo butyl rubber (BBR) and aluminum seal closures. First, all the vials and BBR and aluminum seals were placed in a nitrogen chamber for a couple of days. Second, the vials were sealed with the closures using a hand-crimper in a nitrogen chamber. Next, these vials, filled with nitrogen gas, were placed in a box filled with CO_2 and stored at 23°C.

The result shows the headspace CO_2 partial pressure of OXYCAPT and COP vials. Although the CO_2 partial pressure of COP vials immediately rose, reaching around 700 torr in 60 days, the OXYCAPT vials were able to keep CO_2 partial pressure to very low levels.

We also calculated the CO_2 transmission rate of OXYCAPT and COP vials by using the test results of CO_2 partial pressure. While only 0.018 cm^3 of carbon dioxide transmitted through OXYCAPT 10R vials per day at 23°C, 0.423 cm^3 transmitted through 10R COP vials. This result demonstrates that the CO_2 barrier of OXYCAPT is more than 20 times better than that of monolayer COP.

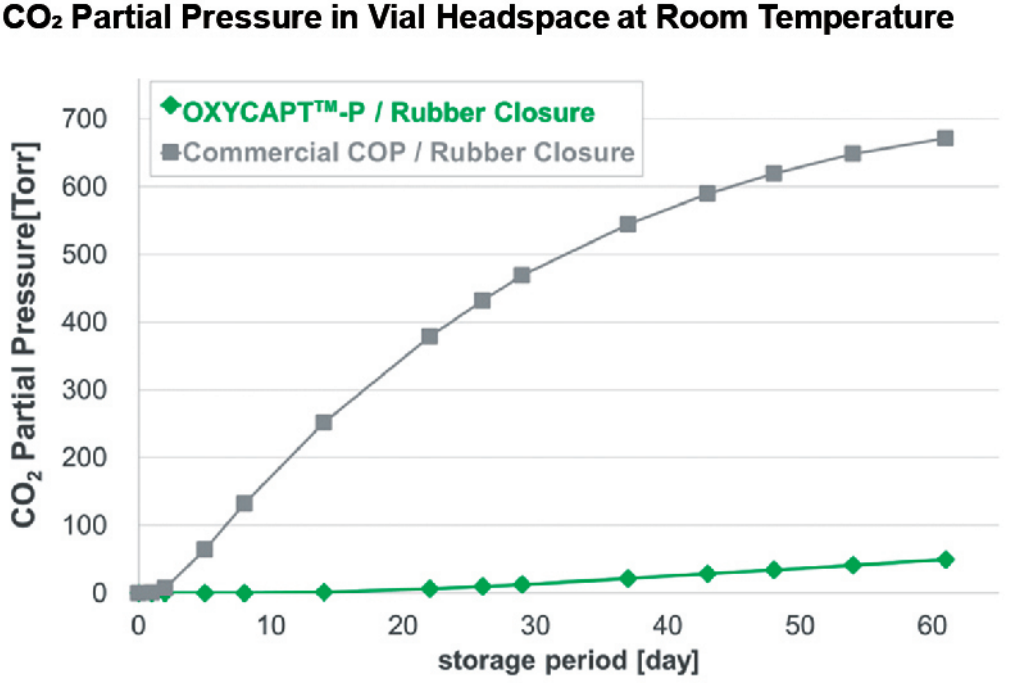
CONTAINER CLOSURE INTEGRITY WITH DRY ICE AFTER FREEZING & THAWING PROCESS

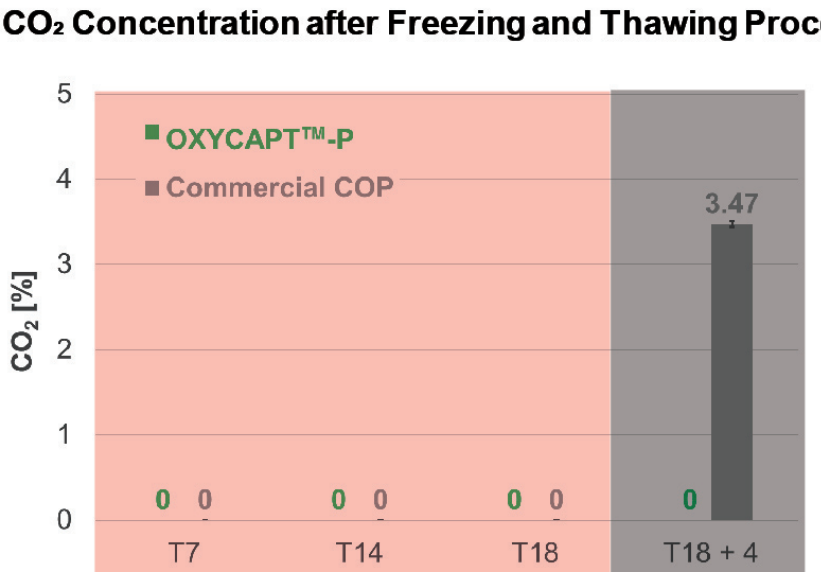
Some research shows CO_2 doesn't permeate into the COP vial's head space that much at deep-cold temperature, although it permeates much more at room temperature. To verify this theory, we conducted some related studies after freezing and thawing processes.

Cell and gene therapy products are usually frozen during storage and transported with dry ices. Before injection to patients, the products are thawed in a hot water bath or at room temperature. Therefore, we kept OXYCAPT and COP vials at -75°C in CO_2-rich environment for 18 days and then placed at room temperature for 4 days.

As we had expected, both the COP and OXYCAPT vials could keep 0% of CO_2 at -75°C under a CO_2-rich environment for 18 days. However, the COP vials couldn't keep 0% of CO_2 after additional storage at room temperature for 4 days, although OXYCAPT could.

There are basically two phenomena of gas molecule permeation with plastic containers, dissolution and diffusion. The diffusion speed at -75°C is much slower than at room temperature, but the coefficient of dissolution at -75°C is higher at room temperature. Therefore, a lot of CO_2 is dissolved into the COP polymer at -75°C and permeated into the COP vial's headspace during the thawing process at room temperature. On the other hand, as OXYCAPT has a high gas-barrier property, it can prevent CO_2 permeation into the headspace.





NEXT STUDY

To verify the excellent properties of OXYCAPT for cell and gene therapy products, we have begun additional studies, such as CCIT in liquid-nitrogen gas phase and pH shift with dry ice. As it is said that glass cannot be used for cell and gene therapy products stored at deep-cold or cryogenic temperature, we have also added type 1 glass vials to the samples to confirm if this is true or false. As a chemical company, we contribute to sharing more scientific data with the pharmaceutical industry.

CONCLUSION

In conclusion, these latest results have contributed to the on-going studies verifying OXYCAPT's superior properties for cell and gene therapy products. In addition to the advantages of COP, such as a strong water vapor barrier, high break resistance, very low extractables, and low protein adsorption, OXYCAPT also provides a strong oxygen, carbon dioxide, and UV light barrier. We believe OXYCAPT offers a multitude of benefits to the rapidly growing field of cell and gene therapy products. ◆

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BIOGRAPHIES

Shota Arakawa is a Research Manager in the R&D Division of Mitsubishi Gas Chemical Company, Inc. (MGC). He earned a Diploma in Science in 2007 and a Master's of Science in 2009 from Osaka University. Since April 2009, he has been working for MGC and is in charge of macromolecular science, specifically in synthesis of polymers and material development. Since 2012, he has joined the development team for multilayer plastic vial and syringe for biologics.

Tomohiro Suzuki graduated from Waseda University in 1997 and joined Mitsubishi Gas Chemical in 1998. He was a part of the Oxygen Absorbers Division until 2011, and was transferred to the Advanced Business Development Division in 2012 to be a member of the OXYCAPT development team. Since then, he has been in charge of project management of OXYCAPT Plastic Vials & Syringes. His current position is Associate General Manager.

DRUG DEVELOPMENT

Targeting the CD40L Pathway to Improve Immunosuppression Therapy & Help Organ Transplants Last Longer

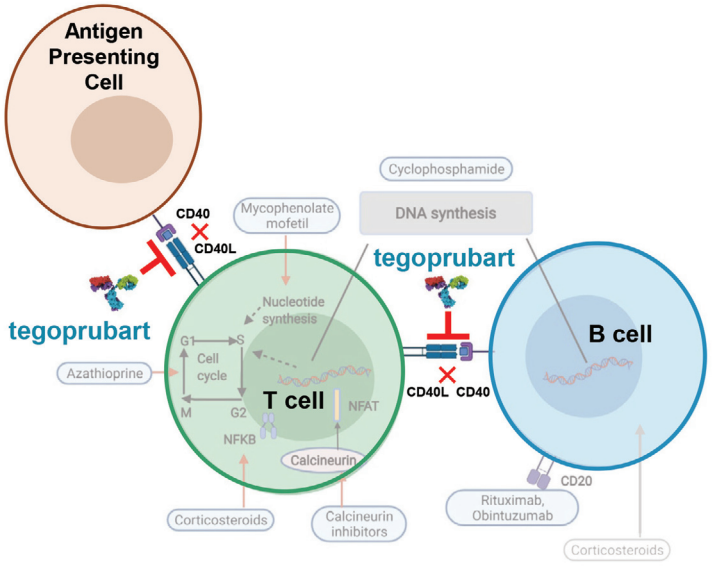
By: David-Alexandre C. Gros, MD

ADDRESSING THE NATIONAL DONOR ORGAN SHORTAGE

Kidney transplants are a life-saving option for about 25,000 Americans per year suffering from end-stage renal disease (ESRD), but due to the ongoing shortage of available kidneys, transplants are not available for everyone who needs them.[1] In the US, for every five people who receive a kidney transplant, one person dies waiting for a kidney that never materializes. Moreover, for the 90,000 Americans on the Kidney Transplant Waitlist, most will see their health continue to decline as they wait, often for years, for a kidney.[2] Efforts to encourage more people to become organ donors or to salvage more organs, while important, have been unable to address this critical shortage.

In cases where someone is fortunate enough to find a suitable match and receive a kidney transplant, the fact that most transplanted kidneys typically fail after only about 10 to 15 years is both a harsh reality and another factor that reduces the number of kidneys available.[3] Given that kidney transplant recipients in the US are in their 50s on average, many eventually need a second or even third transplant to last a normal lifespan. Indeed, one in six patients on the Kidney Transplant Waitlist is awaiting a repeat transplant. While it is possible for some patients to return to dialysis once a transplanted kidney fails, this is not an ideal alternative. Dialysis is a grueling, cumbersome, and costly treatment option, with many patients continuing to bear a high burden of disease and low quality of life. The survival span for patients on dialysis is only 5 years on average.[4]

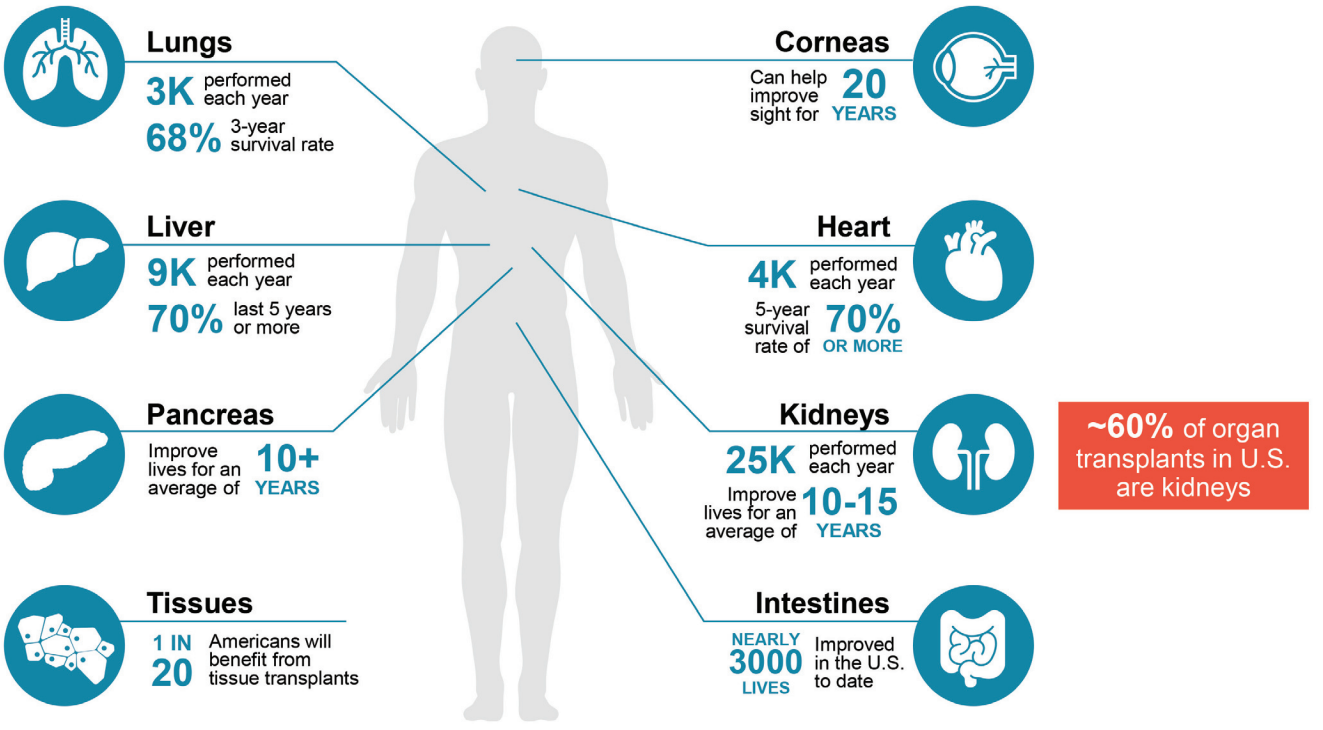
FIGURE 1



Mechanism overview of CD40L inflammatory signaling and tegoprubart site of action: Interaction of CD40 with CD40L on immune cells mediates activation of the co-stimulatory immune pathway, controlling "cross talk" between the adaptive and innate immune systems. Blocking CD40L shifts polarization away from proinflammatory signaling to T-cell anergy, apoptosis, and polarization to a "T-reg" environment. (Source: Adapted from Kant et al., Principles of Immunosuppression in the Management of Kidney Disease: Core Curriculum 2022, AJKD.)

While efforts to increase the number of available organs continue, another focus is emerging that could play a central role in addressing the donor challenge. Researchers are targeting strategies in immunosuppression that can help donated kidneys remain healthy and viable for much longer post-transplant, thus alleviating the need for repeat transplants and making more organs available for first-time transplant recipients.

FIGURE 2



Every transplant begins with altruism and each donor can provide multiple organ types. Numbers are for the United States. (Sources: golm.org; USDHHS.)

TARGETING CD40L TO INCREASE TRANSPLANT FUNCTION & LONGEVITY

One promising avenue of research involves targeting a pathway called CD40 ligand (CD40L, also known as CD154) that has been shown to play a central role in immune system activation and controlling inflammation in the body.[5] By blocking CD40L, we may be able to inhibit multiple co-stimulatory receptors, including CD40 and CD11, key components of how immune cells communicate with one another, and increase polarization of lymphocytes into "T-regs," a specialized subpopulation of T cells that act to suppress immune response.[6] The central role of CD40L signaling in generating pro-inflammatory responses makes it a highly attractive candidate for therapeutic intervention in the protection of transplanted organs and prevention of transplant rejection. Based on research conducted thus far, inhibiting CD40L has the potential for better efficacy and improved safety, including reduced risk of lymphopenia, diabetes, hypertension, and other side effects associated with many current immunosuppressive drugs, including the current standard of care, calcineurin inhibitors (CNIs).[7,8]

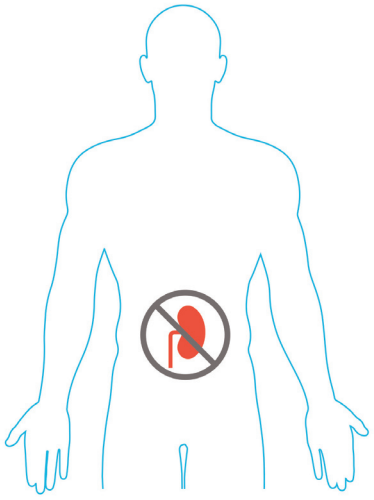
Advances in research are especially encouraging because there has not been much innovation in chronic transplant immunosuppression during the past 30 years. Throughout that time, CNIs, such as tacrolimus, have been positioned as the standard of care to reduce the risk of organ rejection. While tacrolimus is considered to have a positive risk-benefit profile, it has some significant limitations. Research shows that tacrolimus can be toxic to kidney cells and is associated with side effects, including risk of diabetes and hypertension – the very conditions that lead most patients to require a kidney transplant in the first place.[7,8]

Innovation in immunosuppression therapy and strategies to better protect transplanted organs while reducing the risk of potentially harmful side effects could represent a major advance in patient care in the years ahead while also helping to make kidney transplants available to more patients who need them. If we can reduce the risk of organ failure or rejection, we can make additional organs available for other patients on the waiting list.

THE POTENTIAL OF TEGOPRUBART, A NOVEL CD40L INHIBITOR

The research team at Eledon Pharmaceuticals is advancing development of tegoprubart, a novel anti-CD40L antibody

FIGURE 3



Without immunosuppression, the **host** sees **donor** kidney as "foreign" and attacks (i.e., rejects) it

Immunosuppression must normally be taken for life or the organ will be rejected even years after the transplant

Immunosuppression is necessary to protect transplanted organs. (Source: Eledon Pharmaceuticals, Inc.)

with high affinity for CD40L. The goal in treatment is to inhibit or "turn off" both the CD40-CD40L pathway necessary for adaptive (ie, T and B cells) and innate (eg, macrophages and dendritic cells) immune cell activation and function. Tegoprubart is the first anti-CD40L antibody to enter multiple clinical trials for patients undergoing transplantation, including kidney transplants. Promising data from both preclinical and clinical studies to date demonstrate the significant potential of tegoprubart to prevent transplant rejection safely and effectively and improve outcomes in patients.

In June 2024, at the American Transplant Congress (ATC), researchers presented updated results from 13 participants from an ongoing Phase 1b clinical trial showing that mean eGFR was above 60 mL/min/1.73m^2 at each reported time point after day 30, with an overall mean eGFR of 70.5 mL/min/1.73m^2 for all the reported time points after day 30 post-transplant.[9] These levels are approximately 20% to 40% above the historical averages seen with tacrolimus. Historical studies have reported average eGFRs generally in the low 50 mL/min/1.73m^2 range during the first year after kidney transplant using standard of care immunosuppression drugs.[10]

Two participants completed 12 months on therapy post-transplant, and both demonstrated mean eGFRs above 90 mL/min/1.73m^2 at one-year post-transplant.[9] This includes a 77-year-old woman with diabetes who had been on hemodialysis before receiving a kidney transplant from a deceased donor, who had an eGFR of 91 mL/min/1.73m^2 – about 80% above historical levels with tacrolimus and higher than what might typically be expected in a woman her age without diabetes and with two native working kidneys.[11]

Importantly, results also showed tegoprubart was generally safe and well tolerated in patients undergoing kidney transplantation, with no cases of hyperglycemia, new onset diabetes, or tremor commonly seen with CNIs.[7-9] There were no cases of graft loss or death.

Tegoprubart continues to be evaluated in the ongoing Phase 1b , Phase 2 BESTOW, and long-term safety and efficacy extension studies, with BESTOW reaching its target enrollment of 120 participants in September 2024.[12] BESTOW is a multicenter, two-arm, active comparator Phase 2 study designed to assess the safety, pharmacokinetics, and efficacy of tegoprubart compared to tacrolimus for the prevention of organ rejection in patients undergoing kidney transplantation in the US and other countries. The study's primary endpoint will assess the potential superiority of tegoprubart versus tacrolimus in post-kidney transplant kidney function at 12 months as measured by eGFR.

Tegoprubart has also demonstrated its potential applications in preventing graft rejection in people undergoing islet cell allotransplants. This type of transplant is an experimental treatment for type 1 diabetes that involves injecting patients with healthy islet cells from a donor pancreas that can produce insulin, with the goal of improving blood glucose levels, preventing severe hypoglycemia, and eliminating the need for insulin injections.[13]

Tegoprubart is being assessed in an investigator-led clinical trial at the University of Chicago Medicine Transplant Institute for its potential to prevent islet transplant rejection in people with type 1 diabetes. In October 2024, positive initial data from this trial demonstrated that the first two islet transplant recipients achieved insulin independence and normal hemoglobin A1C levels, a measure of average blood glucose control.[14] The third patient, who only recently received an islet transplant, decreased insulin use by more than 60% three days post-transplant and continues on an insulin independence trajectory.

These collective data in kidney and islet cell transplantation reinforce the advances being made in immunosuppression research and the potential of an anti-CD40L antibody such as tegoprubart to play a role in modulating the immune system to help protect and improve the vi-

ability of transplanted organs. As research continues to advance, these efforts are helping bring the field closer to a new era in transplant medicine where patients have better outcomes and will be more likely to live a full lifespan after their organ transplant. This research can be positioned as an important element in a holistic strategy to improve access to organ transplantation for all patients who need them.

ADVANCES IN XENOTRANSPLANTATION

One additional potential strategy to address the "organ gap" that has gained traction in recent months is to identify another workable source of donor organs. Xenotransplantation, or transplanting organs from one species to another (eg, animals to humans), may be a promising option, with recent developments marking a historic turning point in research. The faculty from the University of Maryland School of Medicine at the University of Maryland Medical Center performed for the first-time transplantation of genetically modified pig hearts into two humans. In the second procedure, performed in September 2023, tegoprubart was used as the cornerstone of the immunosuppressive regimen administered, along with conventional anti-rejection drugs.[15] Also in March 2024, tegoprubart was used as a component of the immunosuppressive treatment regimen following the first-ever transplant of a kidney from a genetically modified pig to a human, which was performed at Massachusetts General Hospital.[16]

While xenotransplantation is still in relatively early days, this option could someday lead to an additional supply of organs for people who need transplants. Support for xenotransplantation will require continued innovation in multiple areas, including immunosuppression, gene editing, surgical training, and patient management, to improve both safety and access to xenografts in the years ahead.

THE FUTURE OF ORGAN TRANSPLANTATION

The global need for organ transplants, including kidney transplants, is projected to more than double in the next decade, highlighting the urgent need to take steps to address the donor organ shortage and improve patient outcomes.[17] Without viable solutions, the cycle of ESRD, kidney failure, dialysis, kidney transplant, and back to kidney failure will continue. Too many patients go through this cycle, in some cases more than once during their lifetime, transitioning between dialysis to transplantation and back again. This cycle puts a tremendous burden on transplant recipients and their families and represents millions of dollars in costs for healthcare systems. Continued investment in innovative science is key to advance these efforts as rapidly as possible for patients who deserve broader access to donor organs and better outcomes. ◆

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BIOGRAPHY

Dr. David-Alexandre C. Gros is Chief Executive Officer and a member of the Board of Directors at Eledon Pharmaceuticals, Inc. He joined Eledon from Imbria Pharmaceuticals, where he served as Co-Founder, Chief Executive Officer, and Chairman of the Board of Directors. Prior, he was President and Chief Operating Officer of Neurocrine Biosciences, Chief Business and Principal Financial Officer of Alnylam Pharmaceuticals, and Chief Strategy Officer of Sanofi, S.A. Before joining Sanofi, he held leadership positions in healthcare investment banking at Centerview Partners, LLC, and Merrill Lynch, Pierce, Fenner & Smith Inc., and in healthcare consulting at McKinsey & Company. He previously served on the Board of Directors of Eliem Therapeutics, a biotechnology company he also co-founded. He earned his MD from The Johns Hopkins University School of Medicine, MBA from Harvard Business School, and BA from Dartmouth College.

MODIFIED RELEASE

Getting the Right Formula: Using Modified-Release Formulations to Address Complex Challenges in Drug Development

By: Vanessa Zann, PhD

INTRODUCTION

Simple, immediate release (IR), once-a-day (QD) formulations are desired not only by the patient for rapid onset and improved compliance, but also by the pharmaceutical industry due to ease of development and cost benefits. However, many small molecules in today's pipelines have sub-optimal properties for QD IR formulations. Challenges, including poor solubility or permeability, can lead to reduced absorption (input in the body) or high clearance (output from the body) that causes a short duration of therapeutic effect. This results in more frequent dosing regimens, which may not be suitable for patient compliance. Another challenge comes from the significant peaks and troughs in circulating drug concentrations. Using IR formulations, the drug immediately enters the bloodstream, and if dosing is not optimized, this could lead to side effects for the patient and variation in therapeutic efficacy.

For IR formulations that require more than once-a-day dosing, a modified release (MR) formulation, which delivers the drug to the lower GI tract over a sustained period, can be a better choice to achieve the desired therapeutic effects. The following will discuss the opportunities and challenges when transitioning from an IR to MR formulation. It will review the therapeutic benefits and challenges associated with MR formulations, GI physiology environments and API physicochemical properties, technology choices, and how drug developers can achieve translation success.

MR FORMULATIONS CAN OFFER ADDED THERAPEUTIC BENEFITS

MR formulations are a common alternative for drug developers looking to overcome the challenges of IR formulations, including requirements to dose multiple times a day, large peak-to-trough ratios associated with Cmax driven adverse events (AEs), and limited therapeutic efficacy. Fundamentally, MR allows for more control over the rate and location of drug release in the GI tract and may provide added therapeutic benefits, such as:

- The maintenance of drug plasma levels, wherein a prolonged period of release extends drug plasma levels, reducing the dosing frequency requirements
- Attenuation of peak-to-trough ratios, leading to lower peak-related adverse effects and improved therapeutic efficacy; and
- Targeted delivery, or the specific release of a drug at a particular site in the GI tract, whether to target GI disease or reduce the impact of delivering a drug to non-absorptive regions.

MR technologies have traditionally been adopted for life cycle management strategies, the extension of drug product patents, and continued market exclusivity. However, MR is increasingly being used to develop new chemical entities and deliver an optimal formulation at launch.

THE DEVIL'S IN THE DEVELOPMENT: COMMON MR FORMULATION CHALLENGES

Navigating MR formulation development can be challenging when it comes to anticipating regional absorption of the GI tract — this is not normally a consideration when producing IR dosage forms. Accordingly, the development team will typically need to conduct multiple cycles of formulation development, in vitro screening, and preclinical and clinical studies to find the balance of drug release rate and dose to achieve the target plasma concentration profile for the MR formulation to succeed as a QD formulation.

For example, a sustained-release formulation that transits to the GI tract while continuously releasing the drug must also be sufficiently absorbed in the lower GI tract to maintain a therapeutic effect. As most drugs will have reduced absorption in the lower GI tract, the dose of the MR formulation will likely need to be higher than the total daily IR dose to give the same daily exposure.

Another challenge when developing an MR formulation is the disconnect between formulation performance in preclinical species and man. Grass and Sinko (2002) and Musther et al (2013) have shown that animal bioavailability often doesn't predict human bioavailability for IR formulations. The same is true for MR formulations, given the differences in the GI tract physiology between preclinical species and man and the challenge of defining the correct release rate and dose to give the target plasma concentration profile.

While *in vitro* dissolution is used to develop MR formulations with specific release rate profiles, it is assumed in vitro dissolution is equivalent to in vivo dissolution in the GI tract. In practice, we have found this is often not the case. In vitro to in vivo correlation is not fully known until an MR formulation has been dosed in the clinic The chances of optimizing an MR formulation in a canine or a primate and having the desired concentration and time profile for that MR formulation later to translate seamlessly into first-in-human studies and achieve a QD profile, without further optimization (release rate and dose), is limited and unlikely.

HOW GI PHYSIOLOGY ENVIRONMENTS & API PHYSICOCHEMICAL PROPERTIES AFFECT MR FORMULATIONS

Successful MR development requires considering the multiple GI environments and different anatomical regions the formulation will encounter. With an MR formulation, drug developers must also be mindful the drug is released slower in the GI tract or to targeted regions than IR formulations.

GI physiology changes from the stomach to the colon, reflecting the change in function of the various regions. The upper GI tract, for example, has villi and microvilli to increase the surface area to optimize the absorption of nutrients, whereas the colon does not. The tight junctions (the tiny, fluid-filled gaps between the GI tract cells) become tighter as moving down the GI tract, this reduction in surface area and increase in tight junction permeability can lead to a reduction in the drug's permeability.

Transfer across the GI tract cells and reduced absorption is often referred to as an absorption gradient, or the ability to cross cells. The function of the lower GI tract is to absorb water, so the fluid volume available in the lower GI tract is reduced when compared to the upper GI tract, which may also affect the drug dissolving and overall absorption.

The pH of the GI tract fluid will also vary and may impact the solubility of the drug and the polymers controlling release from the formulation, or the dissolving of the formulation coating controlling release.

It has been well documented transporters may assist the drug in transferring across the GI tract cells or may remove the drug from the body via efflux transporters. Expression of transporters down the GI tract has been documented to vary and can impact the overall plasma concentration time profile of the MR formulation. Likewise, the GI tract cells express enzymes that break down the drug to help the body eliminate it. These enzymes have also been shown to have regional expression in the GI tract, which can impact overall exposure.[1,2]

Finally, the properties of the API must be addressed, as they will heavily impact how the drug behaves when administered. For example, a highly soluble API will generally have a much quicker release rate and may require a greater percentage of the polymer in the MR formulation to control the release. Basic compounds with higher solubility in the stomach may be subject to a gastric burst effect and must be assessed to ensure the required peak-to-trough ratio is achieved. Some APIs are unstable at low pH; in such cases, an enteric coating may be necessary to protect the drug from chemical breakdown in the stomach. Due to the absorption gradient, drugs with low permeability will be a greater challenge when developing MR formulations.

TABLE 1

Type	Format	Benefits
Sustained or extended-release	Matrix or film-coated tablets Multiparticulates	• Extended-release • Reduces repeat dosing
Delayed release	pH or time-dependent coating systems	• Target delivery • Protect drug from stomach environment if acid labile
Biphasic/pulsatile release		• Instantaneous and extended release • Reduces repeat dosing
Gastro-retention	Swellable, floating, and bioadhesive systems	• Prolonged residence in the stomach, resulting in the delivery of the drug to the upper GI tract when an absorption window exists

Types of Modified-Release (MR) Dosage Forms

CHOOSING THE BEST MR FORMULATION TECHNOLOGY

A clear target product profile (TPP) can be essential to help guide the development of an MR formulation and ensure the desired characteristics are achieved. The TPP is based on the drug product requirements that include the intended clinical use, dosage strength(s), drug release characteristics, stability, and other product quality criteria.

There are different MR technologies that can be considered depending on the goals of the therapy. Figure 1 provides an overview of the common types of MR forms and their benefits.

- Sustained or extended-release technologies allow the MR formulation to release the drug over an extended period (e.g., 100 % release over 12 hours). These technologies can prolong absorption and reduce the peak-to-trough ratio, leading to higher drug levels at the end of the dosing frequency.

- Delayed release technologies use pH or time-dependent coating systems to allow a drug to reach an intended site in the GI tract before release for more targeted delivery.

- Biphasic/pulsatile release technologies allow both instantaneous and extended-release, reducing the need for repeat dosing.

- Additionally, some drugs are only absorbed in the upper GI tract. In this scenario, gastro-retentive formulations are required to target this region. These formulations are designed to have a longer residency time in the stomach, during which they release drug, which, on gastric emptying, is delivered to the upper GI tract to target the absorption window. Gastro-retentive formulations are required to be dosed in the fed state with a moderate to high-fat meal to maximize the chance of achieving the desired stomach retention.

CHOOSING THE BEST PROVIDER TO ACHIEVE TRANSLATION SUCCESS

Choosing a contract research, manufacturing, and development (CRO/CDMO) provider with the right expertise in MR formulation development can be pivotal in adding speed and efficacy to drug development. However, traditional formulation development and clinical research/testing services often rely on successfully testing several formulations developed in vitro within a preclinical in vivo model before entering human clinical testing. As there are complex biological differences between in vitro and in vivo models compared to human clinical testing, approximately 40%-50% of candidates fail due to not meeting the TPP.

The integration of services for rapid formulation development, drug product manufacturing, and clinical testing, such as those offered through Quotient Sciences' Translational Pharmaceutics® platform, allows for different iterations of MR formulations to be manufactured and tested within a clinical study, all within the same organization and under the same program of work. This model allows formulation optimization to be achieved using clinical PK data, removing the reliance on non-predictive in vitro and preclinical models.

Additionally, bracketing the upper and lower limits of critical formulation parameters, such as dose and polymers or controlling release rate, in a "design space" can allow for manufacturing CMC regulatory batches on the extremes of those parameters for greater flexibility in testing. Small batches of typically 300 units can be GMP manufactured just before

clinical dosing. In these cases, stability requirements are reduced to cover the clinical dosing only, generally 7 to 35 days, as opposed to 6 months in traditional formulation development. ◆

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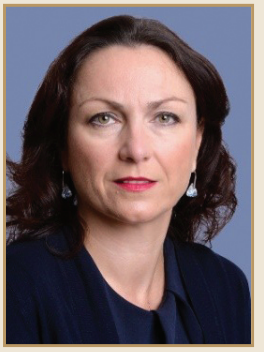
BIOGRAPHY



Dr. Vanessa Zann is an Executive Drug Development Consultant at Quotient Sciences with over 2 decades of industry experience providing biopharmaceutics support to discovery, development, and clinical programs. Since joining Quotient Sciences in 2012, she has led the implementation of modelling and simulation and has been heavily involved in pharmaceutical sciences' in vitro characterization strategy, as well as designing clinical studies and providing scientific support through clinical study delivery.

Prior to joining Quotient Sciences, she worked at AstraZeneca as a permeability expert in the Pharmaceutical Development department. Here, she led the global Caco-2 facility for the development and was responsible for liaising with discovery scientists to ensure the selection of new chemical entities (NCEs) with appropriate biopharmaceutical properties. She introduced the intravenous (IV) microtracer technique and provided biopharmaceutical support to both discovery and development programs. She completed postdoctoral research in buccal transport mechanisms at Cardiff University, and earned her PhD in Pharmaceutical Sciences and a Bachelor of Science in Applied and Human Biology, both from Aston University.

Drug Development
EXECUTIVE

Gael Touya

President

Aptar Pharma

Sai Shankar

President, M&A, Strategy, BD, Marketing, Drug Services

Aptar Pharma

Aptar pharma

Aptar: Advancing Patient-Centric Drug Delivery & Digital Health Solutions

The pharmaceutical and digital health landscapes are constantly shifting, driven by technological advancements, regulatory changes, and evolving patient and consumer demands. Aptar, a global leader in drug and consumer product dosing, dispensing, and protection technologies, stands at the forefront of the changing landscapes by continuously innovating around nasal drug delivery, components for injectables, patient experience, sustainability, and more. Aptar's digital health solutions place patients at the center of the equation and give pharma companies and healthcare teams solutions to enhance patient experiences with the goal to improve healthcare outcomes. This patient-centric philosophy is pivotal to Aptar's strategy.

Drug Development & Delivery interviewed Gael Touya, President of Aptar Pharma, and Sai Shankar, President, M&A, Strategy, BD, Marketing, Drug Services, Aptar Pharma, to discuss the burgeoning potential in the future of pharma and digital health, how the company is a strategic partner to key players in these spaces, and the investments Aptar is making to support the growing demand.

Q: Where do you see the biggest opportunity within the pharma industry? Where is Aptar investing?

Gael: The pharmaceutical ecosystem is constantly evolving. Today, we lead in drug delivery solutions for certain delivery routes, including nasal, pulmonary, ophthalmic, and dermal. Right now, we see injectables, nasal drug delivery, and digital

therapeutics, which Sai will talk more about, as some of the largest market opportunities within the pharmaceutical industry, and we are actively investing to ensure we are at the forefront of shaping the future of these spaces.

For 2023, the pharma industry's total addressable market was over $1.4 trillion[1], and we estimate that injectables made up about 45% of that.[1] When looking at our own business, injectables accounted for 18% of all pharma sales in 2023. It is likely this market will only continue to grow over the next few years, especially considering the continued demand for biologic drugs. Our $180 million, multisite, international expansion project for injectables is intended to significantly boost capacity, enabling us to industrialize our higher value product offerings.

We also see nasal drug delivery solutions as a driving force in the Pharma industry, with opportunities for more needle-free drug delivery solutions. For example, the opioid overdose treatment NARCAN® uses our proprietary Unidose nasal system. In this space, Aptar is uniquely positioned to support customers on everything from formulation development all the way through to clinical trials and commercial product manufacturing. To meet increased customer demand, we are expanding the manufacturing capacity of our Unidose nasal drug delivery system at our Congers, NY, facility.

Allergic rhinitis was one of the fastest growing categories for us in 2023, and we are a leader in the delivery of nasal allergy medications, with a proven track-record of getting products to market around the world. Our delivery solutions are on over 300 market references.

Q: What are the biggest regulatory hurdles your customers face with drug development, and how does Aptar Pharma support its customers through the process?

Gael: From clinical trials, regulatory filings, robust R&D documentation, intellectual property protection, and more, it is no secret the regulatory process surrounding drug development is strict and time-consuming. While these guidelines are in place for good reason, it makes navigating the ever-changing regulatory landscape complex. Even more so for emerging companies that might not have the data, experience, or technical capabilities to successfully meet regulatory compliance.

Working on a product with a new API, from early stage development through market launch, can be a 10-year-plus process. Success in our business requires strong regulatory expertise, and we have established ourselves as a trusted partner in this ecosystem. We have more than 3 decades of experience with the different regulatory bodies, and we partner with our customers early in the drug development program. We also have strong scientific expertise in specialized drug delivery systems and help our customers to de-risk and accelerate the drug development programs.

Through our pharma services businesses, we support our customers' research and development needs, from concept to initial design, device, and formulation development, through the clinical trial phase and regulatory filings, and on to market launch and post-launch activities. We have also invested in expanding our expertise in patient on-boarding for adherence improvement. This is apparent in our service companies like Noble, an industry leader in medical device training solutions, bringing expertise in Human Factors engineering, market insights, and device design and training for self-administration of drug therapies, as well as Metaphase, which allows us to provide insights into patient behaviors. We provide valuable input to our customers to bring to market the best drug delivery solutions in terms of safety and compliance.

Our commitment to quality and services allows us to build our pipeline, positioning us as a partner throughout the drug development process.

Q: Sustainability is a growing focus for the pharma industry, yet many players are still facing barriers. What does the future of sustainability in pharma look like?

Gael: Sustainability is core to our Beauty and Closures consumer facing businesses, and our Pharma business is building upon key learnings and successes to become an early leader in this space. Understandably, ensuring sustainable practices, packaging, products, etc within pharma can be difficult as there's a delicate balance between the needs of the environment and the quality and safety requirements of the delivery systems. The timeline to achieve approval on pharma products and bring them to market is much longer than other industries and therefore the ability to change materials is not a quick process.

But with major drivers for the push to sustainability, including consumer demand for more sustainable products and regulations that call for more circular business approaches, we are dedicated to helping our customers overcome these barriers. As we help contribute to a more sustainable future for the pharma industry, we expect to see a few priorities arise as more companies transition to circular economic models.

For these goals to come to fruition, circularity will involve expanding the use of alternative resin materials and designing recyclability into new devices. For example, products made from pure polyolefin materials, free from recycling disruptors and resins from renewable feedstock or chemically recycled ones that are made with the same properties as conventional resins. Our Futurity™ solutions platform, which includes a metal free nasal spray pump, is specifically designed for improved recyclability and to meet the needs of our customers and their consumers.

Q: The digital health space is booming. What do you believe is the biggest driver of this growth?

Sai: The COVID-19 pandemic has revealed the importance of remote patient management in the context of difficult access to care. It accelerated some of the first adoptions of remote patient management technologies and remote consultations with healthcare professionals. It also accelerated conversations around reimbursement of these new care delivery pathways.
In addition to meeting market demands, digital health can bolster healthcare systems in a variety of ways, including improving care delivery and outcomes, empowering patient compliance, reducing the burden on care workers, and diminishing costs. In most healthcare systems, providers are paid based on the number of performed activities, not on the delivered quality over time. Data is needed to measure the value of a medical act and shift toward what is called Value-Based Healthcare. Collecting these data points (disease evolution, patient quality of life, etc) is possible due to digital health.

Today, we see the digital health market is starting to consolidate. In the past few years, there have been hundreds of small digital health players. Today, we are seeing the industry move toward more industrial champions, and Aptar is one of them.

Q: What potential do artificial intelligence and machine learning have in transforming digital health, specifically around patient experiences?

Sai: Artificial intelligence (AI) and machine learning (ML) hold tremendous potential to transform digital health, particularly in enhancing patient experiences through, for example, personalized care. AI can potentially analyze vast amounts of data from various sources (electronic health records/EHRs, genetic information, lifestyle factors, etc) to help generate tailored treatment paths to patients. ML algorithms can potentially predict health events, such as disease outbreaks or the likelihood of hospital readmission, allowing healthcare providers to offer proactive, preventative care and better manage chronic conditions.

At Aptar, we are focusing on accelerating the diagnosis timeline through image analysis. We are currently integrating AI algorithms to analyze skin images, voice biomarkers, and eye fundus images, which may lead to a faster and more accurate diagnosis, particularly in dermatological and other conditions. We also invest in disease prediction and identification. In leveraging ML models, we can identify patterns in data that may indicate the onset of a disease, often before traditional symptoms present themselves. Finally, we use Large Language Models and generative AI to optimize the end-user experience with our products, making navigation easier and providing new ways to interact, find content, and provide data inputs into our solutions.

Q: Aptar has recently announced several new collaborations, like with Biogen and Healint, for example. What makes Aptar so attractive as a partner in both Pharma and Digital Health?

Sai: Aptar's position is very attractive for the market. We are experienced digital health leaders with established strategic relationships with pharmaceutical companies. With Aptar's global capabilities, we can also build products and services at scale and help mitigate the risk involved with product roll outs for our pharmaceutical partners.

Unique to the market, we also blend hardware and software engineering technologies, differentiating Aptar Digital Health with its strong expertise on topics such as self-administration, adherence monitoring, or digital patient support programs for injectable drugs. Our ability to roll these capabilities out across several geographies and conditions is an invaluable asset in a consolidating digital health market. ◆

Reference

1. IQVIA; total worldwide drug sales value

DIGITALIZATION PLATFORM

Breaking Down Communication Barriers in Pharma Manufacturing

By: Andreas Eschbach

INTRODUCTION

A people-centered approach to digitizing manufacturing operations helps ensure the success of any digitalization initiative. But in pharmaceutical manufacturing, having insights into each area of operation is critical to production quality and compliance.

Pharmaceutical operators must be involved at early stages, so their needs and requirements need to be clearly understood. Identifying an enterprise platform that can be configured and customized to meet the needs of end users is key, as well as using an iterative process to ensure optimal configuration for each department and end user.

In a recent LinkedIn post, Jörg Walter, a Senior Manager for Operational Excellence at AbbVie Germany, says "By digitizing our shop floor communication, we not only streamline our processes. We empower our employees to be architects of progress. Their know-how, coupled with state-of-the-art technology, drives our industry forward."

AbbVie is a global, research-based biopharmaceutical company focused on research and innovation spanning immunology, oncology, neuroscience, eye care and virology, and medical aesthetics. With 50,000 employees, enabling clear communication and aligning operational objectives across shifts and tiers are critical priorities.

Their Ludwigshafen R&D and operations site in Germany employs more than 2,000 people. The facility produces medicines for more than 100 countries. Keeping everything on track requires effective communication and collaboration across teams, shifts, areas of responsibility, and levels of management. However, without centralized systems for knowledge transfer and management, employees faced numerous challenges. Shift handover is naturally highly people- and situation-dependent, possibly leading to loss of knowledge, misunderstandings, and less-efficient action tracking. Information for the site was documented across various systems, making it sometimes difficult to find and use historical data and creating "information overload" for supervisors juggling multiple data streams. Performance information generated by humans and machines was not properly integrated, slowing down improvement initiatives. The seen risk? Loss of knowledge, lower operational efficiency, and a greater risk of failures.

AbbVie in Ludwigshafen, Germany, realized they would benefit from structures and systems in place that would make knowledge more accessible, searchable, and traceable for everyone at the site. They implemented the Shiftconnector enterprise software platform to digitize shift handover and other key aspects of plant process management (PPM). The platform acts as a centralized knowledge management platform and "single source of truth," streamlining communication at all levels.

SIMPLIFYING COMMUNICATION ACROSS SHIFTS & TIERS

The Ludwigshafen facility runs four shifts for 24/7 operation. One of the key challenges they wanted to improve with digitization was streamlining communications across shifts and roles. They needed a system that would support all relevant operational processes and work for everyone, including shift technicians and supervisors, process scientists and laboratory staff, maintenance,

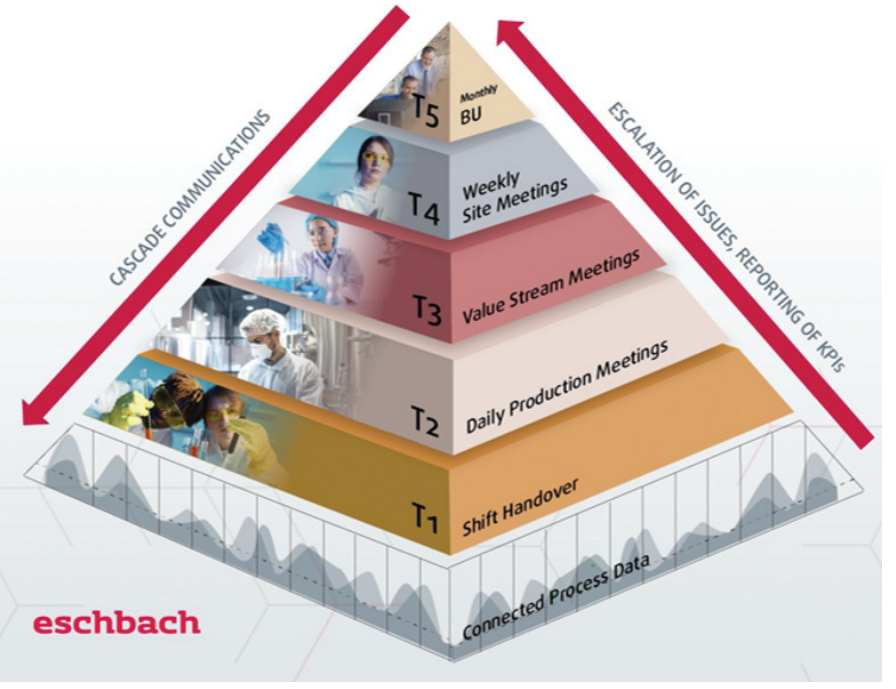
schedulers, and site managers. In addition, they wanted a platform that was usable on any device, configurable for their specific processes and procedures, and fully compliant with FDA CFR 21 and other regulatory standards for GxP and non-GxP information.

To serve as a central knowledge repository, the platform had to bring together both process data (such as sensor data and equipment alerts) and human input (such as shift handover notes and instructions, inspection reports, and observations). Both types of data are required for effective troubleshooting and decision-making.

Shiftconnector brings everything together in one place to streamline knowledge management and transfer. It provides a structured system for shift handover, task management, and process management. Everyone has easy access to both historical data and knowledge and up-to-the-minute notes, checklists, instructions, and observations.

AbbVie in Ludwigshafen now uses Shiftconnector to manage daily operations and drive continuous improvement efforts at the plant in an advanced way. Important information for each shift — such as event logs and temporary instructions — is clearly documented and accessible to everyone, even if they missed the shift handover meeting. Automatic notifications and information transfers keep other departments, like maintenance and scheduling, in the loop.

With the new digitalization platform, tier communication is transparent for all tiers to see live, 24/7. This helps them facilitate communication for shift handover (operator to operator and team lead to team lead), daily review meetings between team leads and production management, value stream meetings (with supply chain, maintenance & engineering, production management, quality assurance, and quality control), the daily huddle for the plant board, and plant walkthroughs by management. The Shiftconnector collaboration dashboard enhances communication both within and across tiers, ensuring issues and questions are escalated up for proper attention and instructions and support filter down to the right people on the floor.



HOW KNOWLEDGE MANAGEMENT DRIVES OPERATIONAL EXCELLENCE

Having a centralized digital platform for knowledge transfer and PPM at the site has significantly increased efficiency and accountability and reduced the workload for shift supervisors. For example, the enterprise platform solution has helped the AbbVie site realize time savings for supervisors on each shift, a decrease in time spent on shift activities and an impactful decrease in nonconformities.

Other operational improvements the AbbVie Ludwigshafen site has seen include:

- Clear communication of tasks and priorities, resulting in fewer mistakes, lost requests, and production delays.
- A structured escalation process to ensure that information reaches the right people for efficient resolution.
- Fewer inquiries from shift operators and other departments because everyone has access to the information and instructions they need.

The AbbVie site credits improved communication and knowledge management for these operational gains. Marcel Weiler, an AbbVie team lead, says "Shiftconnector offers numerous benefits that enhance our daily work. With this tool, we can create tasks and assign them to individuals, resulting in shortened handover times and eliminating the hassle of searching through multiple tablets, documents, or systems. Instead, we have a clear overview of all tasks and instructions, and

all crucial information is readily accessible."

SOLVING THE KNOWLEDGE PROBLEM FOR PHARMACEUTICAL MANUFACTURING

Many pharmaceutical manufacturers struggle with knowledge transfer and alignment across shifts and tiers. And it's no wonder the typical pharmaceutical manufacturer operates on a 24/7 schedule with three or more shifts, multiple production lines, and many interdependent departments. Smooth operations depend on achieving operational alignment across shifts and organizational tiers and functional areas, including production operations, quality control, laboratory, maintenance, and management. To achieve that close alignment, facilities need to have everyone on the same page with real-time data and efficient transfer of knowledge.

Despite the industry's complex and high-stakes nature, most pharmaceutical manufacturers still rely on fragmented data systems and ad-hoc communication methods. Essential information for shift handover may be communicated primarily orally during a stand-up meeting, with supplemental notes in a spreadsheet or manual log. Critical production and equipment data may only be accessible to certain people. Calculating key performance indicators (KPIs), such as Overall Equipment Effectiveness (OEE), Batch Cycle Time, or Deviation Rate, often involves complex spreadsheets that are hard for non-technical employees to understand. As a result of this fragmentation, we often see communication problems develop in pharma facilities, including:

Benefits of a Digital Knowledge Management Platform

- Tighter alignment of priorities across shifts, departments and organizational tiers
- Reduction in human errors leading to quality and safety events
- Improved productivity and overall operational performance
- Greater accountability and task management
- Access to historical data for faster troubleshooting and problem resolution
- Retention of valuable tacet knowledge for training and troubleshooting
- Clear data to drive continuous improvement

Information Silos: Key knowledge is not shared effectively across departments, shifts, or tiers of the organization or not accessible to people who need it. Relevant information may not be shared or is lost in an information overload situation.

Poor Visibility: Information is available, but people do not know where to find it or even that they should be looking for it.

Complexity: People do not understand how to interpret the information or how to apply it to make day-to-day decisions on the job.

When there are breakdowns in communication and knowledge transfer within the organization, several problems can develop, including missed production quotas, quality and compliance issues, safety violations, inefficient troubleshooting, and poor alignment between shifts or departments. This adds up to higher costs, poor customer satisfaction, and a greater risk of legal or regulatory repercussions. Poor communication also impedes continuous improvement efforts, both suppressing the generation of innovative ideas from across the organization and reducing acceptance of and compliance with improvement initiatives.

That is where a digital knowledge management platform like Shiftconnector can help. By bringing both production data and human-generated notes and information together under a single platform, a digital knowledge management platform makes knowledge more accessible, understandable, and usable for the people who need it. That results in fewer human errors and tighter alignment across the organization for increased safety, quality, and productivity.

Digital tools for knowledge management and collaboration can help prevent communication breakdowns and improve alignment and operational efficiency across the organization. To be effective, these tools need to be designed with the needs of 24/7 process industries like pharmaceutical manufacturing in mind. They also need to work for — and with — the people in the organization. Some things to look for include:

- Easy-to-use digital tools for recording and sharing notes for shift handover, equipment inspection and maintenance, and other key facility processes.
- Integration with other plant systems (such as MES and ERP systems) for centralized data management and analysis.
- Data visualization tools that make KPIs and other plant data easily understandable and accessible for non-technical staff.
- Collaboration dashboards for easy

transmission of information, directives, and ideas up and down the organizational chain and across shifts and departments.

- Task management and accountability tools to ensure that directives are transmitted to the right people and departments and critical tasks do not slip through the cracks.
- Customization tools so dashboards and other functions can be tailored to the specific needs, language, and processes of the manufacturing facility.

Digitalization in the pharmaceutical industry is about empowering people to do their best work and make better decisions over the day. ◆

To view this issue and all back issues online, please visit www.drug-dev.com.

BIOGRAPHY

Andreas Eschbach is CEO of the global software company eschbach and inventor of the award-winning plant process management (PPM) platform, innovated Shiftconnector (www.shiftconnector.com) to help production teams streamline shift-to-shift communications and enable a safer and smarter environment through better data sharing and workforce collaboration. Earning a degree in computer science, he draws his practical experience from leading a variety of international software initiatives for major process manufacturing companies, especially in chemical and pharmaceutical industries.

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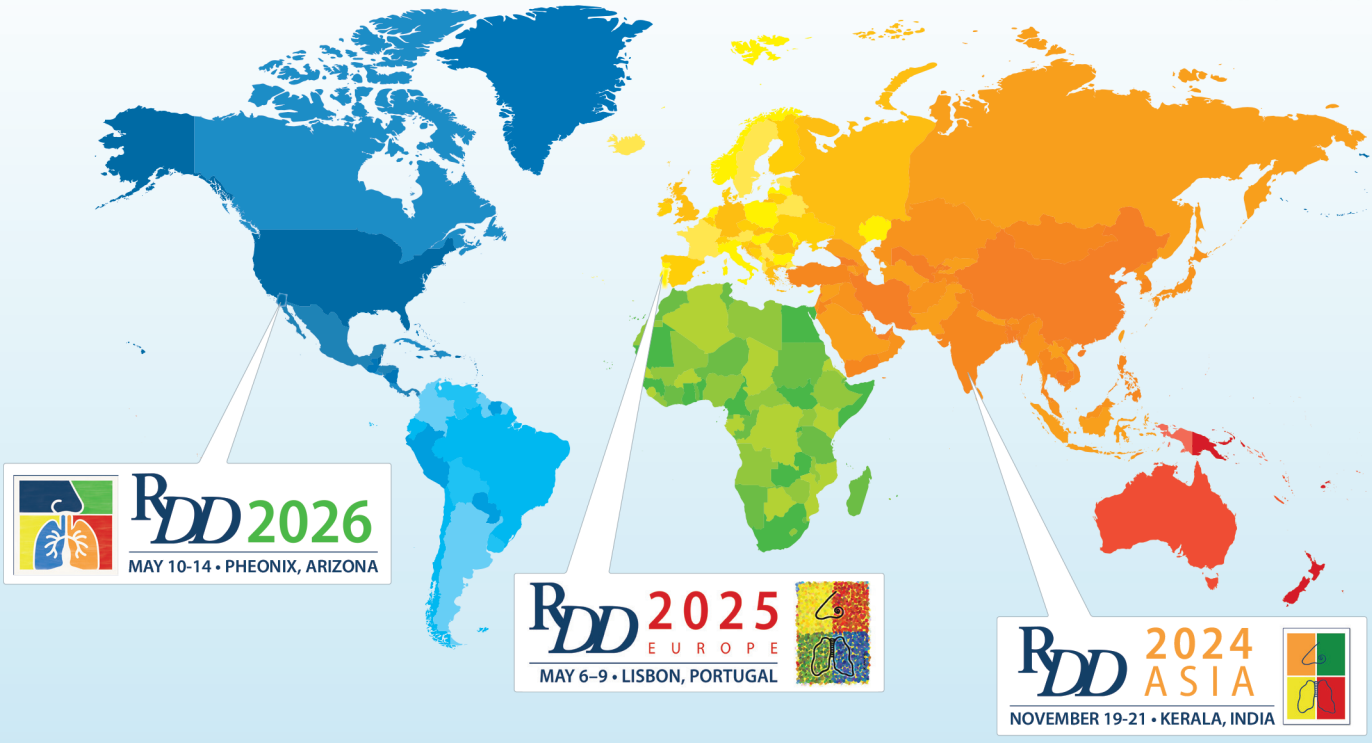

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Deadlines and details: rddonline.com | Questions: info@rddonline.com

COMPANY DESCRIPTION

AbbVie is devoted to the discovery, development, manufacturing, and marketing of products that span the continuum of care in pharmaceutical therapies. Leading-edge science and technologies that hold the potential for improving lives are advanced through AbbVie's dedication to research. Our uniqueness is created by the work we do - producing innovative medicines, continually investing in our pipeline, and giving back to create healthier, more vibrant communities. We have sustained our success by staying true to the key principles on which our company was forged: innovative care and a desire to make a meaningful difference in all that we do.

COMPANY BACKGROUND

AbbVie has a rich heritage of developing and producing pharmaceutical products for more than 130 years. By choosing AbbVie Contract Manufacturing, your team gets so much more than the typical CMO engagement. Alongside our state-of-the-art cGMP manufacturing facilities, AbbVie's partners gain integrated access to deep scientific expertise and processes that have successfully supported many small molecule and biologic medicines through to commercialization.

SERVICES

AbbVie's Contract Manufacturing Business has been serving our partners for more than 40 years. Our contract development and manufacturing capabilities span across 11 production facilities in North America and Europe. Our capabilities are:

- Aseptic Fill Finish (Vial and Prefilled Syringe)
- Custom API & Bulk Manufacturing
- Oral Solid Dose
- Fermentation
- Hot Melt Extrusion
- Potent
- Biologics
- Packaging
- Eye Care
- Topicals

AbbVie Contract Manufacturing
1401 Sheridan Rd
North Chicago, IL 60064
T: +1-800-240-1043 (USA)
T: +1-847-938-8524 (Outside USA)
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Eyecare | Topical | Aseptic Fill-Finish | Hot Melt Extrusion (HME) | Oral Solid Dose
Microbial Fermentation | Biologics | Antibody Drug Conjugate (ADC) | Custom API

AbbVie Contract Manufacturing partners with companies around the globe to develop, scale and manufacture their pharmaceutical products.

With decades of experience, we see the complete picture to deliver your vision and real-world results, while improving people's lives.

Start the journey, at abbviecontractmfg.com

Vision. Expertise. Success.

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ABITEC
AN ABF INGREDIENTS COMPANY

ABITEC CORPORATION
501 W. 1ST Ave.
Columbus, OH 43215 USA
W: www.abiteccorp.com

ABITEC develops and manufactures lipid-based excipients to enhance the bioavailability of poorly water-soluble and poorly permeable Active Pharmaceutical Ingredients (APIs) for the pharmaceutical industry. And now with the addition of Larodan, ABITEC has expanded its offerings to include high-purity research grade lipids.

New in 2025, **ABITEC** is offering **Lipids for LNP Therapeutics**. With a catalogue of over 3000 lipid chemistries and the ability to customize and manufacture GMP lipids at both research and manufacturing scale, ABITEC is your partner of choice for customized functional lipids for the formulation of advanced drug delivery platforms, such as lipid nanoparticles.

ABISORB-DC™ is ABITEC's co-processed excipient system for the direct compression of liquid lipids and self-emulsifying drug delivery systems at industry tableting speeds. ABISORB-DC can absorb up to 20-25% w/w of liquid lipids and then be subsequently compressed into tablets.

The **ABISOL™ Emulsion Preconcentrate Kit** is a series of varying HLB, preformulated preconcentrates for the formulation of self-emulsifying drug delivery systems. Fast track your lipid-based formulation with the **ABISOL Emulsion Preconcentrate Kit**.

ABITEC has an expansive portfolio of **CAPMUL®** bioavailability enhancers, which are medium-chain mono- and di-glycerides and propylene glycol esters. These functional lipid excipients act as solubilizers and emulsifiers in oral, topical, transdermal, and parenteral drug delivery systems. **CAPMUL** excipients are recognized as the ideal starting point when formulating BCS Class II & IV (poorly water soluble) and BCS Class III & IV (poorly permeable) molecules.

CAPMUL-based formulations may be customized with the inclusion of **CAPTEX®** medium-chain triglycerides and/or **ACCONON®** non-ionic surfactants to formulate self-emulsifying drug delivery systems.

ABITEC manufactures high-quality lipid excipients for drug delivery applications in accordance with strict cGMP and applicable IPEC (International Pharmaceutical Excipient Council) guidelines in ISO-certified facilities. ABITEC's customer-preferred portfolio of pharmaceutical excipients are monograph compliant, supported by drug master files (DMFs), and have precedence of use.

Dosage Forms Include: Oral, Injectable, Topical & Transdermal, Suppositories, Ophthalmic, and Inhaled

Application Include: Solubilization, Emulsification, Lubricating Dry Binder, Permeation Enhancement, Encapsulation, Controlled Release, and Self-Emulsifying Drug Delivery Systems

Lipids for LNP Therapeutics:
https://www.abiteccorp.com/en/pharmaceutical/pharmaceutical-applications/lnp-therapeutics/

ABISORB-DC:
https://www.abiteccorp.com/en/pharmaceutical/pharmaceutical-products/abisorb-dc/

ABISOL Emulsion Preconcentrate Kit:
https://www.abiteccorp.com/en/landing-pages/abisol-emulsion-kits-available-now/

To Request a Sample: visit https://samples.abiteccorp.com/

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ABITEC

High-Purity Lipids for LNP Therapeutics

ABITEC is your **premiere partner** for the synthesis of **customized research and c-GMP grade lipids** for your drug-delivery applications.

Learn More

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T: (858) 550-4094

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BABRAHAM RESEARCH CAMPUS - CAMBRIDGE, UK CB22 3AT
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Abzena is the leading end-to-end CDMO + CRO for bioconjugates, ADCs and complex biologics. From discovery through commercial launch, we support customers with fully integrated programs or individual services designed to de-risk and streamline the development of new treatments for patients in need. With the ability to tailor our strategy and customer experience to each project, Abzena develops and implements innovative solutions that enable biotech and biopharma companies to realize the full potential of their molecule.

Over the past 20 years, Abzena has helped hundreds of customers ranging from emerging biotechs to the top large pharmaceutical firms achieve their regulatory and clinical milestones. With extensive scientific knowledge and technical expertise, our global teams provide customers with comprehensive support that minimizes risks and moves new medicines forward faster- with greater success. Our global locations include San Diego (CA, USA), Bristol (PA, USA), and Cambridge (UK).

Comprehensive biologics & bioconjugate support:
Monoclonal Antibodies (mAbs), Antibody Fragments (fAbs), Antibody-Drug Conjugates (ADCs), Antibody-Oligonucleotide Conjugates (AOCs) Bispecific Antibodies (bsAbs), Radioconjugates (RDCs/RACs) Fusion Proteins, Cytokines, Recombinant & Conjugate Vaccines, and Biosimilars

Services that expedite timelines
Abzena develops and implements fully integrated services and tailored, innovative solutions that are designed to rapidly advance your program to its next milestone.

- Lead Discovery, Design and Selection
- Robust Analytics, Bioassays and Immunogenicity
- Antibody Engineering and Developability
- Mammalian Cell Line Development
- Linker Payload Design and Synthesis
- Bioconjugation & Complex Chemistry
- Analytical Method & Formulation Development
- Process Development and cGMP Manufacturing
- Technology Transfer & Scale-Up
- Regulatory Support

Solutions for improving development
Our proprietary solutions are designed to give your program the best chance of clinical and commercial success.

AbZelectPRO™ – high-yielding mammalian cell line development (CLD) platform for accelerating the generation of production cell lines in just 10 weeks with 8g/L in high-performing titres for antibodies, bispecifics and recombinant proteins.

EpiScreen™ 2.0 – a comprehensive suite of assays that predict and evaluate potential risks of preclinical immunogenicity in protein, antibody, and gene therapy. This high sensitivity, multi-dimensional, data-rich platform streamlines candidate selection, helping to de-risk the drug development process

Composite Human Antibody™ – a platform used for designing safer, more effective, humanized antibodies.

Composite Proteins™ – a deimmunization technology that designs safer therapeutic proteins, devoid of human T cell epitopes, to minimize potential immunogenicity in patients without compromising activity.

ThioBridge™ – a next generation conjugation linker technology proven to enhance ADC development by overcoming issues with existing technologies to improve stability, potency, and efficacy.

LabZient™ – our analytical platform that combines predictive in-silico evaluation with laboratory methods to de-risk the application of platform analytical procedures and expedites the pathway to IND.

The Abzena Approach
We are focused on getting it right from the start. From early discovery through commercial, our experienced scientists work with you side-by-side, functioning seamlessly as part of your team – using real-world insights to bring new ideas to the table and then turning them into action. With quality top of mind, we plan the best route, steering your drug program toward regulatory approval, and getting it into the hands of patients.

Connect with us today at info@abzena.com or by visiting Abzena.com to discuss your drug program's needs with our experts.

ABZENA | Moving medicine forward.

What if you knew during drug design

What could happen in the clinic

Or better still, beyond?

That's the kind of information we can put in your hands.

From generating robust data for your IND to optimizing formulations for the clinic, we leverage vast product knowledge and in-house capabilities to identify risks and overcome challenges early. So your biologic or ADC can progress faster—with greater success.

- → Fully Integrated CDMO + CRO Support
- → Unparallelled Scientific + Technical Expertise
- → Better Biologics, ADCs + Bioconjugates

We can help de-risk & streamline your biopharmaceutical's path from discovery to commercial.

Learn more at abzena.com/knownow

ACTYLIS
4 Tri Harbor Court - Port Washington, NY 11050
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About Us

Actylis is a leading manufacturer of critical raw materials and performance ingredients serving the Life Sciences industry. Through our hybrid approach we provide combined capabilities in GMP and non-GMP manufacturing and outsourcing, and global sourcing of critical raw materials and ingredients, offering unrivalled choice to pharmaceutical & biopharmaceutical companies.

The inherent flexibility in our hybrid approach alleviates common internal customer concerns over time constraints in delivery to market and capacity pressures. We enable customers to consolidate their supply chain with one reliable partner, backed by best-in-class quality and regulatory accreditation, while retaining valuable flexibility.

Global Industry Experts

Actylis has a growing global portfolio of GMP and non-GMP manufacturing sites led by experienced teams. Our production facilities are routinely audited by accreditation bodies and customers, and feature state-of-the-art technology & equipment, industry-leading quality systems, and excellent regulatory performance.

As a global manufacturer and distributor of critical ingredients, Actylis has sector experts worldwide who are always accessible to consult and collaborate with customers' development and manufacturing teams. We are committed to getting to know our customers intimately, understanding their critical ingredient needs and finding the right solution among the flexible manufacturing capabilities we offer, and the hybrid option of global manufacturing and sourcing.

GMP Ingredients

With our hybrid manufacturing/sourcing model, we optimize supply solutions for over 4,000 compounds, including raw materials, cell culture ingredients, excipients, buffers, process solutions, process intermediates, APIs, Water for Injection, amino acids, nucleosides and nucleotides.

Whatever your needs, from regulatory starting material, active ingredients, early or late intermediates, to ingredients for clinical or commercial manufacturing stages, we have the solution for you.

GMP Services

We offer GMP custom manufacturing, liquid blending, ingredient development, custom packaging, R&D and analytical services. Our custom manufacturing offers a valuable, reliable source for niche, difficult-to-find ingredients, providing confidence in secure long-term supply to support drug products. Our expertise begins with process R&D to solve your most complex chemical problems, then it continues with our team of agile scientists during the synthesis stage and concludes with GMP clinical manufacturing.

Quality

Our products are backed by world-class quality, reliable delivery, and a strong regulatory record, which is another key component of the trusted partnerships we build with customers, supporting rapid commercialization and uninterrupted supply of finished products.

Actylis is renowned for its high-quality standards and provides full transparency in the supply chain. Our pharma & biopharma GMP and non-GMP manufacturing facilities hold all the major certifications and applicable licenses from the main accreditation bodies and agencies.

ADARE®
PHARMA SOLUTIONS

ADARE PHARMA SOLUTIONS
7722 Dungan Road - Philadelphia, PA 19111
E: BusDev@adareps.com W: AdarePharmaSolutions.com

COMPANY DESCRIPTION

Adare Pharma Solutions is a global technology-driven CDMO providing end-to-end integrated services, from product development through commercial manufacturing and packaging, with small molecule expertise focusing on oral dosage forms. Adare's specialized technology platforms provide taste masking, customized release, solubility enhancement, and patient-centric dosing solutions. With a proven history in drug delivery, Adare's seven facilities in the US and Europe have developed and manufactured more than sixty-five products sold by customers worldwide.

SERVICES & CAPABILITIES

Adare provides end-to-end CDMO services, from clinical trial materials and product development to commercial manufacturing and packaging. We can develop and manufacture oral dose products from start to finish, and we can tech transfer pre-established projects into our facilities.

TECHNOLOGIES

Adare's industry-leading experts possess unparalleled experience in the development of unique dosage forms that provide taste masking, customized release, and patient-centric solutions. Our technology platforms overcome complex formulation challenges to improve the lives of all patients, with expertise in pediatric, geriatric, and dysphagic requirements.

FACILITIES

Adare operates seven facilities in the US and Europe, staffed by nearly 800 employees. With our global manufacturing network, Adare is capable of serving markets throughout the world. From our state-of-the-art facilities in the US and Europe, we can provide development-scale through commercial-scale production, with a continuum of highly specialized manufacturing services and capabilities to meet any customer's oral solid dose needs.

Development Services

- Preformulation
- Formulation development of
  - o Solid dose tablets
  - o Capsules
  - o Liquids
  - o Solutions
- Pediatric formulation
- Product design
- Formulation optimization
- 3D printing capabilities
- Sourcing of APIs & excipients
- Analytical method development & validation
- Prototype development
- Small-scale non-GMP & GMP development capabilities

Manufacturing Services

- Granulation and mixing
- Fluid bed processing
  - o Wurster
  - o Top Spray
- Pan coating
- Blending (Bin and Static)
- Tableting
- Multi-layer tablets
- Capsule filling
- Oven drying
- Spray drying
- Small-scale GMP manufacturing
- Tech transfer
- Warehousing & distribution

Specialized Services

- Microencapsulation
- Orally disintegrating tablets (ODT)
- Dry syrup/suspensions
- MMTS™ Minitabs
- Controlled substances manufacturing licenses for Schedules II, 2N, III, 3N, IV, V, and L1
- High Potency: 1 mcg/m^3 and above
- Fixed-dose combination manufacturing
- Liquid filling in hard-shell capsules with banding
- Solvent granulation and coating processes
- Food sprinkle dosage forms

Packaging & Logistics

- Clinical and commercial contract packaging
- Two packaging facilities
- A full range of solid-dose packaging solutions
  - o High-speed bottle filling
  - o Blister packaging
  - o Stick pack and cartoning
  - o Specialty packaging
  - o DEA Schedules II, 2N, III, 3N, IV, L1
  - o Serialization & aggregation
- Regulatory support
- Stability testing
- Expanded labeling support
- Warehousing & distribution

YOUR PARTNER FOR SMALL MOLECULE ORAL SOLID DOSE SUCCESS

Adare Pharma Solutions is a global technology-driven CDMO providing end-to-end integrated services, from product development through commercial manufacturing and packaging, with small molecule expertise focusing on oral dosage forms. Adare's specialized technology platforms provide taste masking, customized release, solubility enhancement, and patient-centric dosing solutions. With a proven history in drug delivery, Adare's seven facilities in the US and Europe have developed and manufactured more than 65 products sold by customers worldwide.

TRANSFORMING DRUG DELIVERY. TRANSFORMING LIVES.

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ALMAC

Partnering to Advance Human Health

ALMAC GROUP
20 Seagoe Industrial Estate
Craigavon, BT63 5QD
E: almacanalytical@almacgroup.com
W: Analytical & Solid State Services - Almac

Company Description

The Almac Group is a global leader in providing a range of expert services and support across the drug development lifecycle.

We are trusted experts in R&D, diagnostic services, API manufacture, formulation development, clinical trial supply services and technologies through to commercial-scale manufacture and distribution.

We are recognised as an industry leader in client service, providing understanding, experience and knowledge to our clients as we work together to advance human health.

Almac is trusted by the leading global biopharma companies to provide crucial services across their drug development projects. In the last 5 years alone, we have contributed to over 50% of all FDA approved New Molecular Entities (NMEs) and are currently supporting 25% of EU approved /pre-registered Gene therapy products.

A privately owned organization, Almac has grown organically over the past five decades, employing over 7,500 highly skilled employees across 18 facilities in Europe, North America, and Asia.

SERVICE HIGHLIGHTS

API Services & Chemical Development

Providing integrated services from development to commercial scale of advanced intermediates and Active Pharmaceutical Ingredients (API), we offer a wide range of services for small molecules (including highly potent) and peptides. We have a proven track record of saving time and costs through the integration of our services and application of innovative biocatalysis and technology solutions:

- API development and manufacture
- Peptide & Protein Technologies
- Analytical Services
- Physical Sciences
- 14C-radiolabeling
- Biocatalysis solutions
- Continuous flow chemistry
- Non GMP starting materials/intermediates

Pharmaceutical Development

Addressing the increasing pressure to bring clinical candidates through pipelines faster and with greater efficiency, we provide expert solid, oral dose pharmaceutical drug product development solutions. From developing a fit-for-purpose formulation for First-in-Human trials, to scaling up for late phase trials and ultimately commercialization, our solid oral dose, pharmaceutical development solutions are customized to meet our client needs.

- Pre-formulation
- Non-GMP development
- Early-stage development
- Scale-up and later stage development
- Clinical trial manufacture
- High potency processing
- Analytical support

Commercial Services

Meeting all your commercial needs, we provide a wide range of customized commercial services from supporting your drug product launch, commercial drug product manufacturing and/or specialized packaging of your drug product, to securing your supply chain with global serialization solutions.

- Commercial Product Launch & Distribution
- Oral Dose Commercial Manufacturing
- Oral Dose Commercial Packaging
  - o Specialized Commercial Packaging
  - o Via /PFS/Autoinjector Labeling
  - o Complex Kit Assembly
- Ultra Low Temperature Labeling & Packaging for gene and cell therapy products

RECENT INVESTMENTS

Almac has significantly enhanced the versatility of its analytical services to meet diverse demands through several key initiatives:

- Recent global analytical services expansion investment of £11 million, creating >100 jobs and includes new labs and upgrades to existing labs across Europe and US, increasing overall capacity and capabilities.
- Specialised instrumentation and techniques to support new offerings including spray drying for poorly soluble drug products.
- A multi-million-pound digitisation upgrade, including enhancements to our laboratory information management system (LIMS), allows for seamless information sharing across our multiple teams and facilities; optimising operations and improving service delivery.

AGNO PHARMA

Agno Pharmaceuticals: Purer Solutions for a Better Life

Agno Pharmaceuticals is a leading, global, small molecule Contract Development and Manufacturing Organization (CDMO), catering to the specific needs of the branded pharmaceutical, biotech, generic, and CDMO sectors. Agno Pharmaceuticals is a US-based, end-to-end premier service provider. We specialize in supplying Registered Starting Materials (RSMs), custom Chemical Intermediates, Active Pharmaceutical Ingredients (APIs), highly potent APIs, sterile APIs, and complex Drug Product formulations (including long-acting injectables/implants) to our valued clientele worldwide. Our US-FDA inspected cGMP compliant manufacturing facilities ensures that we are able to provide our services at a level of unparalleled quality and compliance to our customer base.

With a dedicated drug product formulation research and development laboratory, we enhance our capabilities, particularly in the areas of complex injectables and drug eluting devices. Agno Pharmaceuticals is committed to investing in our people and facilities, offering a broad spectrum of service capabilities throughout the entire drug development and commercialization process. Our track record speaks for itself, with a proven history of delivering both development and commercial stage cGMP manufacturing solutions to clients globally since 2004. At Agno Pharmaceuticals, we are dedicated to exceeding the needs of our clients at every stage of their journey.

Particle Sciences: A Division of Agno Pharmaceuticals

Our Bethlehem site was founded in 1991 as Particle Sciences, Inc. The company was acquired by Agno Pharmaceuticals on December 15, 2023 and is now seamlessly integrated into Agno Pharmaceuticals. The Bethlehem site retains its reputation as a leading contract development and manufacturing organization for insoluble drugs. Looking to the future, Particle Sciences will continue its legacy of excellence in providing its customers with solutions that strive to be client centric. Our team of experienced leading industry experts specializes in offering complex drug product formulation development and manufacturing, drug-eluting device development, and a comprehensive suite of supporting services.

From providing analytical services, including physicochemical characterization, to cGMP clinal supply manufacturing, we offer an end to end solution to our customer base within a diverse range of formulation development technology platforms. Our expertise in developing and implementing solutions, at both laboratory and commercial scale, for poorly soluble and highly potent compounds, in both sterile and non-sterile environments

Agno Pharmaceuticals
Headquartered in Bethlehem, PA
3894 Courtney St, Bethlehem, PA 18017
E: info@agnopharma.com
W: www.agnopharma.com
LinkedIn: https://www.linkedin.com/company/agno-pharma

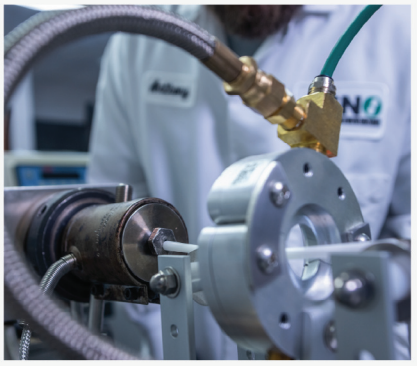
AGNO PHARMA

PURER SOLUTIONS FOR A BETTER LIFE

Agno Pharmaceuticals is a global Contract Development and Manufacturing Organization (CDMO) based in the U.S., specializing in small molecule drug development and manufacturing. We provide services across the pharmaceutical, biotech, and generic sectors, including the supply of Registered Starting Materials (RSMs), Active Pharmaceutical Ingredients (APIs), highly potent APIs, sterile APIs, and complex drug products such as long-acting injectables and implants. Our US-FDA inspected, cGMP-compliant facilities ensure high-quality and regulatory-compliant solutions.

Your Global Premier End-To-End CDMO

Our recent acquisition of Particle Sciences, now a division of Agno Pharmaceuticals, strengthens our capabilities in insoluble drug development. The Bethlehem site, established in 1991, continues to lead in complex drug formulation and cGMP clinical supply manufacturing, offering end-to-end solutions for both poorly soluble and highly potent compounds.



In addition to API manufacturing, we offer specialized drug product formulation services, particularly for complex injectables and drug implant development, supported by a dedicated R&D lab. With a proven track record since 2004, we serve clients globally, guiding them through the entire drug development and commercialization process.

www.agnopharma.com

APRECIA™
THE 3DP PHARMACEUTICAL COMPANY

The Leader in Development & Manufacturing of 3D Pharmaceutical Printing

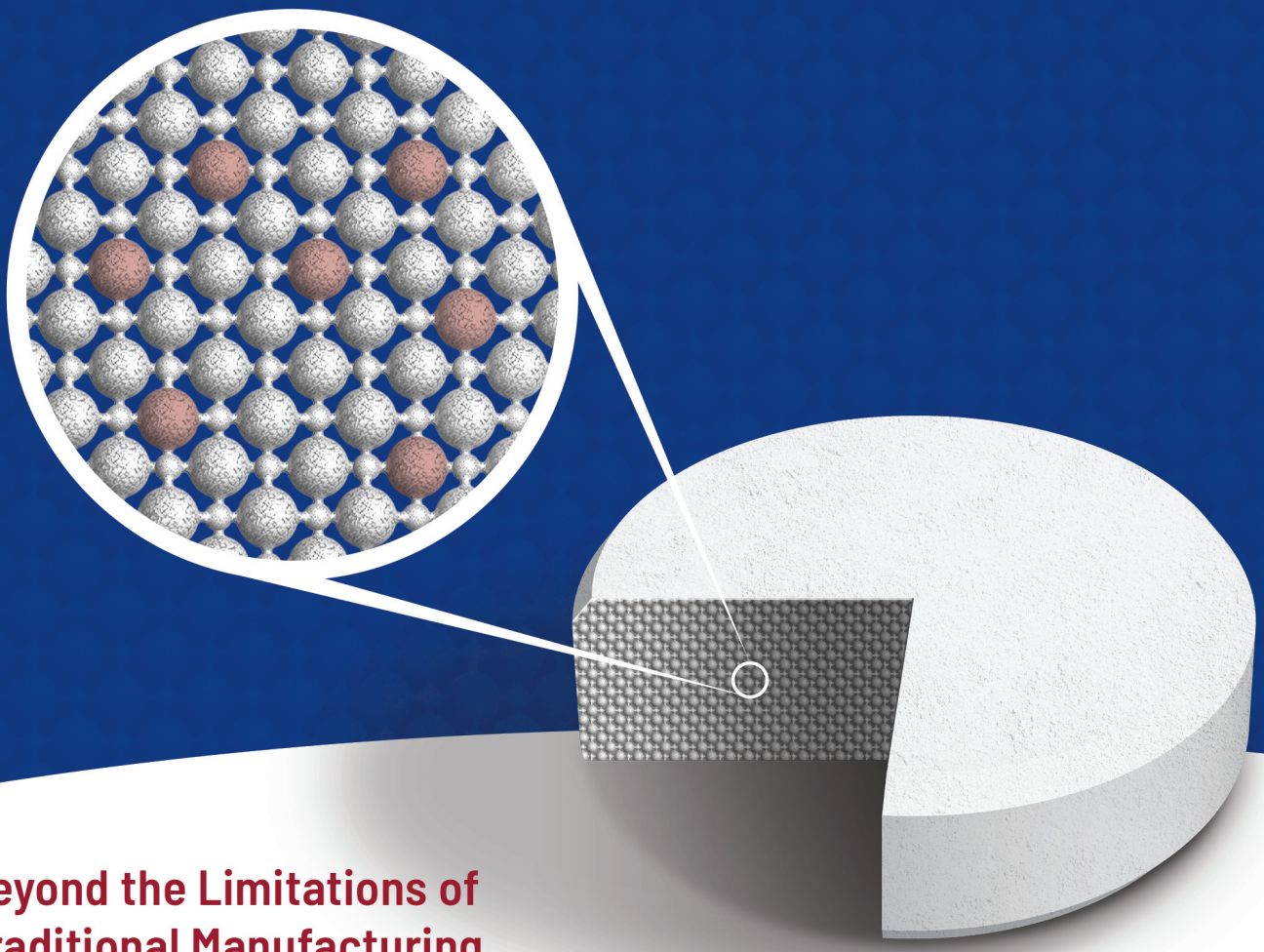
Aprecia offers commercial-scale production systems designed to accelerate clinical development and optimize commercial success. Our industry-leading 3DP formulation and manufacturing platforms transform drug development and delivery, meeting the unprecedented demand for complex and patient-friendly dosage forms.

Aprecia Headquarters in Cincinnati, Ohio

- 190,000 sq. ft. center of excellence
- FDA registered and inspected cGMP facility
- Engineering innovation laboratories
- Analytical laboratory & warehouse

Who We Are

- Collaborated with MIT to bring groundbreaking 3DP technology to market
- Sister company of Prasco, the leader in Authorized Generics since 2002 and trusted pharmaceutical partner with over 90 AG launches and more than 110 product agreements
- First and only 3DP FDA product approval
- 126 granted patents, 52 pending



Beyond the Limitations of Traditional Manufacturing

Aprecia's versatile and scalable platforms allow our partners to create innovative applications including:

Product development through commercial scale

Compression free process, complex geometries

Flexible Oral Administration — Traditional, Sublingual/Buccal, & Orodispersible Tablets

Embedded Functionality — Taste Masking, Modified Release, Enhanced Bioavailability, & Anticounterfeiting

Broad API Compatibility — High Dose, Ultra-Low Dose, Fixed-Dose Combos, & Potent Compounds

If you would like more information about Aprecia business opportunities or if you have any general questions, please feel free to contact us.

Aptar Pharma
W: https://www.aptar.com/pharmaceutical/
E: info.pharma@aptar.com

With over 75 years of proven experience, Aptar Pharma is the go-to drug delivery expert, for pharma customers worldwide, from formulation to patient, providing innovative drug delivery systems, components and active material solutions across the widest range of delivery routes, including nasal, pulmonary, ophthalmic, dermal and injectables. Aptar Pharma Services provides early-stage to commercialization support to accelerate and derisk the development journey. With a strong focus on innovation, Aptar Digital Health is a leading provider of integrated digital health solutions to enhance patient experiences across their treatment journey. With a global manufacturing footprint of 14 manufacturing sites, Aptar Pharma provides security of supply and local support to customers. Aptar Pharma is part of AptarGroup, Inc.

End-to-End Support at Every Stage of Your Development Journey

From concepts to initial design, device and formulation development through the clinical trials phase, analytical testing, regulatory filings, and on to market launch, Aptar Pharma Services can support you at every stage of your product development pathway.

Unparalleled Expertise in Inhalation

Aptar Pharma is the global leader in pulmonary drug delivery solutions, delivering gold standard devices to manage asthma and COPD, and is leading the way in developing more sustainable pMDIs with end-to-end solutions.

Market-Leading Solutions for Effective Nasal Drug Delivery

We are the global leader in nasal drug delivery solutions with over 280 market references worldwide using our Unidose, Bidose and multidose nasal spray pumps.

Best-in-Class Complete Injectable Solutions

Our best-in-class injectable solutions for Vial, Lyophilization & Pre-Filled Syringes, including Aptar Pharma's PremiumCoat® ETFE-coated solutions, meet the highest quality standards to protect your drug and your patient. Our pure formulations, state-of-the-art manufacturing process and Premium finishing derisk your drug development and accelerate your time to market.

Proven Know-How in Ophthalmic Drug Delivery Devices

Clearly the world leader in preservative-free multi-dose eye care devices, Aptar Pharma's proven OSD platform has over 500 market references worldwide for prescription medications and OTC products.

Meeting the Growing Market Need in Dermal Drug Delivery

We offer a versatile solution platform for dermal drug delivery, serving the pharmaceutical market to enable brand differentiation and meet evolving regulatory needs. Aptar Pharma's Airless+ range offers a clean, hygienic, efficient, and sustainable customer experience, and our Airless+ Extended Support (ES) provides regulatory, analytical and filling support for seamless dermal drug delivery project development.

Building Innovative Digital Device Solutions for Improved Patient Healthcare

Aptar Digital Health creates end-to-end solutions to enhance patient experiences every day, leveraging a holistic ecosystem of digital interventions. Amplified by an industry-leading portfolio of products and solutions, Aptar Digital Health's offerings combine mobile and web apps, connected drug delivery systems, onboarding, training and advanced data analytics services to actively empower patients and create a positive treatment journey.

Our Sustainability Progress

At Aptar, we operate with care for our employees, communities and the environment by continuously improving our impact and reducing our footprint. We are collaborating with customers, suppliers, industry coalitions and nonprofits to innovate and enable progress towards better outcomes for people and planet. Following the approach to circularity, we are helping the industry advance the system-scaled change that will benefit people in the long run by addressing climate change and the waste crisis.

Our PremiumCoat® production is taking a giant leap in size

...to help you protect billions of sensitive doses.

Big health challenges require transformative thinking. At Aptar Pharma, we're transforming expectations of what an injectables partner can be.

To meet increasing demand and expectations for drug/container compatibility, we're expanding our manufacturing footprint to deliver billions of additional injectable components each year, including 1 billion PremiumCoat® ETFE film-coated solutions. We've already implemented advanced robotics and added new clean rooms to enhance quality and derisk your sensitive drug development.

With our increased capacity and agility, together we can meet the world's biggest health challenges, today and tomorrow. Join us.

visit www.aptar.com/pharmaceutical

Shaping the future of injectables, together

Aptar pharma

KEEPING YOU CONNECTED TO YOUR TARGET AUDIENCE.

For more than 20 years, Drug Development & Delivery has successfully connected technology and service providers with R&D scientists, business development professionals and corporate managers working at pharmaceutical and biotechnology companies.

Marketing your technologies, services and products with Drug Development & Delivery keeps you engaged with your key audience.

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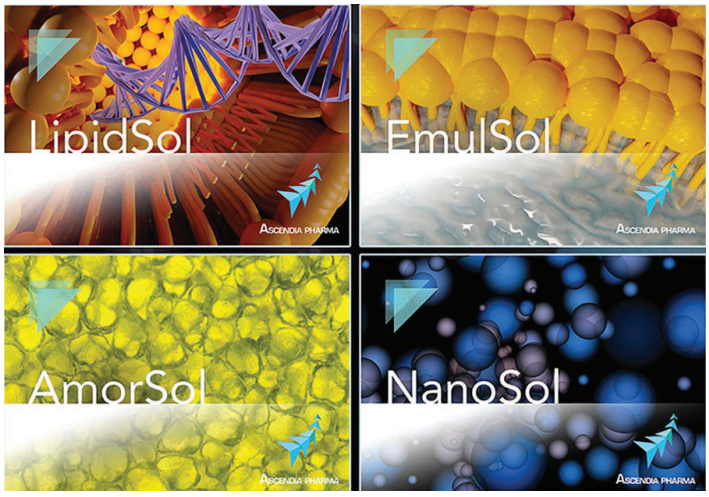
John Kiesewetter: 541-338-0022
jkiesewetter@drug-dev.com

Amy Nicklaus: 862-274-5872
anicklaus@drug-dev.com

Ralph Vitaro: 973-263-5476
rvitaro@drug-dev.com

drug-dev.com



Ascendia Pharmaceutical Solutions
(formerly Ascendia® Pharmaceuticals, Ascendia® Pharma)
661 US Highway One
North Brunswick, NJ 08902
T: (732) 638-4028
E: bd@ascendiaCDMO.com
W: www.ascendiacdmo.com

Company Description

In only a decade, Ascendia Pharmaceutical Solutions has evolved from a specialty formulation research organization to a valued CDMO partner that provides comprehensive solutions from pre-formulation through to commercialization. Ascendia Pharmaceutical Solutions has become a Partner of Choice by consistently making the Impossible Possible through its experienced scientific teams, proprietary nanotechnologies, and advanced manufacturing capabilities.

Its comprehensive services are used in a variety of drug development initiatives for small molecules, as well as biologics and gene deliveries. Ascendia Pharmaceutical Solutions addresses evolving market needs, including lipid nanoparticles (LNPs), through the simple elegance of its nanotechnologies and sophisticated processes, such as lyophilization, that result in overcoming drug development challenges where others have failed. This includes the ability to optimize dosage forms, allowing drugs to be delivered in new ways, for the well-being of patients.

Pharmaceutical and biotech companies partner with Ascendia Pharmaceutical Solutions from discovery through commercialization because all GRAS (Generally Regarded As Safe) materials are used, so drugs can be brought to market on time, cost efficiently, and in dosage forms previously unattainable.

Company Background

Founded in 2012, the company offers a comprehensive suite of pre-formulation, formulation development, cGMP manufacturing, and ICH stability services for all dosage forms. Ascendia Pharmaceutical Solutions built its foundation of success on its customer-centric culture that exudes its **BEST** philosophy (**B**rilliant technology, **E**xcellent service, **S**uperior quality, and **T**rust). This approach has led to Ascendia Pharmaceutical Solutions doubling in size in the past three years and being named to the prestigious Inc. 5000 list four consecutive years.

Markets Served/Facilities

Ascendia Pharmaceutical Solutions is headquartered in the New Jersey Bioscience Center, North Brunswick, NJ. Its 60,000 square-foot facility has Class 10,000 (ISO 7) and Class 100 (ISO 5) cleanrooms, as well as Class 100,000 (ISO 8) manufacturing suites. It provides custom sterile and non-sterile enabling formulations, along with analytical methods for new chemical entities, complex dosage forms, and 505(B)(2) product development, as well as OTCs, veterinary drugs, and nutraceuticals.

Products, Services & Capabilities

Ascendia Pharmaceutical Solutions delivers sophisticated formulations to enhance bioavailability and solubility using four proprietary nanotechnologies – AmorSol®, EmulSol®, LipidSol®, and NanoSol®. Its state-of-the-art facility supports GLP and cGMP manufacturing in accordance with ICH guidelines.

Drug development teams rely on Ascendia Pharmaceutical Solutions for:

- Pre-formulation services/screening
- Formulation development
- Proprietary nanotechnologies
- ICH stability studies
- Sterile and non-sterile manufacturing
- Analytical services, QC and Micro testing
- Clinical trial material supply
- Niche commercial product manufacturing

AUSTINPx™

PHARMACEUTICS / MANUFACTURING

COMPANY DESCRIPTION

AustinPx was founded to help developers realize the full potential of their drug candidates. There are many obstacles to bringing a drug to market, including poor bioavailability and accelerated timelines. That's where we come in. Our client-centric approach is designed to simplify the complexity of outsourcing and our team of formulation, analytical, and manufacturing experts work with you to overcome challenges and identify opportunities to do more, faster. As the inventors of KinetiSol™ Technology, a next-generation amorphous solid dispersion (ASD) technology for poorly soluble APIs, with its smaller footprint, broader design space, and greener processing solutions, we aim to disrupt the ASD industry.

SERVICES & CAPABILITIES

Preclinical Development

- Molecule Characterization
- Preformulation Testing
- Formulation Technology Screening- including dry and wet granulations, amorphous dispersions, cyclodextrin complexations, particle size reduction, and lipid-based formulations.

Formulation Development

- Drug Product Intermediate and Finished Dose Development that include solutions, suspensions, tablets, and capsules
- Immediate and Modified Release
- Bioavailability Enhancement Technologies, such as KinetiSol™ for amorphous solid dispersions, spray-drying, hot melt extrusion, and lipid delivery
- API in Capsule or Bottle

Analytical

- Chemical Analysis
- Dissolution/Flux
- Drug Product Test Methods
- Preclinical through Commercial: qualification/validation
- Release Testing and GMP Stability Studies

GMP Manufacturing

- KinetiSol™ Technology
- Blending
- Milling
- Granulation
- Encapsulation
- Tableting
- Packaging- botting and clinical labeling

AUSTINPx
111 W. Cooperative Way, Bldg. 3 - Georgetown, TX 78626
T: (512) 686-4740
E: info@austinpx.com - W: www.austinpx.com
LinkedIn: https://www.linkedin.com/company/2556372/

Where we're from

What we do (Pharmaceutics)

AUSTINPx™

Our Name is our Brand. Austin is where we're from and Pharmaceutics (Px) is what we do. To our core we are a pharmaceutics company—a band of development and manufacturing professionals guided by data and science and driven to provide exceptional service. From API in Capsule to amorphous dispersions and controlled release, our formulation strategy is tailored to the molecule's characteristics, the patient population, and your corporate goals.

WE ARE PHARMACEUTICS (Px). WE ARE

AUSTINPx™

PHARMACEUTICS / MANUFACTURING

Connect with our Experts today

info@austinpx.com | www.austinpx.com

BASF We create chemistry

BASF Pharma Solutions

W: https://pharma.basf.com/general-contact

BASF Pharma Solutions is a leading provider of innovative and high-quality excipients and APIs for the pharmaceutical industry. Our dedicated team of industry experts, supported by our cutting-edge digital solutions, works closely with customers to develop efficient and reliable formulations.

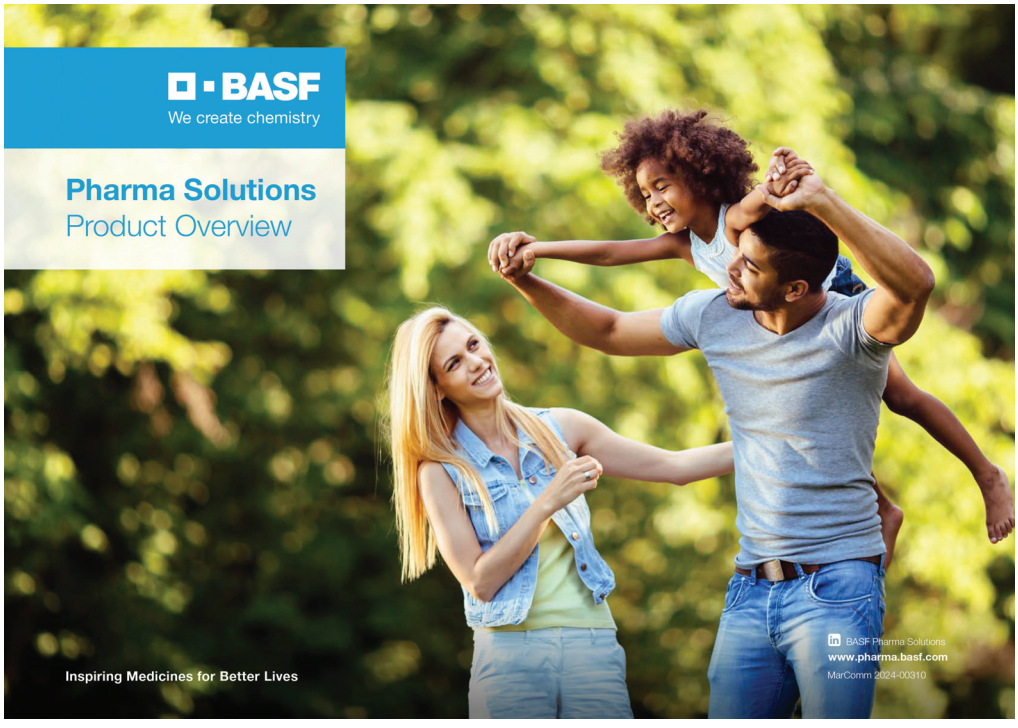
Based in Florham Park, United States, our operations span across the globe, with production facilities that spread across multiple continents, we are able to provide support and solutions to pharmaceutical industries worldwide.

At BASF, we prioritize the production of pharmaceutical ingredients in accordance with the highest quality standards. With over 75 years of experience, we offer the expertise and continuity necessary to meet the diverse needs of your pharmaceutical business.

We combine our in-depth knowledge of chemistry with a broad understanding of pharmaceutical formulations to develop next-generation excipients. Additionally, our leading digitalized services, such as RegXcellence®, ZoomLab™, and MyProductWorld, empower you to create better and more sustainable solutions at a faster pace.

Sustainability is a core value at BASF. As a global leader in sustainable sourcing solutions and carbon production management, we are committed to helping your industry become more sustainable. Learn more about our initiatives and how we can support your sustainability goals.

Choose BASF Pharma Solutions for innovative, high-quality products, expert support, and a commitment to sustainability.



BASF
We create chemistry

Overcome direct compression challenges

Introducing Kollitab™ DC 87 L

The new all-in-one tableting solution with filler, binder, disintegrant and lubricant

BASF Pharma Solutions' new coprocessed excipient **Kollitab™ DC 87 L** is designed to achieve excellent blend, tableting, and flow properties for manufacturing robust and rapidly disintegrating tablets with high content uniformity.

- Kollitab™ DC 87 L formulation has high stability and low sensitivity to overblending
- Can produce strong tablets across a broad range of compression forces, reducing stress and punch damage on the tablet press, and less tablet defects
- Ensures fast tablet disintegration to quickly deliver the intended benefits of the API
- "All-in-one" nature enables fast tablet development, simplifies formulation processes, and reduces manufacturing complexity

KEY BENEFITS	Manufacturing	Quality & Regulatory
	Enables fast tablet development	Based on monographed excipients
	Simplifies formulation development	Provides advantages of all-in-one products (reduced Quality Control efforts, handling and documentation)
	Reduces manufacturing complexity	

Request a sample of Kollitab™ DC 87 L

Inspiring Medicines for Better Lives

www.pharma.basf.com

Contact us @drugdeliverysystems.bd.com/contact-us

United States
1 Becton Drive
Franklin Lakes, NJ 07417
T: +1 800 225 3310

Europe
11 rue Aristide-Bergès
38800 Le Pont-de-Claix
France
T: +33 4 76 68 36 36
W: drugdeliverysystems.bd.com

BD

BD Medical - Pharmaceutical Systems

BD Medical – Pharmaceutical Systems: Committed to Drug Delivery Excellence

As a partner of choice for pharmaceutical and biotech companies across the globe, BD Medical - Pharmaceutical Systems provides a broad range of parenteral drug delivery systems including glass and plastic prefillable syringes, safety and shielding systems as well as advanced drug delivery solutions that help ensure pharma meets its drug delivery goals while considering drug complexity, viscosity and dosing volume.

With an emphasis on patient-centered innovations and strong technical expertise, BD Medical - Pharmaceutical Systems partners with pharmaceutical and biotechnology companies to help them achieve their combination product commercialization goals. We support product launch and life cycle management through a comprehensive set of services and solutions that help to de-risk the combination product development process.

Prefillable Syringe Systems

Featuring a comprehensive portfolio of innovative prefillable syringe systems, BD offers drug delivery solutions designed to help decrease development risk, improve speed to market, and increase flexibility to meet patients' needs across a wide range of drug types and therapeutic areas.

Self-Injection Systems

BD offers an extensive portfolio of patient centric, self-administered drug delivery solutions including disposable autoinjectors, disposable variable dose pen injectors, and wearable injectors designed to deliver a wide range of volumes and viscosities and help de-risk combination product development.

Safety & Shielding Systems

BD Safety & Shielding Systems provide pharmaceutical companies with a wide range of both active and passive manual injection solutions available in 0.5ml, 1ml, and 2.25ml formats, suitable for a variety therapeutic indications.

Services That Provide Value Beyond Product

BD Pharmaceutical Services and Solutions are designed to help you achieve your combination product goals, from development to launch.

Manufacturing Expertise & Footprint to Meet Your Production & Supply Needs

When partnering with BD for your drug delivery solutions, you gain access to +50 years extensive experience in operations, the power of a global integrated supply chain and regulatory experts with global authority relationships, allowing you to minimize the risk of disruptions in your operations. Through our extensive global manufacturing network, we aim to offer security of supply and business continuity to our customers.

BD Medical – Pharmaceutical Systems at a Glance:

- >3Bn Prefillable Syringes* (PFS) manufactured per year1
- $2Bn Yearly revenue (2022)**
- 7500 Associates globally
- 8 Manufacturing plants worldwide
- Global headquarters in Pont-de-Claix, France

* PFS containers
** BD Annual report 2022
1. BDM-PS Financial file November 2022, "Actual FY22" Perimeter.

Every small detail is essential to de-risk your next big breakthrough in biologics

Meet our advanced biologics prefillable syringe system offerings

BD offers an integrated Prefillable Syringe system approach, backed by a comprehensive portfolio of syringes, stoppers and other drug delivery solutions.

The BD Neopak™ Glass Prefillable Syringe platform is designed to address key development needs for biologic drugs, such as enabling drug-container and autoinjector compatibility and accommodate a range of viscosities and sensitive drug formulations.[1,2,3,4] It is available in both 1mlL and 2.25mL formats.

The latest addition to the BD Neopak™ Glass Prefillable Syringe platform is our BD Neopak™ XtraFlow™ Glass Prefillable Syringe.

Featuring a shorter (8mm) needle length and thinner wall cannula, the BD Neopak™ XtraFlow™ Glass Prefillable syringe has been designed to optimize subcutaneous delivery of higher viscosity drug formulations >15cP.[3,*]

The BD Neopak™ Glass Prefillable Syringe Platform can be leveraged with our BD SCF™ PremiumCoat® Plunger Stopper, available in 1mlL and 1-3mL sizes.

BD SCF™ PremiumCoat® supports:

- Improved functional performance due to reduced glide force and glide force variability**[5,6]
- Container Closure Integrity with guarantee of no ribs not touching[7,8]
- Integration into combination products through a robust system data package[9,10]

Developing new biologics is complex, choosing the right partner is not.

Partner with BD today.

*When compared to 12.7 mm special thin wall (STW) needle
**When compared to the BD SCF™ FluroTec® Plunger Stopper. Results are based on a sample of 100 pieces of BD Flurotec® and BD SCF™ PremiumCoat®. Variables compared were Mean (glide force reduction) and standard deviation (glide force variability)
¥ Gliding test performed at nominal design space, in BD Neopak™ Glass Prefillable Syringe 2,25mL 27G filled with WFI

1. BD Neopak™ 1mlL customer quality specification, Le Pont-de-Claix, France; Becton, Dickinson, 2017 **2.** BD Neopak™ and BD Neopak™ XSi™ 2.25 mL customer quality specifi cation, Le Pont-de-Claix, France; Becton, Dickinson, 2020 **3.** Injection time and ejection force calculation [internal study], Le Pont-de-Claix, France; Becton, Dickinson and Company, 2021 **4.** Depaz et al. Cross-Linked Silicone Coating: A Novel Prefilled Syringe Technology That Reduces Subvisible Particles and Maintains Compatibility with Biologics JOURNAL OF PHARMACEUTICAL SCIENCES 103:1384–1393, 2014 **5.** DVTR20192507_DV data BD SCF™ PremiumCoat® 1 mlL R&D data [internal study]. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2023. **6.** TR20234488 Le Pont-de-Claix, France; Becton, Dickinson and Company; 2024 **7.** BD SCF™ PremiumCoat® Plunger Stopper 1mlL Customer quality specifications. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2022. **8.** BD SCF™ PremiumCoat® Plunger Stopper 1-3mL Customer quality specifications. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2023. **9.** Design Control Evidence BD SCF™ Premiumcoat® 1mlL with integrated biologics system data in Neopak Syringes. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2021 **10.** Design Control Evidence BD SCF™ Premiumcoat® 1-3mL with integrated biologics system data in Neopak Syringes. Le Pont-de-Claix, France; Becton, Dickinson and Company; 2024

Biovectra

We care about making better therapeutics.

BIOVECTRA, now part of Agilent Technologies, is a global biotech and pharmaceutical CDMO that specializes in clinical-to-commercial scale production capabilities for biologics, small molecules, bioreagents, pDNA and mRNA manufacturing, and fill/finish. Flexibility, creativity, process optimization, and compliance are at the heart of our method. Our teams leverage decades of expertise and a proven track record of excellence to optimize, adapt, and perfect innovative technologies and drug substance development approaches to deliver world-class solutions for pharmaceutical manufacturing.

- 50+ years of pharmaceutical manufacturing experience
- Flexible, creative systems designed to deliver solutions quickly and efficiently
- Extensive regulatory expertise backed by long standing relationships with major regulatory bodies

Our Facilities:

- 8 cGMP facilities in Atlantic Canada
- 270,000+ sq ft manufacturing facility
- 118,000 L of chemical reactor space
- 64,000 L of fermentation bioreactor capacity

Accelerate the Success of Your mRNA Therapeutics with BIOVECTRA

Looking for a reliable partner to advance your nucleic acid program?

BIOVECTRA is accepting projects at its state-of-the-art biomanufacturing center located in Prince Edward Island, Canada. The facility features 36,000 square feet of cGMP manufacturing space for mRNA, pDNA and lipid nanoparticle formulation, vaccine and therapeutic production capacity for 160 million doses per year, and fill/finish capacity for 70 million doses per year for commercial distribution.

Our experienced team excels in custom lipid manufacturing. With more than 50 years of expertise in fermentation, small molecule production, and quality management for regulatory compliance, we ensure scalability and precision at every production stage.

As a full-service CDMO, BIOVECTRA offers analytical testing, QA release, regulatory support, project management, and more.

Learn more at www.BIOVECTRA.com.

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11 Aviation Avenue, Charlottetown, PE C1E 0A1
Canada
T: (866) 883-2872
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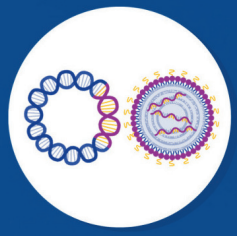
WE CARE ABOUT
MAKING BETTER THERAPEUTICS

Fermentation: Biologics

Synthesis & Purification, MPEGs, Linkers



pDNA, mRNA & LNP

HPAPIs

Bioreagents

Fill/Finish

BIOVECTRA is a global CDMO with
50+ years of experience

BIOVECTRA
A part of **Agilent**

Bora Pharmaceuticals

Bora Pharmaceuticals
7333 Mississauga Rd.
Mississauga
ON L5N 6L4 Canada
T: Toll Free: 1-844-636-BORA (2672)
E: info@bora-corp.com
W: https://www.boracdmo.com/
LinkedIn:
https://www.linkedin.com/company/borapharmaceuticals

Bora Pharmaceuticals is a global contract development and manufacturing organization (CDMO) specializing in complex oral solid dosage (tablets & capsules), biologics, liquids (solutions, suspensions, ophthalmics & nasal sprays), powders, semi-solids (creams, ointments & gels), and sterile injectables for pharmaceutical products for Clinical through Commercial manufacturing and packaging.

Bora owns and operates sophisticated cGMP manufacturing facilities across North America and Asia (US, Canada, Taiwan), built to the highest international standards for development, manufacturing, packaging, and analytical testing. Our sites deliver to more than 100 markets around the world.

As a future-focused CDMO, we know better than most that our success is shaped by our partners' victories. That's why, when you choose Bora, we make success more certain by infusing Boras' 5P's – Promises, Partnerships, Pride, People, and Progress – into every step of our work together.

We're proud of the work we do every day to help make success more certain.

Bora Pharmaceuticals

A Global CDMO

Making Success More Certain

- Biologics
- Ophthalmics
- Sterile Fill-Finish
- Semi-Solids
- OSD
- Liquids

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CAPTISOL LEGACY

Captisol is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Captisol was invented and initially developed by scientists at the University of Kansas' Higuchi Biosciences Center, for specific use in drug development and formulation. This unique technology has enabled 15 FDA-approved products, including Gilead's VEKLURY, Amgen's KYPROLIS, Baxter International's NEXTERONE, Acrotech Biopharma L.L.C.'s and CASI Pharmaceuticals' EVOMELA, Melinta Therapeutics' BAXDELA, Pfizer's VFEND IV and Sage Therapeutics' ZULRESSO. The most recent approval in March 2023 was Novartis' MEKINIST, a pediatric oral product. There are many Captisol-enabled products currently in various stages of development.

We maintain broad global patent portfolio for Captisol with approximately 440 issued patents worldwide relating to the technology (including 45 in the U.S.) and with the latest expiration date in 2035. Other patent applications covering methods of making Captisol, if issued, extend to 2041. In addition to solid Captisol powder, we offer our partners access to cGMP manufactured aqueous Captisol concentrate. This product offering was established in 2017 to reduce cycle time and increase Captisol production capacity for large volume drug products. We maintain both Type IV and Type V DMFs with the FDA. These DMFs contain manufacturing and safety information relating to Captisol that our licensees can reference when developing Captisol-enabled drugs. We also have active DMFs in Canada, Japan, and China.

SEAMLESS TRANSITION TO CLINICAL TRIALS

Captisol may increase systemic exposure for toxicology studies of investigative compounds and has a proven clinical safety record. In early development, Captisol formulation can lead to a seamless transition from nonclinical safety to clinical trials. Captisol has helped more than 10 million patients in over 120 countries.

MULTIPLE ADMINISTRATION ROUTES ENSURE TARGETED DELIVERY

Captisol's chemical structure was designed to create new products by improving solubility, stability, bioavailability, and dosing of active pharmaceutical ingredients. Routes of administration investigated include parenteral, oral, ophthalmic, nasal, topical, and inhalation products. Once inside the body, Captisol releases the drug agent, which then travels to its target. The interaction between Captisol and the agent is not permanent, and Captisol is safely expressed from the kidneys.

PATENTED & VALIDATED MANUFACTURING

Of all modified cyclodextrins, Captisol is an ingredient in the most approved products in the U.S. Manufactured under cGMP, at multiple locations, using a patented and validated all-aqueous process, annual manufacturing capacity has been increased to 500 MT. Captisol is supplied in ultra-low endotoxin, ultra-low bioburden, low-chloride forms. Pack sizes available for R&D use include 100g, 1kg, 5kg, and 20kg. Commercial pack sizes include 1kg, 5kg, and 20kg, with the ability to fill metric-ton orders.

FORMULATION SERVICES AVAILABLE

The scientists at Ligand Pharmaceuticals have developed in-house and aided clients in developing parenteral, oral, ophthalmic, nasal and inhalation formulations with Captisol and other cyclodextrins. With the recent addition of internal resources and analytical tools, we can provide greater responsiveness for collaborative feasibility and development programs. In addition, the Captisol team have successfully completed or assisted with orphan designations and approvals, preclinical, CMC and clinical development for ANDA, 505b2 and traditional NDA programs.

Our Team is Ready. Are you? Contact us Today!

CAPTISOL®

A LIGAND TECHNOLOGY

Oral use of Captisol* is here.

Applications and benefits include:

- Chronic use
- Pediatric dosing
- Preservative-sparing
- Increase bioavailability
- Mask unpleasant tastes

Our Team is Ready. Are you?
Contact us today!
858.550.5632 | cdinfo@captisol.com

Captisol.com

*Captisol is a sulfobutyl ether beta cyclodextrin

CAYMAN CHEMICAL
1180 EAST ELLSWORTH ROAD - ANN ARBOR, MI 48108
T: (800) 364-9897
E: SALES@CAYMANCHEM.COM - W: WWW.CAYMANCHEM.COM
LinkedIn: HTTPS://WWW.LINKEDIN.COM/COMPANY/CAYMAN-CHEMICAL

Cayman Helps Make Research Possible

With extensive expertise in lipid chemistry, synthesis, and purification, **Cayman Chemical** supports biopharma and biotech companies advancing lipid nanoparticle-based therapies from early discovery through clinical development with industry-leading research tools and services.

Our portfolio includes an expansive collection of high-quality lipids for LNP formulation, including ionizable cationic lipids, helper lipids, sterol lipids, and PEGylated lipids. We also offer LipidLaunch™ research-ready LNPs and reagent kits for LNP discovery and provide in-house custom lipid synthesis, LNP formulation, screening, and CGMP lipid manufacturing services.

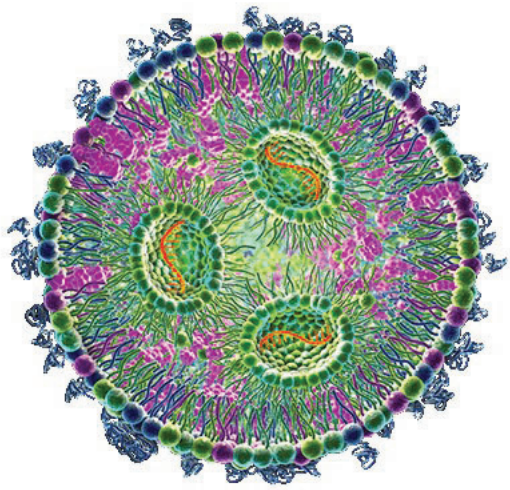
From R&D to GMP, Cayman Supports LNP Development

Cayman helps our clients reach important milestones in their LNP R&D with stand-alone services or a comprehensive LNP development program. Backed by an interdisciplinary team of scientists, Cayman offers on-site R&D facilities for LNP development, characterization, and screening.

Our experts can also help design and synthesize novel ionizable lipids to expand your intellectual property portfolio, and they have the foresight and in-house process development expertise to guide you toward scalable, CGMP lipid components from Cayman's CGMP manufacturing facilities in Ann Arbor, Michigan. We work with you to develop the best experimental design within your budget constraints to provide high-quality data with prompt, professional communication and quick turnaround.

Cayman's LNP Development Services

- **Design & Planning** – Discuss your project and goals with our scientists, who will help you determine the optimal lipid LNP components and experimental design for your cargo and tissue or cell type of interest.
- **Component Sourcing**
  - **Cargo** – Clients supply their own nucleic acid cargo, choose from one of several reporter options we offer, or provide a sequence for outsourced custom synthesis.
  - **Lipids** – Select from more than 350 ready-made lipids for LNPs or rely on our chemical synthesis experts for design and synthesis of custom lipids.
- **Formulation** – Microfluidic formulation using variable flow rates and lipid ratios for screening LNPs or bulk preparation of R&D-optimized LNPs.
- **Characterization** – Analysis of LNP and payload concentration, particle size, polydispersity index, p*Ka*, stability, aggregation, and encapsulation efficiency.
- **Screening** – Bioanalytical services for assessment of payload delivery and downstream biological effects.
  - Ready-made assays and custom assay development with high-throughput options available.
  - Flow cytometry and high-content imaging readout of reporter payload delivery and/or expression, effects on cell viability.
  - Cell-based, immunoassays, enzyme activity, reporter, mass spectrometry, ELISpot, and immunophenotyping assays to measure the impacts of therapeutic payload delivery.
  - BSL2+ cell culture for immortalized or primary cells.
- **CGMP Lipid Manufacturing** – Take your LNPs to the next phase of development with our GMP Division. Our US-based GMP team can optimize the manufacturing and scale-up of lipid components for your formulation, ensuring the highest quality lipids and smooth transition to your CDMO partner of choice.



Delivering Lipid Nanoparticle Expertise

Backed by 40 years of experience in lipid chemistry, synthesis, and analysis, Cayman Chemical is a US-based provider of lipid nanoparticle (LNP) research tools and services. We support the entire LNP research and development process from early discovery through clinical development.

- **LipidLaunch™ Research-Ready LNPs & Reagent Kits**
- **Lipids for LNP Formulation**
- **Custom Lipid Synthesis**
- **CGMP Lipid Manufacturing**
- **LNP Formulation, Characterization, & Screening Services**

Explore End-to-End Solutions from Lipid Experts

www.caymanchem.com/LNPs

Cayman CHEMICAL

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222 West Las Colinas Boulevard
Suite 900N
Irving, TX 75039
E: healthcare@celanese.com
W: vitaldose.com

CUSTOMIZED SUPPORT FOR SUSTAINED RELEASE DRUG DELIVERY THERAPIES

Celanese works closely with you as a strategic partner to create innovative controlled-release dosage forms for biologics, small molecules, and RNA to meet the goals of patient-centric therapies, improved medicine and better healthcare economics.

From FEASIBILITY to DEVELOPMENT to COMMERCIALIZATION

Our scientists and engineers are there from concept to commercialization, providing development services, material supply aligned with GMP principles and regulatory support through the Celanese Development & Feasibility Lab. Our objective is to help our customers reduce R&D time and improve the likelihood of successful drug commercialization.

INTRODUCING THE VITALDOSE® PLATFORM

Our VitalDose® Ethylene-Vinyl Acetate (EVA) copolymer drug-delivery platform is an enabling technology for drug-eluting implants and inserts. The platform is flexible and customizable to address and tailor the release rate of your drug.

- Compatible with biologics, RNA, and small molecules
- Provides reliable local or systemic drug administration
- High drug loading capacity (≤ 75%)
- Achieves drug release over >6 months
- Ease of formulation and configurable into a variety of geometries
- An established regulatory path with long clinical use history

VitalDose® EVA has been approved for use in numerous pharmaceutical and medical device applications. We are actively supporting marketed products and development programs in:

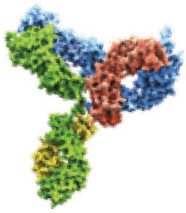
- Ophthalmic inserts & intraocular implants
- Oncology
- Women's health
- Central nervous system disorders
- Rare diseases
- Endocrinology

ABOUT CELANESE

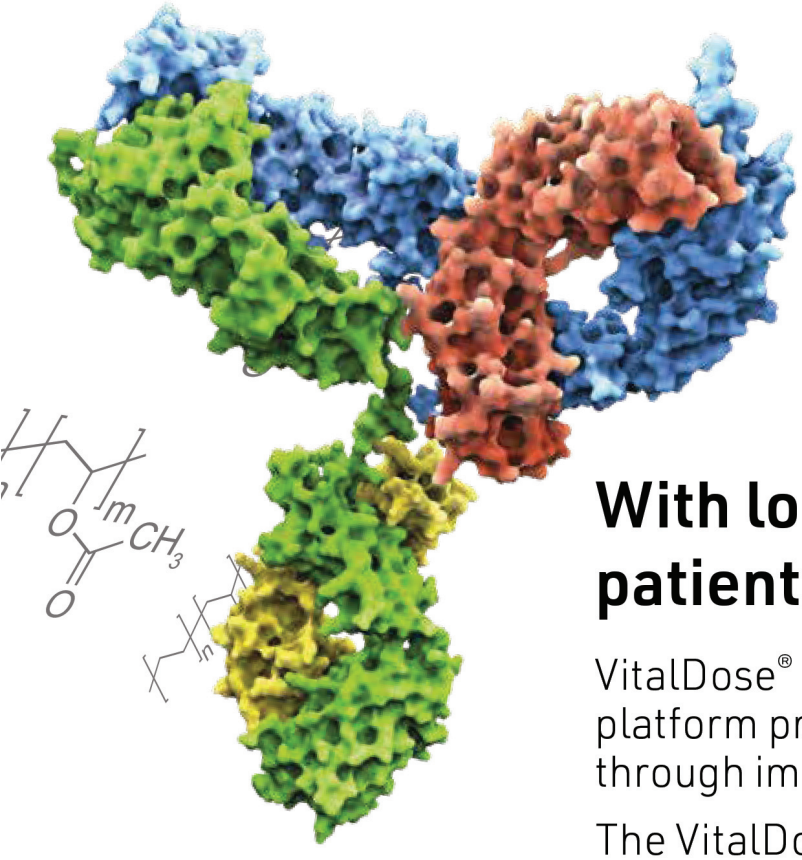
Celanese is a global leader in chemistry, producing specialty material solutions used across most major industries and consumer applications. Our businesses use our chemistry, technology and commercial expertise to create value for our customers, employees and shareholders. We are committed to sustainability by responsibly managing the materials we create for their entire lifecycle and are growing our portfolio of sustainable products to meet increasing customer and societal demand. We strive to make a positive impact in our communities and foster inclusivity across our teams. Celanese is a Fortune 500 company that employs approximately 12,400 employees worldwide with 2023 net sales of $10.9 billion.

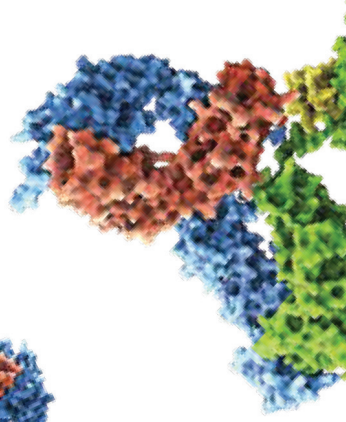
Celanese

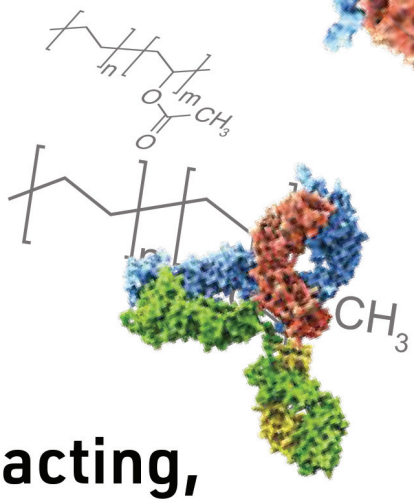
VITAL Dose®



Sustained Drug Delivery







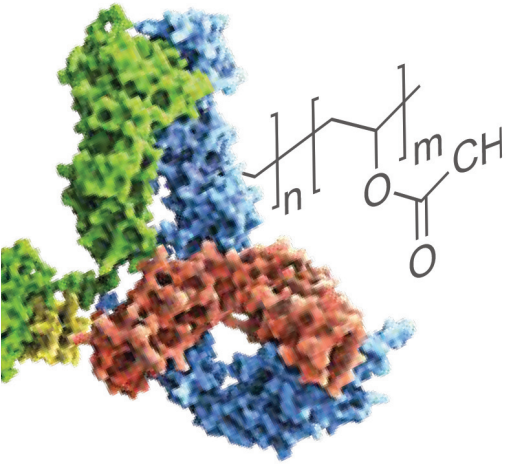
With long-acting, patient-centric therapeutics

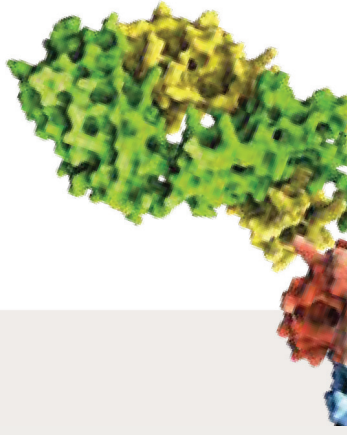
VitalDose® EVA is a copolymer drug-delivery platform providing controlled release through implant and insert dosage forms.

The VitalDose® platform is flexible and customizable with high drug loading capacity (≤75%).

Our scientists and engineers will partner with you to create novel delivery systems for:

- mAbs
- Small molecules
- Peptides
- RNA





Collaborate with us

Email: Healthcare@Celanese.com

Website: Vitaldose.com

CREDENCE MEDSYSTEMS

INNOVATION WITHOUT CHANGE

CREDENCE MEDSYSTEMS, INC.
1430 O'Brien Drive, Suite D
Menlo Park, CA 94025
T: +1-844-263-3797 (+1-844-CMEDSYS)
E: info@CredenceMed.com
W: www.CredenceMed.com

Credence MedSystems, Inc.

Credence MedSystems is an award-winning innovator in drug delivery devices, solving emerging challenges in parenteral drug delivery for the pharmaceutical and biotechnology industry.

Credence's philosophy of Innovation Without Change means that Credence technology is integrated with industry-standard syringe barrels, components and manufacturing processes, thereby providing highly innovative problem-solving products while minimizing the risk and burden of implementation for our pharma customers.

Companion® Product Family

With its integrated needle safety and numerous usability advantages, Companion is designed to ensure safe administration and promote adherence. With automatic needle retraction and reuse prevention, Companion addresses two critical needs in preventing the spread of infectious disease. Its superior sustainability footprint, with significant reductions in weight, plastic consumption and footprint, supports pharma's sustainability goals while driving cost-of-ownership reductions and improved manufacturing efficiency.

Dual Chamber Reconstitution or Sequential Liquid Delivery

Simplify the delivery of your most complex drug products that require separation of constituents during storage due to stability or co-formulation challenges. The Dual Chamber System allows point-of-care reconstitution or sequential injection of two liquids, combined with passive needlestick protection and reuse prevention, providing vast flexibility and offering the usability, safety and precision that enables at-home delivery of challenging drugs by naïve users.

Credence Isolation Valve™ System

Prevent needle clogging while enabling a preattached needle and integration within an autoinjector, addressing an emerging challenge in the industry as pharma manufacturers compete by increasing the concentration of formulations in order to extend dosing schedules and drive towards room temperature stability.

Credence Connect™ Auto-Sensing Injection System

Bring digital connectivity to any syringe with real-time monitoring, transmission and storage of injection data… all built into a comfortable reusable finger flange. The Credence Connect can help you enhance chronic disease care and improve clinical trial management.

Micro-Dose™, Multi-Site™ and Force-Assist™

Enable extremely precise micro-dosing, either in a single delivery or in a series of repeat injections, and employ force reduction technology to facilitate delivery of viscous products.

Impress. **Provide a better experience for users, consistently, across our entire platform of products.**

Preserve. **Differentiate without disruption.**

Protect. **Safeguard healthcare professionals and patients.**

Stand out among the competition.

At Credence MedSystems, being innovative means bringing value. Our Innovation Without Change approach means we make it easier to meet evolving market demands, with minimal disruption to you.

CREDENCE MEDSYSTEMS

SLEEK

Preferred by users
Reduces wasted materials
Clean and classic award-winning design

SMART

Prevents premature activation
Enables dual sourcing & barrel flexibility
Integrated safety streamlines operations

SAFE

Biotech-friendly: Glue/Steel/Tungsten-FREE options
Automatic needle retraction
End-of-dose cues

THE CREDENCE COMPANION

Innovation Without Change Has Arrived

Credence MedSystems, Inc. - +1-844-263-3797 - www.CredenceMed.com

This product has not yet been evaluated by FDA

CRODA | Pharma

SMART SCIENCE TO IMPROVE LIVES™

Empowering Biologics Delivery

We're enabling drug delivery with high purity, next generation excipients. Our teams work with you to troubleshoot formulations and offer our regulatory expertise. Purity is our forte across both our research and multi-compendial GMP grade materials.

- **High purity excipients for biologics and small molecules:** Solving formulation challenges and enhancing drug delivery across a variety of administration routes and dosage forms with high purity excipient products and speciality chemistries.
- **Adjuvants systems:** Committed to the highest standards, with 80+ years of expertise in adjuvant research and development, and a portfolio of world-leading vaccine adjuvants, immunomodulators and adjuvant formulations.
- **Innovative lipids:** Enabling the delivery and stability of nucleic acid-based vaccines, therapeutics and gene editing technology.
- **Bioprocessing solutions:** Leveraging our expertise in biotechnology and purification to provide you with innovative solutions for bioprocessing.

About Croda Pharma: www.crodapharma.com

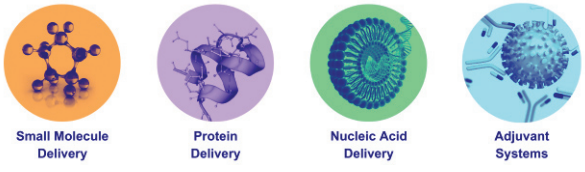
Established in 1925, Croda is the name behind high performance ingredients and technologies in some of the world's biggest and most successful brands. We have a network of over 4,500 passionate and committed employees, working together as one global team across manufacturing sites and offices in 38 countries.

At Croda Pharma, we are committed to empowering biologics delivery. We offer high purity pharmaceutical excipients, world leading vaccine adjuvants, innovative lipids and bioprocessing solutions. This unmatched offering, along with our in-house formulation expertise, make us the ideal partner to navigate drug and vaccine formulation challenges.

A Selection of Our Recent Launches

Virodex™: Sustainable, compendial, cGMP, REACH compliant detergents for viral inactivation and cell lysis.

Super Refined™ Poloxamer 188: Highly purified poloxamer 188, optimised for mammalian cell culture with exceptional batch-to-batch consistency.



Sustainable Squalene: Synthetic biology and purification excellence enable a highly purified alternative to shark-derived squalene.

Sustainable Saponins: QS 21 based on plant tissue culture making a more efficient process with sustainable sourcing.

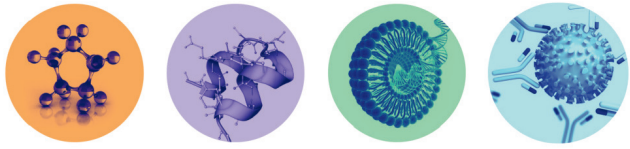
Natural Phospholipids: Highly purified phosphatidylcholine products originated from soybean and egg yolk.

Avanti Research
A CRODA BRAND

A Croda brand, leading the way with highly purified lipids, ingredients, and services for pharmaceutical and fundamental research, and diagnostics. With a catalogue boasting over 2,000 lipids, Avanti Research also offers custom lipid synthesis and formulation development.

Contact Croda Pharma

NAMER: pharma.usa@croda.com - LATAM: pharma.latam@croda.com - APAC: pharma.asia@croda.com
EMEA: pharma.emea@croda.com



Unlocking future therapies

We're developing the next generation of excipients for human and veterinary applications.

Connect with us today.
www.crodapharma.com

CRODA | Pharma

SMART SCIENCE TO IMPROVE LIVES™

Curia is a global contract research, development and manufacturing organization (CDMO) with over 30 years of experience. With an integrated network of 20+ facilities worldwide and a team of 3,000+ dedicated professionals, we specialize in partnering with biopharmaceutical customers to bring life-changing therapies to market.

Our offerings in small molecules, generic APIs and biologics span discovery through commercialization, with integrated regulatory, analytical and sterile fill-finish capabilities. Our scientific and process experts, along with our regulatory compliant facilities, provide a best-in-class experience across drug substance and drug product manufacturing. From curiosity to cure, we deliver every step to accelerate your research and improve patients' lives. Visit us at curiaglobal.com.

A LEGACY OF EXCELLENCE

- **Global Footprint:** Operating 20+ advanced facilities with cutting-edge technology.
- **Skilled Workforce:** 3,000+ industry experts committed to making a difference.
- **Regulatory Trust:** Consistently meeting and exceeding global regulatory standards, including inspections from the US FDA, European health authorities and more.

SERVICES & CAPABILITIES

Curia Small Molecules

Our small molecules offering spans discovery to commercial manufacturing and fill-finish services, integrating scientific, process, regulatory and analytical capabilities for API life cycle. We leverage 30+ years of expertise with 250+ medicinal chemists and 100+ development chemists combined with state-of-the-art facilities to deliver a best-in-class experience across drug substance and drug product manufacturing.

Curia Generic APIs

With over 260 APIs produced across the US, Europe and India covering multiple therapeutic areas, we are one of the largest suppliers of generic APIs and intermediates in the industry. We bring a unique combination of experience and global facilities to meet your expanding needs.

Curia Biologics

Our biologics offering spans discovery to clinic and fill-finish services across monoclonal antibodies, recombinant proteins and mRNA therapeutics. We bring a comprehensive package of solutions and over 21 years of experience in biologics, with ongoing investments to modernize facilities and expand capacity.

Curia
24 Corporate Circle Albany, NY 12203
T: (518) 512-2000
E: marketing@curiaglobal.com
W: www.curiaglobal.com
LinkedIn: https://www.linkedin.com/company/curia-cdmo/
Facebook: https://www.facebook.com/CuriaCDMO
Twitter: https://twitter.com/CuriaCDMO

From curiosity to cure

Curia is a contract research, development and manufacturing organization (CDMO) with over 30 years of experience, an integrated network of 20+ global sites and 3,000+ employees partnering with biopharmaceutical customers to bring life-changing therapies to market.

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To learn more, visit us at curiaglobal.com.

curia

douglas CDMO

2 Te Pai Place, Henderson
Auckland, New Zealand 0610
T: +64 9 835 0660
E: enquiry@douglascdmo.com
W: douglascdmo.com

Company Description

Douglas CDMO, based in New Zealand, has a history dating back to 1967. We offer end-to-end integrated drug development services, specializing in high-potency small molecule softgels, liquids, semi-solids, new chemical entities (NCEs), and branded generics.

Our capabilities extend to manufacturing prescription drugs across key therapeutic areas, including oncology, dermatology, the central nervous system, and immunity. Working with clients across the globe, we pride ourselves on delivering superior quality and excellent service, ensuring our partners achieve successful, timely outcomes.

Our strategic location in Auckland, New Zealand offers our global customers with tax incentives and the ability to start first in human trials quicker than many other jurisdictions due to a streamlined regulatory process.

Services

Our CDMO services offer comprehensive support at every stage of the product lifecycle, from pre-formulation to commercialization. In addition to developing and manufacturing, we can also undertake technology transfers of pre-established projects into our facilities.

We have the capability and procedures to manage your light-sensitive retinoids, hormones, cytotoxics, and immunosuppressants.

Product Capabilities

Softgel capsules
Liquids – including solutions, emulsions and suspensions
Sem-solids – including creams, gels and ointments
Hard gel capsules
Suppositories
Tablets

Packaging Capabilities

Blisters	ALU-ALU blisters
Liquid bottles/sprays	Bottles

World-Class Expertise in Softgels, Liquids & Semi-Solids

Douglas CDMO brings extensive expertise in the development and manufacturing of softgel capsules and their inner fill, having developed approximately one-third of the pharmaceutical softgels available in the U.S. market. With a high success rate in developing complex softgels and securing approvals, we are committed to delivering products that meet the highest standards of safety and efficacy, leveraging our technical expertise and advanced technological capabilities.

If you haven't considered a soft gelatin capsule as your next dosage form, here are some of the key advantages:

- Enhanced absorption rate, and overall bioavailability of the drug to ensure the lowest effective dose is used to achieve its full therapeutic effect.
- Addressing solubility issues.
- Protection of ingredients from exposure to light, air and moisture.
- Easier to swallow than hardshell capsules and tablets.
- A consistent and precise dose of the active ingredient.
- Enhanced shelf life.

The complex nature of softgel manufacturing, which requires specialized equipment and custom formulations, creates significant challenges for generic production. This complexity helps maintain product quality and efficacy, protecting your investment.

Why choose Douglas CDMO for your contract development and manufacturing?

At Douglas CDMO, we deliver a personalized, tailored service designed to meet the unique needs of each customer. We prioritize open communication and close collaboration, ensuring we fully understand and address your specific requirements. We remain agile, quickly adapting to meet the evolving needs of our customers. Customers trust Douglas CDMO to maintain the highest quality standards, honor our commitments, and tackle challenges with resilience and integrity. Quality is at the heart of everything we do — from the initial stages of development to commercial manufacturing and supply.

Douglas CDMO assists pharmaceutical and biotechnology companies in achieving their competitive advantage.

We leverage world-class expertise in high-potency softgel and liquid formulation development and manufacturing. We can help enhance the bioavailability of your APIs, and stability and shelf-life of your products. Explore your next project and contact our team of experts today.

› Learn more at **douglascdmo.com**

douglas
CDMO

ELEMENT MATERIALS TECHNOLOGY
Corporate Headquarters
Davidson Building, 5 Southampton Street,
London, WC2E 7HA

CALL US
Americas - +1 888 786 7555
Germany - +49 800 000 5137
Middle East - +971 800 353 6368
UK & Rest of World - +44 808 234 1667
W: https://www.element.com/life-sciences
LinkedIn: https://www.linkedin.com/showcase/element-life-sciences/

Making Tomorrow Safer Than Today

As a global leader in pharmaceutical and medical device testing, Element Materials Technology delivers comprehensive testing solutions that ensure product safety, quality, and regulatory compliance at every stage of development. From initial R&D through commercialization, our 150+ pharmaceutical experts worldwide bring over four decades of experience to your critical projects. Our expertise spans a comprehensive range of specialized capabilities including, but not limited to, biologics testing, Chemical, Manufacturing, and Controls (CMC), biocompatibility assessment, PFAS testing, extractables and leachables studies, and comprehensive antimicrobial and disinfectant analysis.

CORE SERVICES

Pharmaceutical Testing

With our proud track record at the forefront of pharmaceutical testing, we understand the evolving demands of the global pharmaceutical sector, supporting your needs from prototype to finished product through comprehensive testing solutions.

- Custom Synthesis
- GMP Manufacturing
- Chemistry, Manufacturing, and Controls (CMC) Support
- Method Development
- API, Raw Materials, Excipients Testing and Characterization
- Method Validation, Verification and Method Transfer
- Stability Testing
- Release Testing
- Residual Impurity Testing
- Extractables and Leachables
- Environmental Monitoring, Facilities Qualification/Validation

Medical Device Testing

We partner with manufacturers of all sizes – from innovative startups to global enterprises – providing precise, reliable testing solutions that help bring new medical technologies to market safely and efficiently.

- Computational Simulation
- Physiological Monitoring and Clinical Validation
- Regulatory and Risk Assessment Support
- Materials Characterization
- Mechanical and Functional Testing
- Biocompatibility
- Electrical and Battery Testing
- Packaging Validation
- Microbiology, Sterility and Cleanliness Testing
- Stability and Accelerated Aging Testing
- Release Testing
- Sustaining Engineering

Analytical Chemistry

- Our GMP/GLP and ISO/IEC 17025 accredited laboratories offer advanced analytical testing services and expert scientific consultation, serving diverse needs across the life sciences sector.

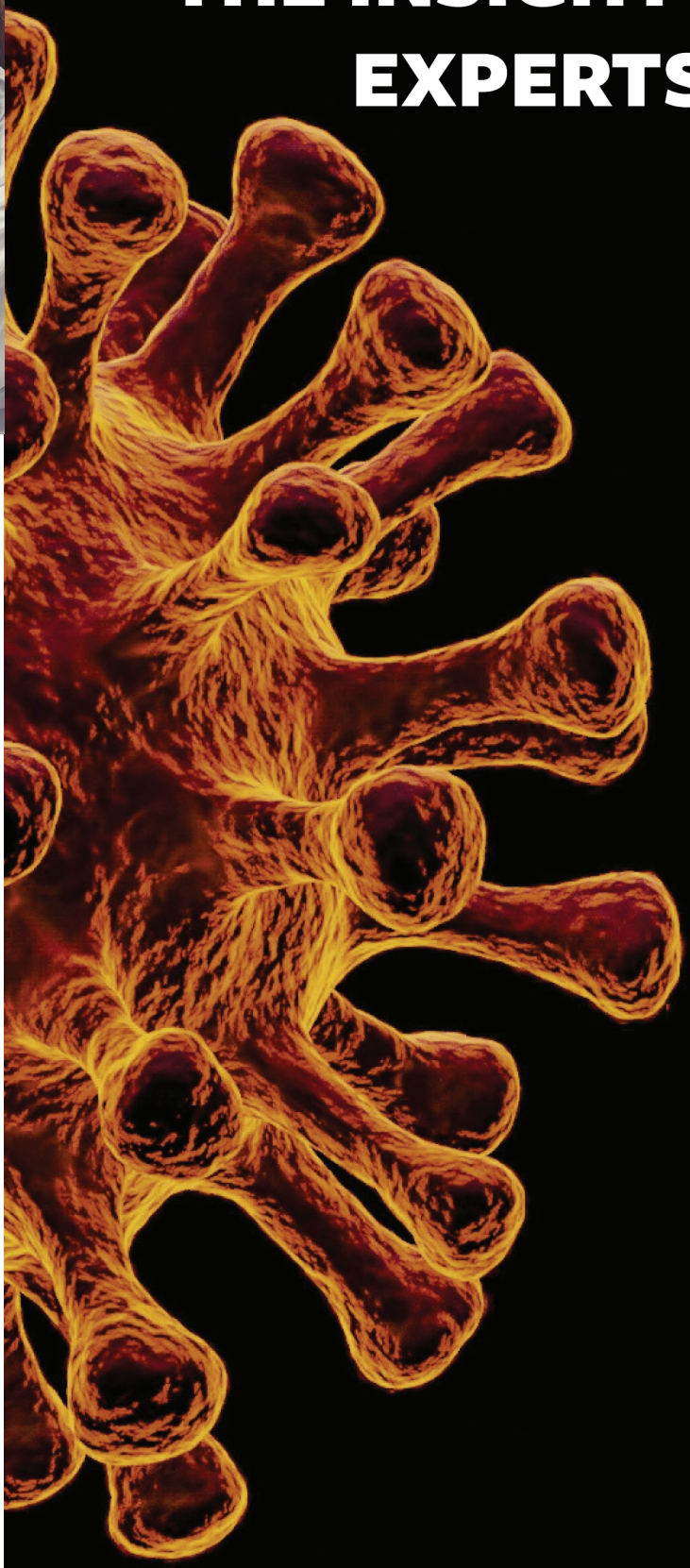
Antimicrobial and Disinfectant Testing

- With over 30 years of expertise, we're the premier partner for antimicrobial product development. Our regulatory and scientific experts have supported the successful registration of thousands of antimicrobial pesticide and biocide products.

At Element, we don't just provide test results – we deliver certainty. Our global network of experts works diligently to mitigate risks, ensure compliance, and support patient safety through every step of your product's journey.

element

THE INSIGHT YOU NEED, FROM EXPERTS YOU TRUST.



Accelerate your product's route to market with trusted testing services that provide certainty in results, mitigate risk, and offer support from R&D to manufacturing.

- Analytical Chemistry Testing
- Pharmaceutical Testing
- Medical Device Testing
- Antimicrobial Testing
- Environmental Testing
- Food Testing

Americas
+1 888 786 7555

Europe
+444 808 234 1667

Germany
+49 800 000 5137

www.element.com

HEALTH SOLUTIONS
12455 Research Blvd
Austin, TX 78759
E: healthsolutions@flex.com
W: flex.com/healthcare

A Partner from Concept to Care

Leading medical technology and pharmaceutical companies turn to Flex for innovative design expertise, advanced manufacturing and supply chain services to build and deliver products to market faster, more reliably and sustainably to transform healthcare and improve lives.

Who We Are

- Flex was founded in 1969
- Number of employees: 160,000+
- Number of medical facilities: 26 manufacturing sites, 6 design & engineering sites, 16 FDA registered entities, 21 ISO13485 designated sites

End-to-End, Vertically Integrated Solutions

- Global design, development and manufacturing provider with over 35 years of medical experience across FDA Class I, II, and III products from simple disposables to smart drug delivery systems and immunoassay diagnostic equipment
- Cross-industry experience with innovations in optics, sensors, miniaturization, human machine interface, cybersecurity, and 5G connectivity
- Vertical integration under one roof from "pellet to packout"
- Global supply chain technology leader with real-time data analysis for speed and agility

Human Factors Engineering

Generative research to identify and meet user needs, formative studies to optimize usability, and summative studies to demonstrate safe and effective use.

Full Design & Development

Accelerate and de-risk design and development and integrate advanced technologies. Engineering and development with manufacturability in mind to ensure an outstanding design can be efficiently manufactured at target cost.

New Product Introduction (NPI)

Flex offers dedicated sites for medical product introductions, including a new 10,000 sq ft facility in Nashua, NH, near one of the largest medtech/biotech hubs in North America. Expertise in NPI and collaboration with both design and operations teams results in efficient, validated and scalable production processes that can be easily scaled to high volume manufacturing.

Manufacturing

Our global footprint allows us to match our customers' regional strategies. Tool making, injection molding, PCBA, system integration, full device manufacturing, complex assembly, sterilization and final packaging comprise our full services manufacturing portfolio. The ability to deliver maximum value with disciplined execution ensures Flex produces at the highest level of quality and efficiency.

Supply Chain, Logistics & Distribution

Flex scale drives incredible supply chain strength. Flex Pulse, a sophisticated set of real-time tools enhances speed and impact in supply chain management.

Circular Economy

Our integrated reverse logistics and circular economy services, including CO_2 analytics, returns and screening, repair, and refurbishment, enable customers to extend the life of medical products at scale.

PRODUCT EXPERIENCE

Medical Equipment

Laboratory diagnostic systems, point of care diagnostics, surgical generators, OR and ER equipment, imaging systems, respiratory care equipment, ophthalmic diagnostics, remote patient monitoring, hemodialysis, monitoring, analytical lab equipment.

Medical Devices

Diabetes management, neural stimulators, surgical tools, personal care, personal diagnostics and monitors, wearables, single use disposables, vascular disposables, wound management, neuromodulation disposables.

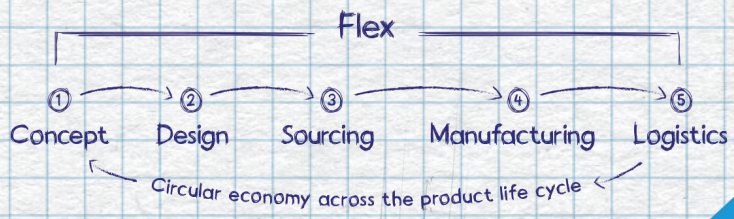
Drug Delivery

Connected and conventional autoinjectors, on-body injectors, smart injection pens, pumps and infusion systems, wearable pumps.

Tooling & Molding

Pipettes, syringes, tubes, IV components and other plastics, high precision molding and tooling.

flex



From concept...

...to care

A medical design & manufacturing partner you can count on

2024 WORLD'S MOST ETHICAL COMPANIES® ETHISPHERE™

From concept to care and everything in between, Flex leverages its global footprint and comprehensive supply chain management to deliver advanced manufacturing across the full product lifecycle, ensuring a seamless path to market.

Together we can create the extraordinary

flex.com/health

flexintl

GATTEFOSSÉ

COMPANY

Gattefossé provides innovative excipients and drug delivery solutions to health and personal care industries. With a service and distribution network that spans over 40 distributors, 12 affiliates, and 90 countries, Gattefossé prides itself on having introduced innovative products that conform to the highest manufacturing and regulatory standards worldwide. Over many decades, Gattefossé has transformed the chemistry of lipid excipients into viable drug delivery systems.

CORPORATE & SOCIAL RESPONSIBILITY

Our business practices are intertwined with corporate social responsibility, with an emphasis on environmental sustainability, for a better world. In this and other regards, achieving a competitive edge by innovation is the hallmark of the Gattefossé enterprise since 1880. Commitment to our customers is reflected in our history of service, with focus on problem solving in drug product development. We continue our research and development programs alongside knowledge sharing with the scientific community in the form of peer reviewed publications, webinars, and seminars.

PRODUCTS

Gattefossé excipients are well-known for their efficacy, safety, and quality. They are suitable for conventional dosage forms as well as modern formulation technologies such as Melt Extrusion, SMEDDS, and SLN/NLC.

Our offer includes:

- Tableting excipients like **Compritol®** and **Precirol®**
- Solubility and bioavailability enhancers like **Capryol™**, **Gelucire®**, **Labrafac™**, **Labrafil®**, **Labrasol®**, **Lauroglycol™**, and **Transcutol®** series
- Ready to-use bases like **Geleol™**, **Geloil™**, **Tefose™**, and **Ovucire®** and **Suppocire®** lines

Designed for improved, enhanced, or modified drug release, each product is fully characterized by physical, chemical, and performance criteria.

CAPABILITIES and SERVICES

It is the aim of Gattefossé to simplify formulation decisions that will minimize attrition rates and shorten the drug development path. Through our Technical Centers of Excellence in the Americas, Europe, and Asia, we offer complimentary support for solubility screening and formulation design and characterization for various routes of administration. Alongside, we provide guidance for regulatory, safety, and preclinical aspects of our excipients. We manufacture our products in France, Singapore, and soon in our new production site in Lufkin, Texas, in order to better serve our customers all over the world with equivalent high standard quality.

GATTEFOSSÉ Corporate Headquarters
Tel: +33 4 72 22 98 00 - infopharma@gattefosse.com

GATTEFOSSÉ USA Regional Office
Tel: +1 201 265 4800 - info@gattefossecorp.com

People make our name

Taste-masking excipients for better patient compliance

GATTEFOSSÉ

Safe to use: Glyceride-based excipients are safe to use, have **IID and GRAS status**, and are used in pediatric and geriatric populations worldwide.

Excellent palatability: Glycerides can offer neutral taste and acceptable mouthfeel.

Versatile in processing: Narrow recrystallization temperatures allow for use in solvent-free processes such as **hot melt extrusion**, **high shear mixing/granulation**, and **hot melt coating**.

Robust: Glycerides have consistent in-process characteristics for reproducible manufacturing and are compatible with a **wide range of APIs**.

Precirol® ATO 5
Glyceryl distearate NF

Compritol® 888 ATO
Glyceryl dibehenate NF

For more product information, samples, and technical assistance, **contact us today**!

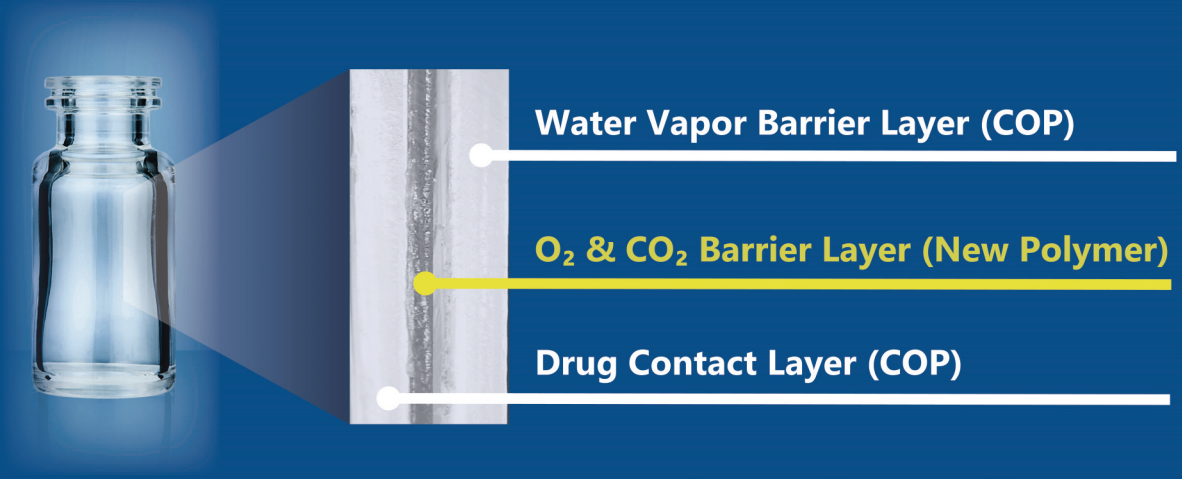
info@gattefossecorp.com

People make our name

OXYCAPT™ Multilayer Plastic Vial

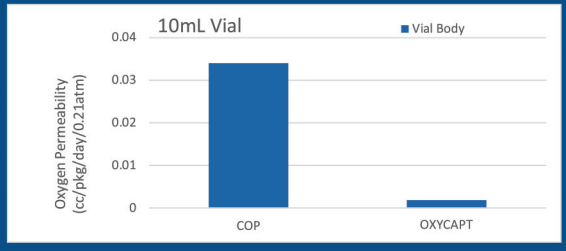
for Biologics & Cell Gene Therapy Products

Multilayer Structure

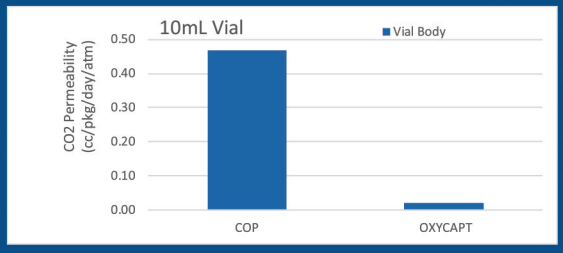


- **Excellent O_2 & CO_2 Barrier**
- **Excellent UV Barrier**
- **Very Low Extractables**
- **Very Low Protein Adsorption**
- **High Compatibility with High & Low pH Drugs**
- **Excellent Break Resistance at Deep Cold Temp.**

Oxygen Permeability



Carbon Dioxide Permeability



- **Excellent CCI at Deep Cold Temp. with Dry Ice**
- **Maintain Excellent CCI after Freezing & Thawing Process**

MITSUBISHI GAS CHEMICAL

Mitsubishi Gas Chemical Company, Inc.
https://www.mgc.co.jp/eng/products/abd/oxycapt.html
Mitsubishi Gas Chemical America, Inc.
http://www.mgc-a.com
Mitsubishi Gas Chemical Europe GmbH
https://www.mgc-europe.de

Halo Pharma is a leading provider of pharmaceutical services, including contract dosage form development, commercial manufacturing and analytical services.

Our capabilities in the areas of tech transfer, process and pharmaceutical product development, formulation development, production, scale-up and validation, and analytical method development allow us to partner with clients from development through commercialization or at any point along the way.

Our expertise across many dosage forms, including complex oral solids, topicals, oral solutions and suspensions and the manufacture of controlled substances is unmatched in North America. Halo Pharma serves a growing global customer base across multiple regulatory environments. These attributes allow Halo Pharma to be a partner of choice for many of today's large pharma, generic pharma and biotech pharma companies.

While we excel at scientific and manufacturing know-how, we strive to be the best partner. We are collaborative and responsive, working with customers to find effective and expedient solutions to their pharmaceutical development and manufacturing challenges. We are engaged and always exploring new ideas and approaches. We are agile and flexible and can easily accommodate changes that may arise in the needs of a customer's project, at any point in a product's life cycle.

Our customers span from many of today's largest pharmaceutical companies to single molecule biotech companies and encompass both generic and branded products. We leverage our expertise and strong compliance focus to bring our customers' products through the development, regulatory, and manufacturing process in the most efficient and cost effective manner possible so that we can meet our customers launch and sales goals.

We specialize in the development and commercialization of controlled substances (CI-CV) including drug products used for pain management and ADHD. We have particular expertise in abuse deterrent technologies and complex IR/ER products. Our array of services includes contract dosage form development, commercial manufacturing, packaging and analytical services.

With our vast knowledge of drug product development and manufacturing, having commercialized a broad base of NDA, ANDA, DIN products as we possess a wealth of know how that can be complementary to our customer's in house expertise. We are always exploring new ideas and approaches. We pride ourselves on being flexible, and unlike many larger CDMO's, we and can easily accommodate changes that may arise during a customer's project at any point in a product's life cycle.

Most importantly we value our customers. We strive every day to be a good partner and deliver on our commitments.

HALO PHARMA
Locations
30 N Jefferson Rd, Whippany, NJ 07981
T: (973) 428-4000
W: HaloPharma.com

17800 Rue Lapointe, Mirabel, QC J7J 1P3, Canada
T: (450) 433-7673

HERMES PHARMA

Get the dose right®

HERMES PHARMA GMBH
Georg-Kalb-Strasse 5
82049 Pullach, Germany
T: +49 – 89 79102 261
W: www.hermes-pharma.com

HERMES PHARMA is the leading expert in developing and manufacturing user-friendly oral dosage forms including effervescent and chewable tablets, instant drinks, lozenges, and orally disintegrating granules.

ABOUT US

HERMES PHARMA is the leading expert in developing and manufacturing user-friendly oral dosage forms. As a CDMO, we offer customized services along the entire pharmaceutical value chain, from new product development and formulation to manufacturing and regulatory support. For more than 40 years, healthcare companies around the globe have worked with HERMES PHARMA to expand their product lines and grow their brands.

Our sister company HERMES Arzneimittel has a rich portfolio of OTC brands and a long history in pharmaceutical excellence. So, we truly understand the challenges of our customers and can support them on their way to market success.

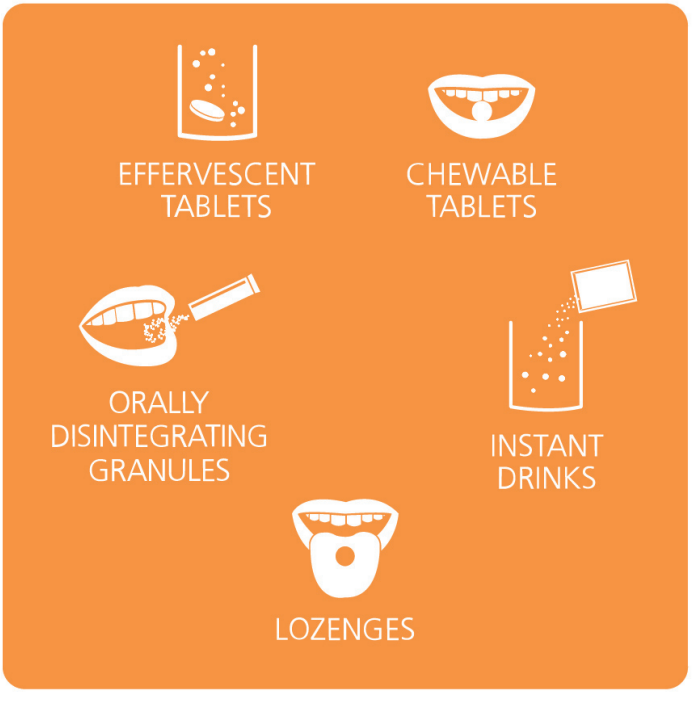
PRODUCTS & SERVICES

We focus exclusively on user-friendly dosage forms and have more than 40 years of experience in this area. The oral route is generally considered a simple and cost-efficient way of drug delivery, primarily using tablets or capsules. However, recent data suggest that difficulties swallowing tablets and capsules are widespread, occurring across all age groups and potentially impacting treatment success. These findings indicate that conventional solid dosage forms may not be the best option for all individuals, and often fail to keep pace with the evolving needs of modern patients.

Our effervescent and chewable tablets, lozenges, instant drinks, and orally disintegrating granules are user-friendly alternatives to conventional tablets and capsules. They provide an added value to patients and consumers as they:

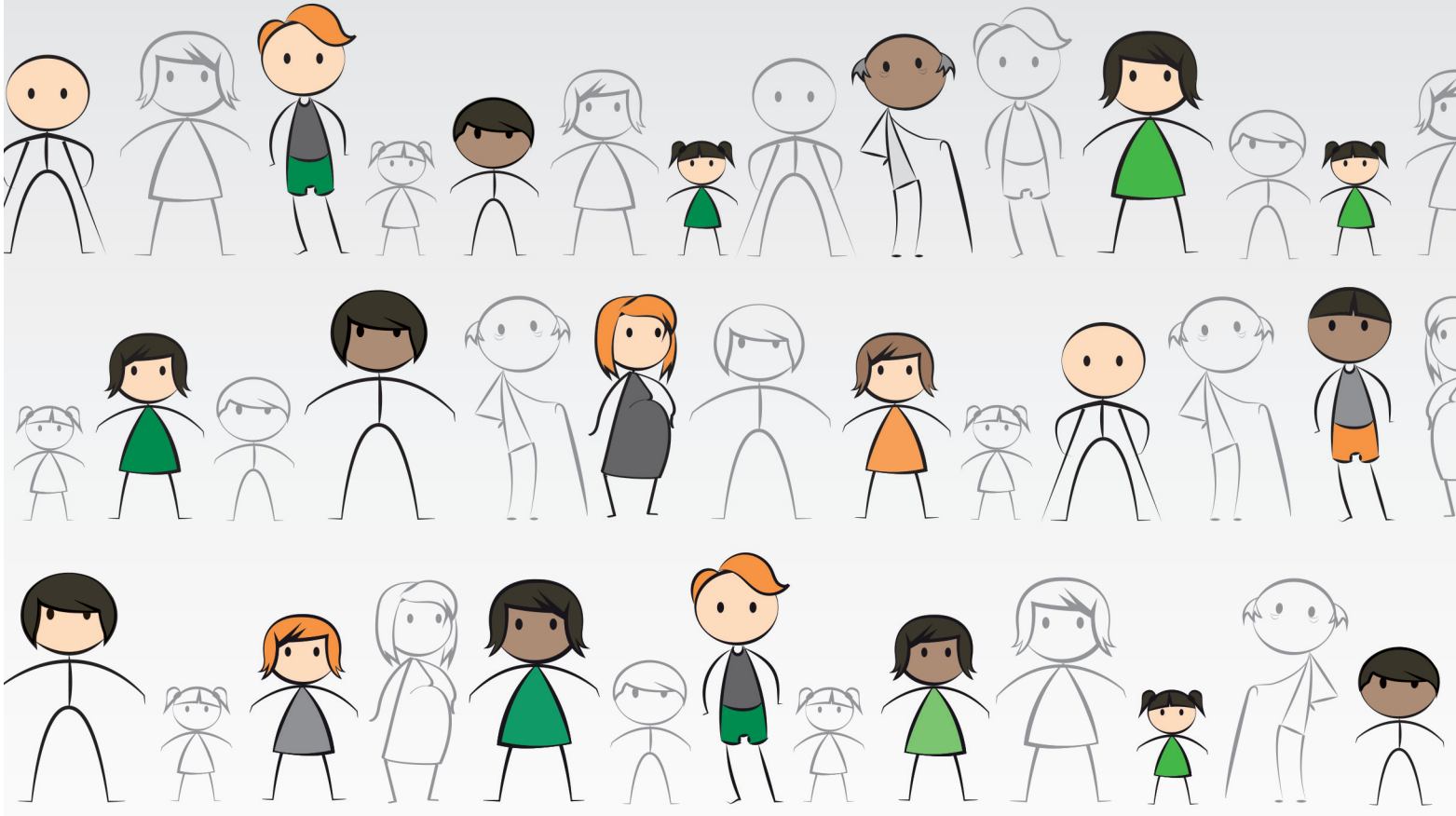
- Are convenient to use and to take.
- Are easy to swallow – even for people with dysphagia.
- Integrate easily into the busy lives of modern patients.
- Can be taken with or without liquids to suit the individual.
- Taste great and offer a variety of choices in terms of flavor.
- Allow greater amounts and different combinations of API to be delivered in a single dose, simplifying treatment regimens.

User-friendly dosage forms help to increase compliance and improve treatment success. Whilst creating a convenient and enjoyable experience for the patient, they also support healthcare companies to revitalize ageing products and boost brand loyalty.



TAKING A PILL IS AS EASY AS PIE?

50% OF YOUR CUSTOMERS WOULD DISAGREE ...



A recent study proves that more than half of the population has problems swallowing tablets and capsules. From breaking and dissolving to not taking them at all, people invent their own strategies to cope with tablets – which may reduce efficacy and treatment success.

At HERMES PHARMA, we have over 40 years of experience in making medicines easier to take – from product design through to manufacturing and packaging. If you need support with developing new products that are specifically designed to meet the needs of modern patients, contact us:
www.hermes-pharma.com

Scan QR-code or visit
www.swallowingtablets.com
to get a free copy of the market study.

HERMES PHARMA

Get the dose right®

KEEPING YOU CONNECTED TO YOUR TARGET AUDIENCE.

For more than 20 years, Drug Development & Delivery has successfully connected technology and service providers with R&D scientists, business development professionals and corporate managers working at pharmaceutical and biotechnology companies.

Marketing your technologies, services and products with Drug Development & Delivery keeps you engaged with your key audience.

Call us today or visit us at drug-dev.com and let us show you how.

- Print & Digital Editions
- Website Marketing
- Email Campaigns
- Videos
- Exclusive Whitepaper & Webinar Marketing
- Online Company Profile
- eBooks
- eNewsletters

John Kiesewetter: 541-338-0022
jkiesewetter@drug-dev.com

Amy Nicklaus: 862-274-5872
anicklaus@drug-dev.com

Ralph Vitaro: 973-263-5476
rvitaro@drug-dev.com

drug-dev.com

LATITUDE Pharmaceuticals: Your Drug Formulation Specialist

LATITUDE Pharmaceuticals is a client-focused CDMO with over 20 years of providing innovative drug formulation services and GMP manufacturing for early-phase clinical trials to the human and animal health industries. Founded in 2003, we have completed more than 1,200 client projects and have established a reputation for successfully formulating highly challenging compounds.

Formulation Development

LATITUDE's formulation scientists are the foundation for our creative custom formulation development, reliability, transparency, rapid turnaround, and client satisfaction. LATITUDE's extensive experience and technical strengths in a wide range of dosage forms successfully address the most difficult formulation challenges including solubility, instability, bioavailability and in vivo adverse reactions. LATITUDE scientists have particular expertise in the formulation of complex injectables including nanoemulsions, liposomes, microspheres and nanoparticles.

Innovative Drug Delivery Platforms

LATITUDE has developed the following cutting-edge drug delivery platforms:

- **ClearSol (Solubilization):** A highly effective and safe solubilization technology that surpasses cyclodextrins in scope and concentration for a wide range of APIs, with all components being GRAS and FDA-approved for injection.
- **PG Depot (Phospholipid Gel Depot):** Designed for customizable, sustained release of subcutaneously or intramuscularly administered drugs over 1-7 days, with up to 20% drug loading as well as administration via fine needles.
- **Nano-E (Nanoemulsion):** A flexible, solubility-enhancing platform suitable for oral and injectable formulations, effective in minimizing vein irritation in injectables.
- **ARTSS (Aqueous Room Temperature-Stable Solutions):** LATITUDE's platform for converting lyophilized powders or cold-stored solutions into RT-stable aqueous solutions.

GMP Manufacturing

In addition to providing materials for preclinical/IND-enabling studies, LATITUDE Pharmaceuticals manufactures and provides analytical testing for GMP-compliant clinical trial materials – we specialize in rapid delivery of Phase 1 and Phase 2 CTM. With a Quality Assurance System managed by an experienced and dedicated staff, LATITUDE can manufacture a variety of dosage forms including sterile injectable or ophthalmic drugs, as well as non-sterile oral or topical formulations, to support GLP toxicology studies or early-stage human clinical trials. LATITUDE is particularly proficient in the manufacture of complex liquid formulations such as nanoemulsions, liposomes, nanoparticles and other controlled-release products.

LATITUDE PHARMACEUTICALS INC.
9675 Businesspark Avenue
San Diego, CA 92131
T: (858) 546-0624
E: Info@latitudepharma.com
W:www.latitudepharma.com
LinkedIn: https://www.linkedin.com/company/latitude-pharmaceuticals

LGM Pharma

PARTNER SMART.

Company Description

LGM Pharma is a leading contract development and manufacturing organization (CDMO) offering a robust suite of capabilities, including comprehensive Active Pharmaceutical Ingredient (API) sourcing, analytical testing services, and drug product CDMO solutions to the pharmaceutical, biotechnology, and compounding pharmacy industries. LGM Pharma assists clients in managing all phases of the drug product development process, from API sourcing through to commercialization. LGM Pharma's extensive global network of qualified API partners enables clients to optimize supply chain management and distribution. Services include API sourcing and procurement, formulation development, analytical method development, method and process validation, ANDA / NDA submission, stability studies, and raw material and finished product testing and packaging. LGM Pharma is committed to quality and has a long-established positive regulatory track record, providing expert regulatory and market intelligence services to its clients. The company is focused on customer service and customized solutions, providing clients a comprehensive one-stop manufacturing solution that reduces risk, increases efficiency, and accelerates the path to commercialization.

Company Background

In July 2020, LGM Pharma acquired the formulation development and drug product contract manufacturing business of Nexgen Pharma, Inc. The combination merged LGM's global leadership in API sourcing, distribution, and supply chain management with Nexgen Pharma's comprehensive drug product CDMO services. The combined firm continues to be known as LGM Pharma and has all the capabilities needed to help pharma and biotech clients accelerate and optimize the new product pathway, from R&D and clinical development through regulatory submission commercial manufacturing. LGM added standalone analytical testing services as an offering in 2023. The combined firm continues to be known as LGM Pharma and has all the capabilities needed to help pharma and biotech clients accelerate and optimize the new product pathway, from R&D, clinical trial materials and analytical testing through regulatory submission and commercial manufacturing.

Service Offerings

- API Sourcing
- Standalone analytical testing services, including rapid sterility testing.
- Formulation Development
- Oral Solid Dose (OSD) development and commercial manufacturing
- Liquids and Suspensions
- Semi-Solids
- Suppositories
- Commercial Scale-Up and manufacturing
- Regulatory Management
- Stability Services
- FDA registered and cGMP compliant

LGM Pharma
Boca Raton, FL 33487
T: (800) 881-8210
W: https://lgmpharma.com/

API Sourcing.
CDMO Services.
Analytical Services.

One CDMO does it all.

Why risk your investment multiple times? Partner smart — once — to secure and optimize your supply chain.

LGM Pharma empowers our clients with expert customized services, from global API sourcing through drug product development and manufacturing, to analytical services and market intelligence.

Choose one CDMO partner to accelerate safe, high-quality therapeutics to market. **That's smart.**

LGM Pharma

PARTNER SMART.

Avoid significant challenges in outsourced analytical testing. Download our whitepaper.

LGMPharma.com/DDD2025

Lifecore Biomedical is a fully integrated Contract Development and Manufacturing Organization (CDMO) with expertise in specialty formulation, aseptic filling, and final packaging of complex medical devices and injectable pharmaceuticals.

Lifecore is also a leading producer of pharmaceutical-grade, non-animal-sourced sodium hyaluronate which is used as an API and excipient. We are a preferred viscoelastic supplier to ophthalmic market leaders and our products have been used in the treatment of more than 150 million patients worldwide.

Process Development & Fill/Finish Services

- Development, fill and finish of sterile injectables.
- Syringes, vials, and cartridges, including proprietary sterile filtration system.
- Expertise in highly viscous (exceeding 100,000 cP) and complex formulations.
- Pre-clinical through commercial support for virtual organizations to large pharma.
- Proven QMS supports:
  - API & Excipient
  - Medical Devices
  - Drug & Combination Products
  - Biologic Products

Additional Services

- Extensive on-site biological, analytical, and physical testing with redundant labs.
- ICH stability studies.
- Range of packaging, handling, serialization and sterilization options.

Sodium Hyaluronate

- Research-grade, pharmaceutical-grade, hydrogels, and custom modifications.
- Broad range of average molecular weights for use in R&D, animal/tox studies, clinical studies, and commercial applications.
- U.S. DMF (FDA for drug and device) approved, EP-certified, and JP-compliant.

LIFECORE BIOMEDICAL
3515 Lyman Blvd. - Chaska, MN 55318
T: (952) 368-4300
W: lifecore.com
LinkedIn: https://www.linkedin.com/company/lifecore-biomedical

MADE IN A FDA REGISTERED FACILITY

ISO 13485 CERTIFIED

GOOD MANUFACTURING GMP PRACTICE

lifecore.com

Lonza

LONZA
Muenchensteinerstrasse 38
4002 Basel, Switzerland
T: +41 61 316 81 11
W: www.lonza.com

Lonza is one of the world's largest healthcare manufacturing organizations, helping pharmaceutical, biotech and nutrition companies to bring their treatments to market. United by our vision to bring any therapy to life, we support our customers with a combination of technological insight, world-class manufacturing, scientific expertise, process excellence and innovation. Our work enables our customers to develop and commercialize their therapeutic discoveries, allowing their patients to benefit from life-saving and life-enhancing treatments.

Our business is structured to meet our customers' complex needs across four divisions: Biologics, Small Molecules, Cell & Gene and Capsules & Health Ingredients. Our services and products span from supporting early-phase discovery to custom development and manufacturing of active pharmaceutical ingredients, as well as innovative dosage forms for the pharma and consumer health and nutrition industries. Our scale and resources mean that we can provide a single integrated solution to meet our customers' complex needs.

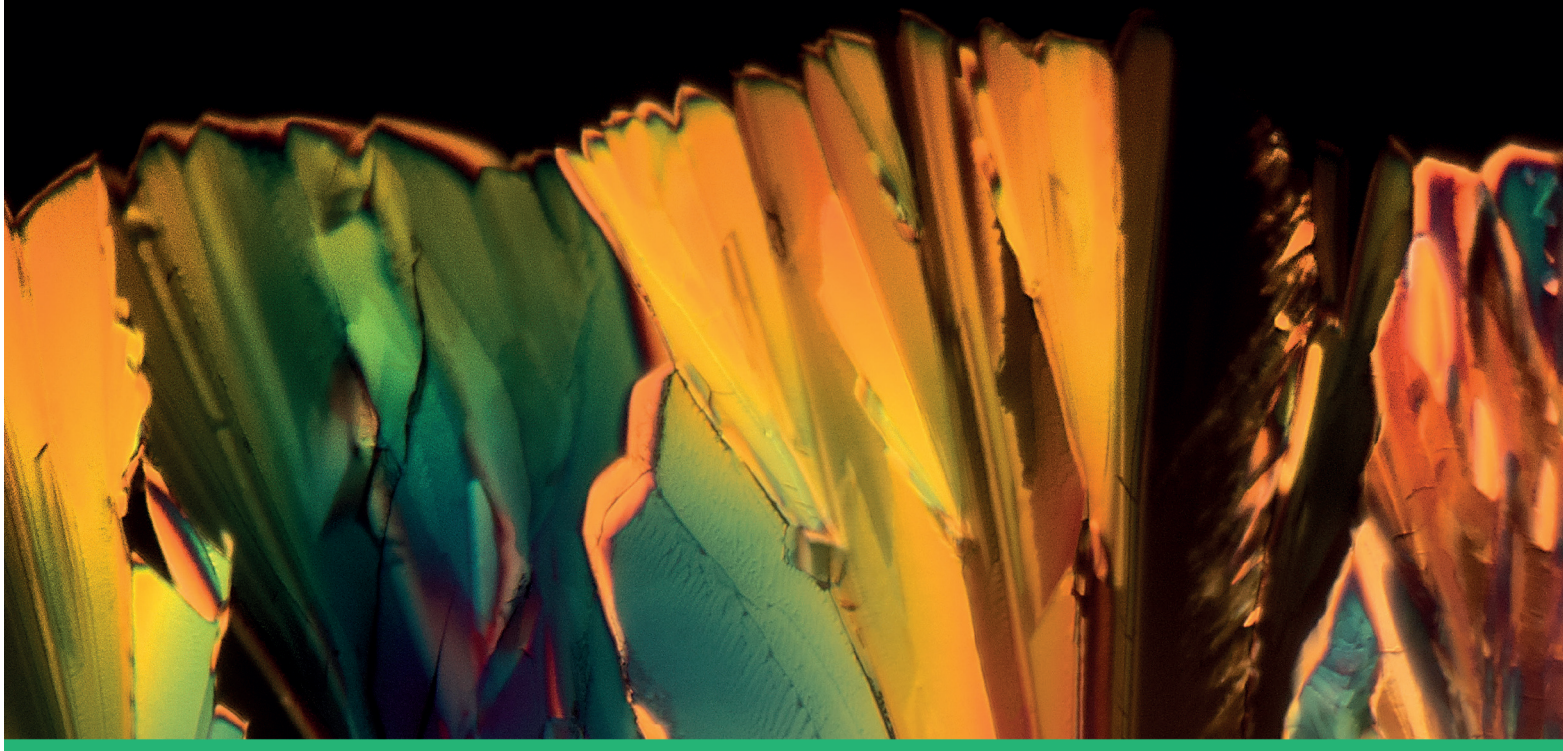
Founded in 1897 in the Swiss Alps, today, Lonza operates across five continents. Our global community, of around 18,000 employees, is comprised of high-performing teams and individual talent that make a meaningful difference to our own business, as well as to the communities in which we operate. Our colleagues are the heart of our business and our global people strategy is designed to enable our colleagues to come, stay and grow at Lonza. While our business benefits from global supply chains, we have worked to maintain the agility to address marketplace needs on a local level.

Sustainable value creation is an ethical, social and commercial imperative for our business and supports us in fulfilling our purpose of enabling a healthier world. Across our global network, we create value by enhancing social engagement, strengthening our governance, and reducing our environmental footprint. We have grouped our sustainability initiatives around material themes and selected key Sustainable Development Goals (SDGs). The SDGs comprise the global blueprint of the United Nations (UN) to achieve a better and sustainable future for humanity. Learn more about our sustainability approach and initiatives within our sustainability section of the website.

Enabling a Healthier World

Lonza
Small Molecules

Always (Bio)Available for Small Biotechs



By ensuring the right science is always on hand to help overcome your bioavailability barriers to solubility and success. We work as one.

LUBRIZOL LIFE SCIENCE

Company Profile

Lubrizol Life Science partners with pharmaceutical and nutraceutical companies to develop innovative solutions that improve patient outcomes and consumer benefits.

Along with our best-in-class pharmaceutical excipients, and nutraceutical actives, we offer our expertise, and capabilities to accelerate your innovations to market.

We can help you with:

- Innovative and multifunctional excipients portfolio, including:
  - Established Carbopol® Polymers, Pemulen™ polymeric emulsifiers, and Noveon® polycarbophil
  - Our newly-launched solubility-enhancing Apisolex™ and Apinovex™ polymers
  - Deep understanding of oral, topical, ophthalmic, and injectable formulation development

- Value added nutraceutical ingredients, including microencapsulated minerals and dietary supplements

HEALTH

Contact Us page: Contact Us about Pharmaceutical Excipient Products and Solutions – Lubrizol
LinkedIn: https://www.linkedin.com/showcase/lubrizol-lifesciences
E: lifesciences@lubrizol.com
Resource Hub: Lubrizol Pharmaceutical Excipient Resource Hub
W: www.Lubrizol.com/Health and www.LubrizolCDMO.com

LUBRIZOL LIFE SCIENCE

FORMULATING WITH CONFIDENCE

Solve your solubility challenges and differentiate your drug products with Lubrizol's solubility-enhancing excipients.

ENABLING PATIENT-CENTRIC DRUG DELIVERY

Our comprehensive excipient range, comprising pharmaceutical grade Carbopol® polymers and novel Apisolex™ & Apinovex™ excipients, improves water solubility and can unlock key patient-centric benefits for oral, parenteral, topical and ophthalmic applications. By incorporating our cutting-edge excipients into your formulations, you can achieve smaller pill size, extended-release, improved sensory properties, and more.

REQUEST A SAMPLE

Discover how you can transform your formulations with Lubrizol excipients.

LS | HEALTH

9111 Brecksville Road
Cleveland, OH 44141-3201 USA

LYOPHILIZATION TECHNOLOGY, INC.
30 Indian Drive
Ivyland, PA 18974-1431
T: (215) 396-8373 F: (215) 396-8375
E: inquiry@lyo-t.com W: www.lyotechnology.com

WHO WE ARE

Lyophilization Technology, Inc. (LTI) is a Contract Development & Manufacturing Organization (CDMO) focused on all aspects of lyophilization of health care products.

Clients leverage on our abilities for bringing new products to the clinic and implementing improvements for current products and processes. Capitalize on over 30 years of excellence and our unparalleled capabilities in product development, process engineering, clinical manufacturing, and technical support.

MAJOR MARKETS

Biotechnology and pharmaceutical organizations spanning virtual companies to large multi-national corporations, along with universities and research institutes have engaged our services in successful collaborations for a variety of projects. These projects span initial product design and process engineering for new entities right out of drug discovery through Phase 1/2 clinical supplies, to technology transfer to commercial manufacturing with regulatory approval. Gaining a global reputation, LTI has been sought after and completed projects with clients in the European, Middle East, and Asian Pacific regions, as well as Canada and the Americas.

SERVICES OFFERED

Capabilities

- Pre-clinical through Phase II Clinical Supplies
- Bulk Lyophilization
- Dedicated/disposable equipment
- Batch sizes: up to 75L
- Vials: 2 to 160 mL
- Dual Chamber cartridges and syringes: 1 to 20 mL
- Novel delivery systems
- Nucleation On-Demand Technology
- DEA license
- US/EU compliant

LTI successfully develops formulations, processes or prepared clinical material for many diverse products, including:

- Biologics (up to BSL-2)
- Oncolytics
- Liposomes
- Anti-Infectives
- Peptides/Polypeptides
- Proteins/mAbs
- Diagnostics
- Nanoparticles/Emulsions
- Vaccines and VLPs
- Controlled Substances
- Highly Potent Compounds
- Antibody Drug Conjugates
- Devices/Delivery Systems
- Small and Large Molecules

Development Sciences

Development Sciences focuses on initial product design and formulation development through finished product characterization. The Process Lab provides capacity for small to medium scale lyophilization. Filtration, filling, stoppering, and loading the qualified pilot-scale lyophilizers are in certified Class A/100 environments, emulating aseptic manufacturing conditions.

- Product Design
- Formulation Development
- Thermal Analysis
- Process Engineering (Cycle Design)/Refinement
- Product Characterization
- Pilot Plant Scale-up
- Isolation/Containment
- Cartridges/Syringes/Dual Chamber Devices

Clinical Supplies Manufacturing

US/EU compliant Clinical Manufacturing Area (CMA) for preparation of clinical supplies enable us to process a wide range of products, including those having unique requirements. The CMA includes an aseptic suite featuring advanced containment/isolation technology using unique disposable negative pressure isolators inspected and approved for handling BSL-2, cytotoxic and highly potent compounds. LTI has also developed the technology that allows us to freeze dry product in both dual chamber cartridges, syringes, and dual chamber devices.

- Aseptic compounding
- Pre-clinical through Phase II
- Toxicology Material Processing
- Small to medium batch sizes
- Liquid/diluents
- All Dual chamber devices

Technical Services

Technical services are available providing support for all aspects of lyophilization.

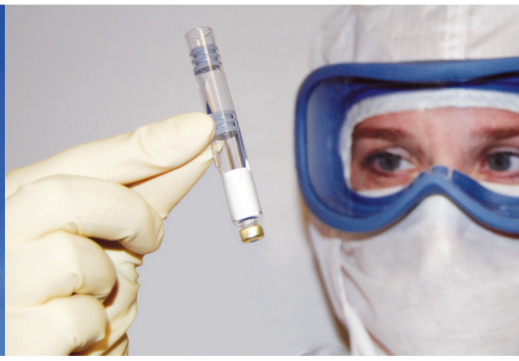
- Customized Training
- Consulting on equipment specifications
- Process requirements
- Guidance on CMC submission
- Support on IQ/OQ and process validation
- Technology transfer
- Process excursions
- Product and process troubleshooting
- Batch record review
- Compliance auditing

Lyophilization TECHNOLOGY Inc.

Integrating Science and Technology

The industry leader with unparalleled capabilites, innovative approaches and effective solutions.





DEVELOPMENT SCIENCES • CLINICAL MANUFACTURING

CONSULTING AND TRAINING

Product Design • Formulation Development • Thermal Analysis • Boundary Studies

Process Engineering • Dual Chamber Processing • Clinical Material Preparation

Quality and Regulatory Support • Technical Services • On-site Training • Consulting

LYOTECHNOLOGY.COM

30 INDIAN DRIVE • IVYLAND, PA 18974 USA • +1 (215) 396-8373

MEDBIO
5346 36th Street SE
Grand Rapids, MI 49512
T: (616) 245-0214
F: (616) 245-0244
E: info@medbiollc.com
W: https://medbiollc.com/

Medbio is a medical manufacturing partner like no other, with the broadest spectrum of medical molding solutions. From precision custom molding capabilities, full-service manufacturing and value-added assembly to a wide range of standard protective parts, medical packaging and labware components, Medbio is the one partner you need.

Medbio is a trusted supplier to the drug delivery industry, specializing in full-service solutions – everything from components to complete assemblies. Including auto injectors, infusion pumps, respiratory devices and more, let us put our vast expertise to work for you. We understand that precision, cleanliness and reliability are paramount to your success. It starts with our in-house team of engineers who combine medical industry and molding expertise to ensure the most effective and cost-efficient solution to meet your needs. We have the flexible capacity for large-scale projects, and as you grow, our support and scalability evolve alongside you. The right design for manufacturability, the optimal material selection, and precise tooling, combined with stringent quality management and control systems, along with assembly and packaging capabilities, ensure your project is completed to your exact specifications.

Our multiple state-of-the-art facilities include over 80,000 square feet of ISO Class 7 and 8 cleanroom manufacturing, for cleanroom molding, assembly and packaging. Fully certified ISO13485, ISO9001, ISO14001 and FDA Registered. Our advanced process and production monitoring and reporting systems can also be tailored to customer's unique requirements. For large, multi-step projects, we can custom design dedicated, lean assembly cells specific to your needs. Let us help you bring your Class I, Class II and Class III medical devices to market with precision and efficiency.

Along with sister company Caplugs, one of the world's leading plastic molders, we have worked with over 1,500 medical and biotechnology customers and boast over 100 years' experience in meeting the very stringent needs of these industries.

Our full-service team helps to ensure your success from initial engagement through specifications and quoting to full production and delivery. Dedicated project management combined with technical depth and exceptional responsiveness for proven commitment to our customers' success. Bring us your next challenge or let us have one of our experts tell you more about how our capabilities may meet your future needs.

A **Medical Manufacturing Partner** Like No Other

As a leader in precision custom molding capabilities and value-added services and assembly, Medbio is a trusted supplier to the drug delivery industry.

Offering a **full spectrum** of solutions:

- Custom Injection Molding
- Custom-Built Automation Cells
- Class 7 & 8 Cleanrooms
- End-to-End Manufacturing

Plus, convenient Caplugs **catalog parts**:

- Standard Caps & Plugs
- Medical Packaging
- Single-Use Labware

From auto injectors and infusion pumps to respiratory devices and more, let us put our vast expertise to work for you.

1,500+	80,000+	ISO 13485 ISO 9001 ISO 14001	FDA
MEDICAL CUSTOMERS	CLEANROOM SQUARE FEET	CERTIFIED	REGISTERED

MEDBIO®
a caplugs partner

www.medbiollc.com | 616.245.0214 | info@medbiollc.com

Full-Service Manufacturing | Precision Custom Plastic Molding | Value-Added Assembly | Standard Molded Parts

MIKART

Company Description

Mikart's 45+ years of experience in oral solid and nonsterile oral liquid dosage forms and specialization in pediatric, geriatric, and controlled-substance make us the ideal contract development and manufacturing organization partner — from formulation development through commercialization. We value long-lasting relationships and a personalized approach; bringing both the reliability and flexibility to meet your needs and exceed your expectations. For the solid foundation and flexible solutions to bring your product to life, choose Mikart.

SERVICES & CAPABILITIES

Mikart specializes in pharmaceutical contract development and manufacturing. Their expertise lies in providing comprehensive solutions for formulation development, manufacturing, packaging, and regulatory support for various dosage forms, including solid oral dosage, liquids, semi-solids, and more. They excel in tailored drug delivery technologies, process optimization, and ensuring compliance with industry regulations, positioning themselves as a reliable partner for companies aiming to bring innovative pharmaceutical products to market.

TECHNOLOGIES

Mikart offers an extensive range of solutions that empower clients to excel in their endeavors. Poor solubility remains one of the greatest challenges in pharmaceutical development. Mikart has exclusive partnerships with Nano PharmaSolutions's proprietary NanoTransformer™, a scalable nanosizing technology that generates drug nanoparticles in the 200-600nm (D50) range, and Fluid Pharma, a licensing and product development company applying its proprietary MicroCoat™ technology to advance new therapies for pediatric, geriatric, and oral liquid modified-release applications.

Mikart's technologies enable clients to navigate complexities, expedite timelines, and achieve success in bringing novel therapies to market efficiently and effectively.

FACILITIES

Mikart has a campus in the Atlanta, GA staffed by 200+ employees. Our 150,000 sq ft facilities in Atlanta, GA can provide development-scale through commercial-scale production. The facility boasts cutting-edge equipment and technologies for pharmaceutical development and manufacturing across various dosage forms. It includes specialized areas for formulation development, analytical laboratories, multiple manufacturing suites equipped for different types of drug products, packaging capabilities, and storage areas compliant with industry standards and regulatory requirements.

MIKART EXPERTISE

- Controlled Substances, including Class 1 Psychedelics
- Pediatric formulations
- Geriatric formulations
- Oral solid dose
  - Tablets
  - Capsules
- Liquid oral dose, solutions & suspensions

AREAS OF EXPERTISE

- Pre-formulation
- Formulation development
- Analytical method development
- Regulatory support
- Process optimization
- Scale-up
- Site and technology transfers
- Product application support

PROCESSING CAPABILITIES

- Delayed release film coating
- Direct compression
- Fast dissolve (ODT)
- Fluid bed top spray
- High shear wet granulation
- Immediate release film coating
- Liquid-to-solid conversion
- Low humidity manufacturing
- Low shear wet granulation
- Modified release film coating
- Multiple unit pellet system

DEDICATED DOSAGE FORMS

- Solutions and Suspensions
- Chewable/ODT
- Liquids/suspensions
- Minitabs
- DEA Controlled substances:
  - Manufacturing: Schedules 1-V
- High Potency

ANALYTICAL SERVICES

- Analytical method development & analytical method validation
- Cleaning validation studies
- Contract resources for specialty analyses
- DEA schedule I-V materials
- Drug release profiles (apparatus I and II)
- HPLC, UPLC, AA, FTIR, UV-Vis, and more
- Method transfer
- Quality control and microbiology laboratories
- Thermal cycling studies
- Verification of USP methods
- Whole and split tablet studies

COMPREHENSIVE PACKAGING CAPABILITIES

State-of-the-art packaging facility with 6 packaging lines with full serialization that can fill over 250,000 bottles per day. Packaging includes bottle filling, blistering, pouch/foil strip packs, cartoning and tray packaging, unit dose cups, and sachet. All of Mikart's packaging lines are contained in individual suites with independent HVAC systems.

MIKART, LLC
1750 CHATTAHOOCHEE AVE NW
ATLANTA, GA 30318
E: HTTP://WWW.MIKART.COM

MIKART

ORAL SOLID & LIQUID ORAL DOSAGE FORM EXPERTS

Mikart invests in new liquid suspension suite and sachet capabilities

DEVELOPMENT

Mikart's development services include a range of pre-formulation and formulation capabilities. We have a proven track record of delivering the highest quality products to our client's exact standards.

MANUFACTURING

Mikart offers pharmaceutical manufacturing solutions for clinical trial materials, physician samples, and commercial products — we customize our approach with flexible solutions to exceed your expectations.

PACKAGING

As a manufacturer of flexible pharmaceutical packaging configurations, Mikart has a solid foundation in pharmaceutical packaging services. Including fully compliant serialization, we offer customized clinical packaging and labeling services.

ABOUT US

Mikart brings 45+ years of experience in oral solids and non-sterile oral liquids, as well as our expertise in pediatrics, geriatrics, and controlled substances, Mikart is the ideal partner for contract development and manufacturing - from formulation development through commercialization.

In order to meet your needs and exceed your expectations, we value long-term business relationships and personalized service.

BizDev@mikart.com

1750 Chattahoochee Ave NW
Atlanta, GA30318

www.mikart.com

MITSUBISHI GAS CHEMICAL

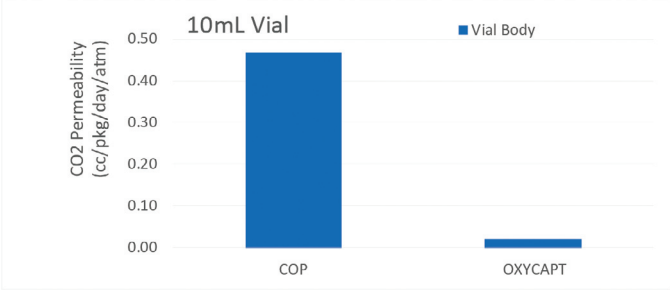
Mitsubishi Gas Chemical (MGC) is a leading company in the field of oxygen barrier and absorbing polymers. Based on these technologies and experiences, MGC launched new multilayer plastic vial named OXYCAPT™ in 2019. It has achieved an excellent oxygen, carbon dioxide, ultraviolet (UV) barrier, high water vapor barrier, very low extractables, high pH stability, low protein adsorption, high transparency, high break resistance, easier disposability, lighter weight, etc.

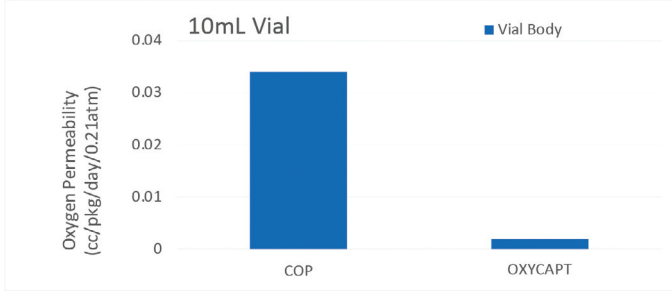
Products

OXYCAPT consists of three layers. The drug contact layer and the outer layer are made of cyclo-olefin polymer (COP), and the oxygen barrier layer is made of MGC's novel polyester.

The oxygen and carbon dioxide barrier of OXYCAPT vial is about 20 times better than that of COP monolayer vial. OXYCAPT also provides an excellent UV barrier. While about 70% of 300 nm UV light transmits through glass and COP, only 1.7% transmits through OXYCAPT. OXYCAPT vials are produced by co-injection blow-molding technology. MGC has also developed inspection methods for testing the oxygen barrier layer. All of the containers are fully inspected by state-of-the-art inspection machinery. MGC can offer ready-to-use (RTU) vials in tray or nest and tub formats. The vials are mainly sterilized using gamma rays. There are 2-, 6-, 10-, and 20-mL variants for vials.

OXYCAPT is especially suitable for biologics and cell and gene therapy products stored at deep-cold or cryogenic temperature. It can maintain container closure integrity (CCI) under such harsh conditions and prevent carbon dioxide permeation generated from dry ice and nitrogen permeation from liquid nitrogen. As the carbon dioxide permeation usually causes pH shift, and nitrogen permeation causes over-pressure in headspace, MGC believes OXYCAPT is an ideal solution for the drugs stored in dry ice and liquid nitrogen.



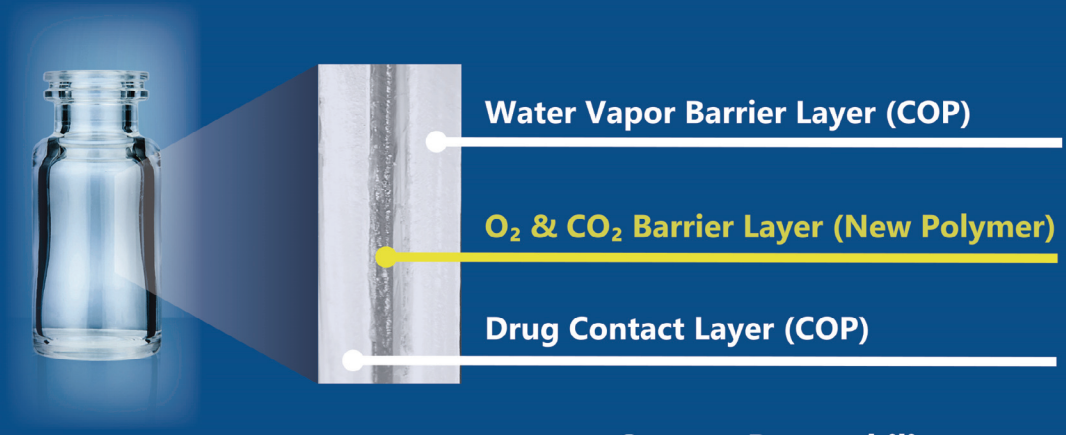


MITSUBISHI GAS CHEMICAL COMPANY, INC.
MITSUBISHI BUILDING, 5-2 MARUNOUCHI 2, CHIYODA-KU
TOKYO 100-8324, JAPAN
T: +81 3 3283 4913
W: https://www.mgc.co.jp/eng/products/abd/oxycapt.html

OXYCAPT™ Multilayer Plastic Vial

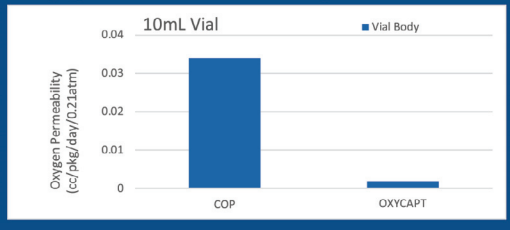
for Biologics & Cell Gene Therapy Products

Multilayer Structure

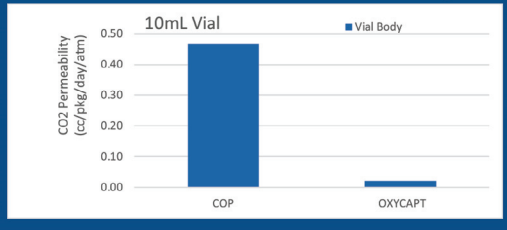


- **Excellent O_2 & CO_2 Barrier**
- **Excellent UV Barrier**
- **Very Low Extractables**
- **Very Low Protein Adsorption**
- **High Compatibility with High & Low pH Drugs**
- **Excellent Break Resistance at Deep Cold Temp.**

Oxygen Permeability



Carbon Dioxide Permeability



- **Excellent CCI at Deep Cold Temp. with Dry Ice**
- **Maintain Excellent CCI after Freezing & Thawing Process**

MITSUBISHI GAS CHEMICAL

Mitsubishi Gas Chemical Company, Inc.
https://www.mgc.co.jp/eng/products/abd/oxycapt.html
Mitsubishi Gas Chemical America, Inc.
http://www.mgc-a.com
Mitsubishi Gas Chemical Europe GmbH
https://www.mgc-europe.de

NEMERA
63 Avenue Tony Garnier - 69007 Lyon, France
W: www.nemera.net
LinkedIn:
https://www.linkedin.com/company/nemera/posts/?feedView=all&viewAsMember=true

As a world-leading drug delivery device solutions provider, Nemera's goal of putting patients first enables it to design and manufacture devices that maximize treatment efficacy. **Nemera** is a holistic partner and helps its customers succeed in the sprint to market with its combination products. From early device strategy to state-of-the-art manufacturing, Nemera is committed to the highest quality standards. Agile and open-minded, the company works with its customers as colleagues. Together, they go the extra mile to fulfil its mission.

CONTRACT DEVELOPMENT, CONSULTING & MANUFACTURING SERVICES

Nemera is your trusted integrated partner for the device and combination product journey. We offer comprehensive end-to-end services and expertise in front-end innovation, device development, combination product consulting, and contract manufacturing. Our diverse portfolio of products is complemented by this approach, enabling us to provide support at every step of the journey, fully integrated as a single partner or stand-alone to meet your specific needs, regardless of your device development strategy or regulatory pathway. Whether it's Nemera products, your organic development, or third-party devices, we are here to assist you.

We apply this know-how and our singular focus on healthcare to realize our vision of becoming the most patient-centric drug-device company in close partnership with our customers, ensuring accelerated delivery of your drug to patients.

OPHTHALMIC: A CLEAR VISION FOR EYE CARE

One of the main criticalities of self-administered eye care treatments today is poor patient adherence, especially with chronic diseases. We strive to improve patient experience by providing safe and effective multidose eyedroppers for preservative-free solutions, used all over the world: **Novelia®** is a preservative-free multidose eye dropper delivering consistent drops for better patient compliance.

NASAL, BUCCAL, AURICULAR: MAKE EVERY SPRAY COUNT

The number of drugs delivered through the ear, nose and throat is expanding. We provide a comprehensive range of pumps, compatible with a wide choice of actuators for each delivery route (ear, nose and throat), suitable for regulated and low regulated markets: **multidose pump systems (SP270+, SP370+, SP27, SP37, *In-vitro* Bioequivalence for nasal sprays, Child-resistant solutions), unidose systems (UniSpray), Retronose®, and electronic technologies (Safe'n'Spray™ and Electronic Nasal device)**. We guarantee precision and dose consistency to maximize treatment efficacy and improve patients' outcomes.

DERMAL: CONVENIENT FOR PATIENTS, PROTECTIVE FOR FORMULATIONS

The dermal application is a convenient non-invasive way to administer liquid sprays, lotions, gels, or creams to the skin for dermatological, anti-inflammatory or systemic treatments. Our airless and atmospheric delivery devices are suitable for RX and OTC formulations and have all the documentation needed to be registered on regulated markets: Sof'Bag®+, Sof'Airless, Spray pumps for vicous formulations and Child Resistant Closure systems.

PARENTERAL: COMPLEX DEVICES, SIMPLE PATIENT CARE

The growing prevalence of chronic diseases, along with the evolution of self-administration at home, is driving new ways of administrating parenteral drugs. As injecting a drug means increased risks of use errors and needlestick injuries, self-administration at home translates into a need for safer, easy-to-use and ergonomic devices. We are committed to ensure adherence and user well-being for patients and healthcare professionals providing a comprehensive parenteral product range that matches their need: **Passive Safety Systems (Safe'n'Sound® 1ml and 2.25ml), Reusable and Disposable Pen platforms, Implanters, and Body injectors (Symbioze®).**

INHALATION: A BREATH OF EXPERTISE

From the concept idea to large scale manufacturing, we're the utmost holistic partner to develop your inhalers. We help our customers succeed in the sprint to market with their formulations targeting the inhalation treatments. We also are an active contributor to the scientific community and we strive to consider in our research evolving trends in inhalation and in patient needs, as well as increasing interest to digital and sustainability related factors.

OVR (ORAL, VAGINAL, RECTAL)

We offer millimeter solutions in medicine applicators and dispensers, being today a global reference for quality and precision in this segment. Our systems aim to be used for oral, vaginal and rectal treatments, such as Oral infections, Vaginal infections, and Rectal diseases.

Nemera

we put patients first

Your partner for drug delivery device solutions and combination product services

Oakwood Chemical, Inc.
730 Columbia Highway
Estill, SC 29918
T: (803) 739-8800
Toll Free: (800) 467-3386
F: (803) 739-6957
E: sales@oakwoodchemical.com
W: www.oakwoodchemical.com

Key Personnel
Greg Butler, President
Dr. Eldon Baird, Vice President, Operations
Wilson Butler, Director of Business Development

COMPANY DESCRIPTION

Oakwood Chemical is a leader in selling high-quality reagents to academic, chemical, and pharmaceutical customers for over 30 years. Located in the South Carolina Lowcountry, we have over 10,000 square feet of laboratory space, as well as two large warehouses totaling 200,000 square feet with over 150,000 chemicals in stock. We offer benchtop to production quantities of inorganic and organic reagents, solvents, salts, catalysts, and biochemicals in numerous grades (reagent, anhydrous, ACS, HPLC, LCMS, NMR, USP) and in different amounts (from lab bench to industrial drum sizes). Let us help you in succeeding in this high growth industry.

We have synthetic chemists with backgrounds in catalyst development, fluorine chemistry, pharmaceutical research, and novel small molecule library synthesis. In our Quality Department, Oakwood has maintained the same analytical chemists for over twenty years, along with the recent introduction of an analytical biochemist with 20 years of work in biochemical assay development, trace metals testing, polymer research, and HPLC/MS analysis. Oakwood Chemical is uniquely positioned to offer both in stock chemicals of high quality and custom synthesis expertise to your projects with our amazing team.

STATES SERVED

We serve every state in the United States and ship internationally worldwide.

PFANSTIEHL, INC.
1219 Glen Rock Ave
Waukegan, IL 60085
T: (847) 623-0370 Toll Free (800) 383-0126
E: cs@pfanstiehl.com
W: www.pfanstiehl.com

Pfanstiehl is a global leader in the manufacture of cGMP-compliant, high-purity, low-endotoxin, low-metal injectable grade excipients and biopharmaceutical components, designed for use in upstream & downstream bioprocessing, and final drug formulation. Additionally, Pfanstiehl is a leading Contract Development and Manufacturing Organization (CDMO), specializing in the isolation, purification, custom synthesis, and scale-up of small molecule Active Pharmaceutical Ingredients (APIs) from gram to multi-ton commercial quantities. Unlike many manufacturers or resellers who serve a variety of industries such as food, cosmetics, agriculture, or nutritional supplements, Pfanstiehl focuses exclusively on biopharmaceutical applications.

Pfanstiehl's ICH Q7-compliant and US FDA-inspected manufacturing facility is strategically located just north of Chicago, a 35-minute drive from O'Hare International Airport. The company's product offerings include platform-enabling parenteral-grade, multi-compendial protein and cell membrane stabilizers such as Trehalose, Sucrose, Arginine, and Maltose, as well as Mannitol and Sodium Succinate Hexahydrate, all crucial for formulation optimization. Recent additions to the portfolio include amino acids such as Histidine, Methionine, Glutamine, and TRIS base, with plans to expand further in response to client feedback. Pfanstiehl collaborates with clients seeking more than just high-quality ingredients, offering partnership in navigating evolving regulatory requirements and addressing emerging formulation challenges.

For upstream applications, Pfanstiehl offers high-purity, low-endotoxin, low-metal galactose to reduce lactate and ammonia production, which enhances overall cell culture performance. The company provides multiple types of D-Galactose, including non-animal-derived options. Mannose is also available to improve native glycosylation and ensure consistent product quality, particularly in high-titer processes.

Founded in 1919, Pfanstiehl celebrates over a century of excellence in carbohydrate and process chemistry. The company supplies many of the world's leading biopharmaceutical, vaccine, and pharmaceutical companies, with products utilized in treatments for life-threatening diseases such as cancer, rheumatoid arthritis, STDs, and diabetes, as well as in leading vaccine platforms, including mRNA and viral vector-based vaccines.

Pfanstiehl's commitment to stringent regulatory standards and high-purity manufacturing is recognized by the FDA and other global regulatory agencies. The company prioritizes product quality, environmental responsibility, and worker safety, designing facilities and training personnel to exceed US FDA, cGMP, OSHA, and international standards. Pfanstiehl is dedicated to ensuring the quality, purity, and safety of its excipients, as well as the security of supply for its clients.

For more information, please visit our website at Pfanstiehl.com

Delivering on the Promise of Purity

Owen Mumford
Pharmaceutical Services

Owen Mumford Ltd
Brook Hill, Woodstock, Oxfordshire
OX20 1TU, UK
T: +44 (0)1993 812021
E: pharmaservices@owenmumford.com
W: www.ompharmaservices.com

Experts in Injectable Drug Delivery

Owen Mumford Pharmaceutical Services creates award-winning, patient-centric
devices and its auto-injectors and pens are distributed around the world.

With more than 70 years' experience in medical devices, Owen Mumford has a global presence extending from manufacturing facilities in the UK and Malaysia to subsidiaries in the US, Germany, and France.

The Pharmaceutical Services division specialises in the design and manufacture of injectable drug delivery systems for the pharmaceutical, biotech, and generics industries. This includes auto-injectors and pens for subcutaneous and intramuscular administration. Pharmaceutical partners can choose between single and multi-dose, and reusable and disposable devices.

The UniSafe® Platform

Flagship products include the UniSafe® platform, a spring-free, passive safety device for 1ml and 2.25ml pre-filled syringes. UniSafe 1ml has regulatory approval as a combination product in Asia and Europe, where it is also in patient use.

An upcoming addition to this platform is the UniSafe® 1ml auto-injector, a reusable device for use with a 1mL UniSafe safety syringe. This is the only part which is disposed of following use, helping to reduce waste. The auto-injector will be available with optional inbuilt connectivity via automatic Bluetooth® connection, enabling data transfer of key medication parameters between patients and their healthcare providers.

Award-Winning Auto-Injector

To accommodate a range of different drug fill volumes, our two-step disposable auto-injector, Aidaptus®, can be used with both 1mL and 2.25mL syringes in the same base device. It can also readily adapt to different fill volumes using auto-adjust plunger technology, providing a solution for formulation changes during development and life cycle management. In sum, if the drug formulation has to change, this device does not.

Aidaptus has a unique, patient-centric design with automatic needle insertion for a simple and consistent user experience. The stopper sensing technology, coupled with independent, two-phase needle insertion and drug delivery, significantly reduces any impact forces on the syringe, mitigating the risk of syringe breakages during use.

With a needle that is shielded before, during, and after use, Aidaptus reassures users who are new to auto-injectors, as well as those who are needle-phobic. The device also gives users confidence that the injection has been successfully completed, with an audible notification at the start and end of the procedure.

Owen Mumford Pharmaceutical Services has an exclusive agreement with Stevanato Group for the manufacture of Aidaptus, which was awarded a distinction in the prestigious Red Dot awards for innovative product design. Stevanato Group is a global provider of drug containment, drug delivery, and diagnostic solutions. This collaboration aims to reduce supply chain risk in combination product development for our pharmaceutical partners.

Aidaptus®

2-step single-use autoinjector platform

With **Aidaptus®**, if your drug product changes your device doesn't need to

reddot winner 2023
innovative product

A true platform device, designed to accommodate:

- A fill volume range of 0.3mL up to 2.25mL using auto-adjust plunger technology
- 1mL and 2.25mL syringes with minimal change parts
- Viscosities with a choice of delivery springs

Commercially available

Find out more by scanning the QR code or visiting **ompharmaservices.com/aidaptus**

In collaboration with Stevanato Group

*In addition to an air bubble and overfill

Owen Mumford
Pharmaceutical Services

PACE® LIFE SCIENCES – PEOPLE ADVANCING SCIENCE™
HQ: Oakdale, MN
1311 Helmo Avenue North
Oakdale, MN 55128
T: 610-279-7450
W: www.pacelifesciences.com

ADDITIONAL CRDMO NETWORK SITE LOCATIONS:
Boston, MA
Salem, NH
San Diego, CA
Norristown, PA
Ann Arbor, MI
Lebanon, NJ
Research Triangle Park, NC
San German, PR

Pace® Life Sciences provides a full suite of contract CMC development, CTM manufacturing, regulatory compliance, consulting, and facility support services to the pharmaceutical, biopharmaceutical, and gene therapy industries. We operate from a network of CDMO sites, GMP analytical testing laboratories, and manufacturing support service centers across the United States. Our highly trained industry experts, and investment in state-of-the-art facilities emphasize our commitment to efficiently advancing client programs through the clinic to commercialization. We are dedicated to delivering the most reliable services with positive customer experiences across all channels of our business.

Our Pharmaceutical Development laboratories provide IND-enabling services to help new therapies progress through the pre-clinical stages, to include: Characterization of new synthetic small molecules, biologics such as proteins, peptides, antibodies, antibody drug conjugates, and gene therapies such as oligonucleotides. Early phase development services include lyophilization process development, spray-drying, phase-appropriate analytical development, Test Article preparation, and Clinical Trial Materials (CTM) manufacturing and packaging services.

Technology transfer to our state-of-the art GMP testing facilities enables our clients to seamlessly and confidently advance their programs from preclinical and clinical studies to commercialization in a manner compliant with regulations and industry standards. Partnering with us is a key accelerator for getting your products to market on time and on budget. We provide a real and tangible difference to your customer experience by combining all essential service elements:

Comprehensive Scope of Services: A broad scope of services to support you from early characterization and Pharmaceutical Development through marketed product support.

Pharmaceutical Development
- Preformulation Characterization
- Formulation Development
- Bioavailability Enhancement
- Clinical Supplies Manufacture
  - o Sterile Products
  - o Tablets/Capsules
  - o Solutions/Suspensions
  - o Semi-solids, Ointments, Creams
- Clinical Packaging
- Method Development and Phase Appropriate Verification/Validation
- Solid State API Characterization
- Nitrosamine Risk Assessment and Analytical Development
- Package Component Evaluation – Extractables/Leachables
- Stability Storage and Testing

GMP Laboratory Commercial Product Support
- Raw Materials Clearance Programs
- Methods Development & Validation
- In-process & Finished Product Testing
- ICH Stability Programs
- Reference Standards Programs
- Extractables/Leachables
- Elemental Impurities
- Physical-functional Testing
- Microbiology Testing Services
- Commercial Product Support

Facility Services
- Facility Commissioning & Qualification
- Critical Utility Qualification
- Equipment Services
- Laboratory Relocations

Consulting Services
- Regulatory Strategy & Agency Support
- Quality & Compliance Consulting

Capacity: Pace® is committed to providing services to all clients, large or small. Our flexible response to demand provides various service models to include fee-for-services, dedicated resource programs, full-time equivalent (FTE) model on-site at Pace®, and/or FTE programs at the client site, which allow for economical options to meet business demands.

Quality: Our facilities have long histories of successful regulatory agency, client, and third-party audits. High-quality data and information provides the confidence you need to advance your products quickly.

Reliability: Our integrated services ensure critical path demands stay on schedule.

Pace®

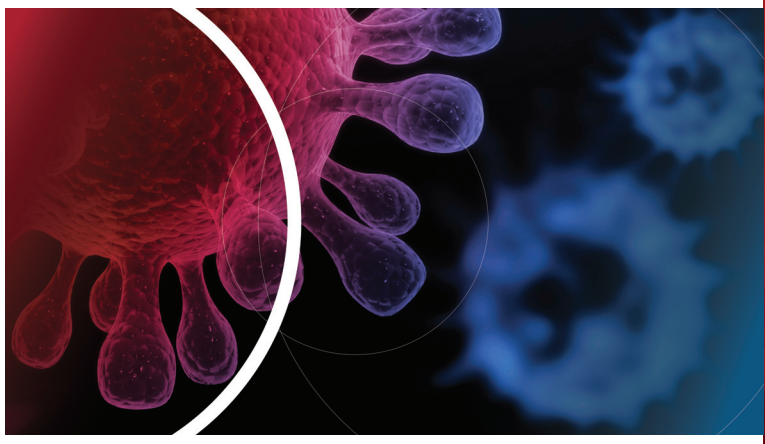
LIFE SCIENCES

PEOPLE ADVANCING SCIENCE™

Our investment in state-of-the-art facilities and highly-trained experts emphasizes our commitment to delivering positive customer experiences across all phases of drug development.

See how Pace® can be the best CRDMO for your project
www.pacelifesciences.com

- REGULATORY STRATEGY & COMPLIANCE CONSULTING
- CMC DEVELOPMENT
- GMP CLINICAL TRIAL MATERIALS
- GMP ANALYTICAL TESTING
- SCIENTIFIC INSOURCING SOLUTIONS
- TECHNICAL FIELD SERVICES



PCI Pharma Services

PCI is your world leading CDMO, truly spanning the cycle, connecting development and commercialization, de-risking the supply chain providing integrated drug development, manufacturing and packaging capabilities that increase product speed to market, and opportunities for commercial success.

PCI brings the proven experience that comes with more than 90 successful product launches each year and over five decades in delivering CDMO services. Leading technology and continued investment enable us to address global outsourcing needs throughout the product lifecycle.

PCI offers a global network of centers of excellence for developing, manufacturing, packaging, and distributing life changing therapies. Our specialist contained manufacturing and packaging facilities dedicated to processing highly potent drug products, combined with our renowned lyophilization and sterile manufacturing capabilities are complemented by a global network of packaging facilities delivering a true end-to-end service. Our aim is simple, to accelerate your product from development to commercialization as efficiently and cost-effectively as possible.

SERVICES & CAPABILITIES

Development & Manufacturing

We provide clinical to commercial scale sterile manufacturing, lyophilization, and world class potent drug processing. We offer full-service formulation development including in-house analytical development services for sterile and non-sterile dosage forms.

Clinical Trial Services

As global clinical supply chain experts we provide speed-to-study solutions with unmatched flexibility. We seamlessly support the global supply of investigational medicines with drug product manufacturing, packaging, labeling, storage, and distribution.

Advanced Drug Delivery & Drug Device Combination Products

PCI offers unparalleled expertise and solutions in sterile fill-finish and final assembly, testing and packaging of prefilled syringes, pens, autoinjectors and on-body devices. Our integrated injectable solutions provide convenient, easy to use patient centric therapies.

Commercial Packaging

PCI provide comprehensive product launch services and packaging solutions for all dosage forms including oral solids, powders, creams and gels, and injectable delivery formats. Our expertise and leading technology supports the unique requirements of each product type and global market supplied.

Key facts:

- More than 50 years' experience in the healthcare services business
- Operating from 30 GMP facilities across North America, Canada, Europe, UK and Asia Pacific
- Over 7,000 employees work to bring life changing therapies to patients
- Delivering over 200 protocols a year in over 100 countries
- Supporting more than 90 commercial product launches each year
- Awarded Bronze Sustainability rating, putting PCI among the top 35% of all companies assessed by EcoVadis

PCI Pharma Services
3001 Red Lion Road
Philadelphia, PA 19114
T: (215) 613-3600
E: talkfuture@pci.com
W: www.pci.com


pci
PHARMA SERVICES
pci.com
Your world leading CDMO.
talkfuture@pci.com
As a respected industry leader and trusted partner, we provide a comprehensive range of pharmaceutical services from the earliest stages of development through to commercial launch and ongoing supply.
Our CDMO services include:
• Development & Manufacturing
• Clinical Trial Services
• Advanced Drug Delivery & Drug Device Combination Products
• Commercial Packaging Technology
Supported by speedsolutions™
Together, delivering life changing therapies | Let's talk future™

PharmaCircle™

The Difference is in the Details

PharmaCircle is a leading provider of authoritative information, global insight, and expert analysis on the pharmaceutical, biotech, drug delivery technology and device, and animal health industries.

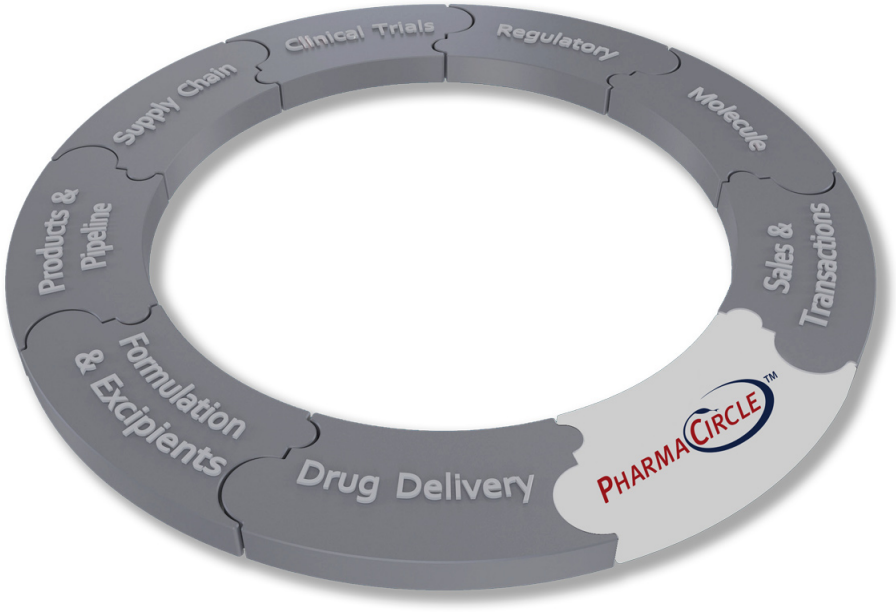
PharmaCircle's premier database tracks drugs, biologics and combination products in all stages of development, connecting pipeline and product information with formulation and component details. The database delivers seamless integration of scientific, clinical, safety, regulatory, manufacturing and commercial information, and detailed analyses on over 9,000 drug delivery technologies and delivery devices.

PharmaCircle provides the broad and deep global coverage, and powerful search and analysis tools needed to answer challenging questions so you can uncover new opportunities and make informed decisions.

Key content and capabilities include:

- Pipeline & Products Intelligence
- Drug Delivery Technology Analyses
- Company Capabilities Profiles
- Business Prospecting Tools
- Trial Landscape Insights
- Formulation & Excipient Details
- Strategic Deals Analyzer
- API & Finished Dosage Form Manufacturers Finder
- Physical Chemical & Pharmacokinetic Data
- Venture Capital Investment Tracking
- Service Provider Comparisons
- Patent Exclusivity Tracking
- Drug Label Comparisons
- Key Product Sales, Forecasts & Pricing
- Epidemiology Data
- Medical Diagnostics Explorer

To learn more about how PharmaCircle can help your company, please visit our website www.pharmacircle.com.



PharmaCircle LLC
323 Sunny Isles Blvd., Suite 700
Sunny Isles Beach, FL 33160 USA
E: contact@pharmacircle.com T: 1-800-439-5130 www.pharmacircle.com

Why PharmaCircle?

Since 2003, PharmaCircle has been providing clients with the integrated data, powerful analysis tools and industry knowledge needed to solve complex, real world challenges in product development and innovation.

PHARMACIRCLE™

www.pharmacircle.com

PORTON J-STAR
6 Cedarbrook Drive
Cranbury, NJ 08512
T: (609) 860-1300
E: (general contact): business@portonusa.com
W: www.portonpharma.com
LinkedIn: www.linkedin.com/company/porton-pharma-solutions-ltd

Vital Statistics

Year Founded: 1996
Number of Employees: 4300
Number of Facilities: 11

Who We Are

With over 4300 customer-centric employees and commercial operations across the US, EU and China, Porton J-STAR provides pharmaceutical and biotech companies with innovative, reliable and end-to-end process R&D and GMP manufacturing services for Drug Substance and Drug Product across Small Molecules, Tides, Biologics and Conjugates. Porton J-STAR is recognized for our process innovation, supply chain performance and compliance with global Quality and EHS standards. Constantly striving for excellence and enabling the public's early access to good medicines.

Major Markets

Porton has steadily added and continues to expand in the areas of Process Chemistry, Analytical R&D, QC/QA, GMP delivery, Crystallization R&D, Solid States Screening, Catalysis Screening, Enabling Technologies, High Potent Compound Handling (HPAPI), Impurity Isolation and Structural Elucidation, Pre-formulation, Formulation R&D, and Oral Solid Drug Product GMP manufacturing.

Porton J-STAR has assembled a team of chemists, scientists, and engineers committed to creatively solving complex and matrixed chemistry problems. The emphasis of this support is focused on chemistry-related problem solving centered on Active Pharmaceutical Ingredients and Intermediates in the pre-clinical and clinical development arena.

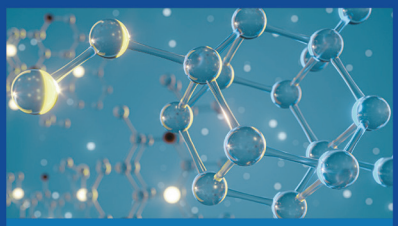
Services Offered

Porton J-STAR provides pharmaceutical companies with innovative, reliable and end-to-end process R&D and GMP manufacturing services for Drug Substance and Drug Product across Small Molecules, Tides, Biologics and Conjugates.

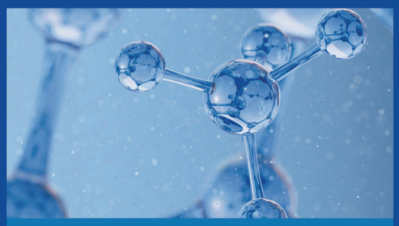
PORTON

J★STAR

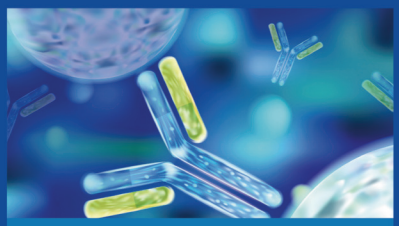
Solving Complex Chemistry Problems with Creative Solutions for Over 25 Years



Small Molecules



Tides



Biologics & Conjugates

API and Drug Product CDMO

OEB 1 to 5 | Sub-g to Metric-ton Scale | Pre-clinical to Commercial

America

Slovenia

China

business@portonpharma.com
www.portonpharma.com

LinkedIn

ProMed Pharma, LLC
15600 Medina Road
Minneapolis, MN 55447
T: (763) 331-3800
F: (763) 331-3888
E: jim.arps@promedpharmallc.com
W: www.promedpharmallc.com

Your CDMO Partner for Complex, Long-Acting Dosage Forms

ProMed Pharma is your distinguished development partner in long-acting injectable and implantable dosage forms. With nearly 20 years of operational history, we have honed our expertise in polymer-based dosage forms, achieving mastery in extended-release dosing. Our proficiency spans molding, extrusion, and microencapsulation techniques, leveraging a diverse spectrum of polymeric excipients encompassing silicones, thermoplastics, and biodegradables. At ProMed Pharma, our commitment to rapid project execution is underpinned by a steadfast dedication to scientific inquiry and technical finesse. Whether you represent an emerging biotech venture or a global pharmaceutical entity, entrust us as your CDMO partner, as we diligently translate scientific concepts into finished dosage forms.

Markets & Applications

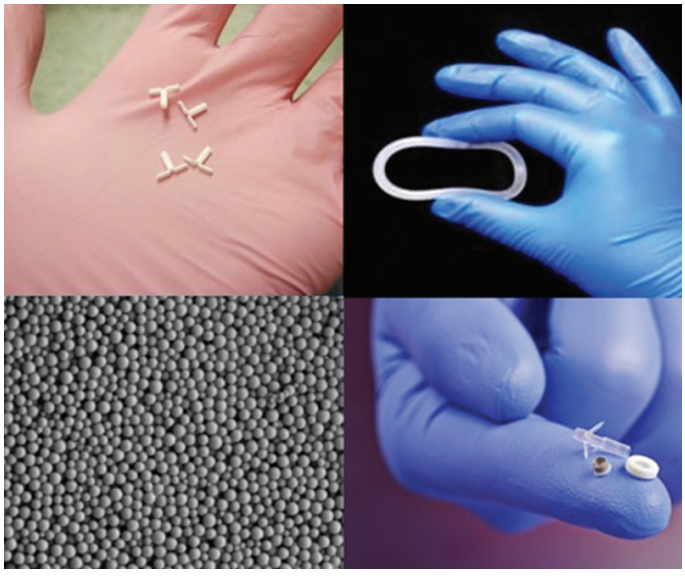
Key markets for our services include women's health, ophthalmology, oncology, and ENT. Representative drug-device applications include steroid-eluting pacing and defibrillation leads, implantable sensors, antimicrobial eluting devices, and sinus stents. ProMed also supports pharmaceutical companies developing extended-release formulations utilizing subcutaneous implants, intratumoral pellets, intrauterine devices, intravaginal rings, and ophthalmic inserts. We have over 10 years of history developing and manufacturing PLGA microspheres.

Drug Product Capabilities & Facilities

- Plastic injection molding and hot melt extrusion – bio-material options such as EVA, TPU, PLGA and other biodegradable polymers
- Silicone molding: transfer, liquid injection, insert and compression molding
- Formulation of drug-loaded PLGA microspheres (typically 2-50 micron with excellent size control)
- Experience with steroids, hormones, antibiotics, microbicides, and prostaglandins
- Small molecules, peptides, macromolecules (mAbs, siRNA)
- Micro molding and extrusion of parts as small as 0.1mg, minimum shot size of 100mg
- Design assistance, tooling, molding and assembly, final packaging, and sterilization
- Class 10,000 clean rooms, Class 5 isolators
- More than 10,000 square feet of available manufacturing space for new pharma operations

Quality Control & Quality Assurance

ProMed utilizes both in-house testing and partnerships with state-of-the-art analytical facilities to ensure that drug content, drug elution, purity, mechanical strength, and dimensional specifications are consistently met. The Quality System is compliant to 21 CFR 210/211 and 820 and is ISO13485 certified. ProMed Pharma is registered with the FDA with over 15 years of inspection history.



ProMed
Pharma

Your CDMO Partner for Complex, Long-Acting Dosage Forms

Contract R&D, clinical trial supply, commercial manufacturing, assembly and packaging under cGMP

Molding and extrusion of silicone, EVA, PU, and PLGAs with a variety of APIs including highly potent APIs

Formulation of drug-loaded microspheres

Applications including long-acting implants, women's health, ophthalmology, and drug eluting devices

FDA registered, ISO 13485 certified

Start with us. Stay with us.

763.331.3800 | info@promedpharmallc.com | promedpharmallc.com

15600 Medina Rd | Plymouth, MN 55447

PROVERIS SCIENTIFIC CORPORATION
2 Cabot Road - Hudson, MA 01749
T: (508) 460-8822 E: contactus@proveris.com
W: www.proveris.com

Testing True Product Performance

Leader in spray and aerosol product testing and contract services

Proveris® Scientific's focus is helping its customers unlock the complex relationships between formulation, device, and human usage — knowledge that's essential for timely and effective OINDP development and commercialization. Our industry standard instruments offer rapid insight into critical spray and aerosol parameters, and our team of scientists provide expert consultation and contract test services, taking into account key regulatory and operational nuances of orally inhaled and nasal drug products. As key partners to our clients we help to:

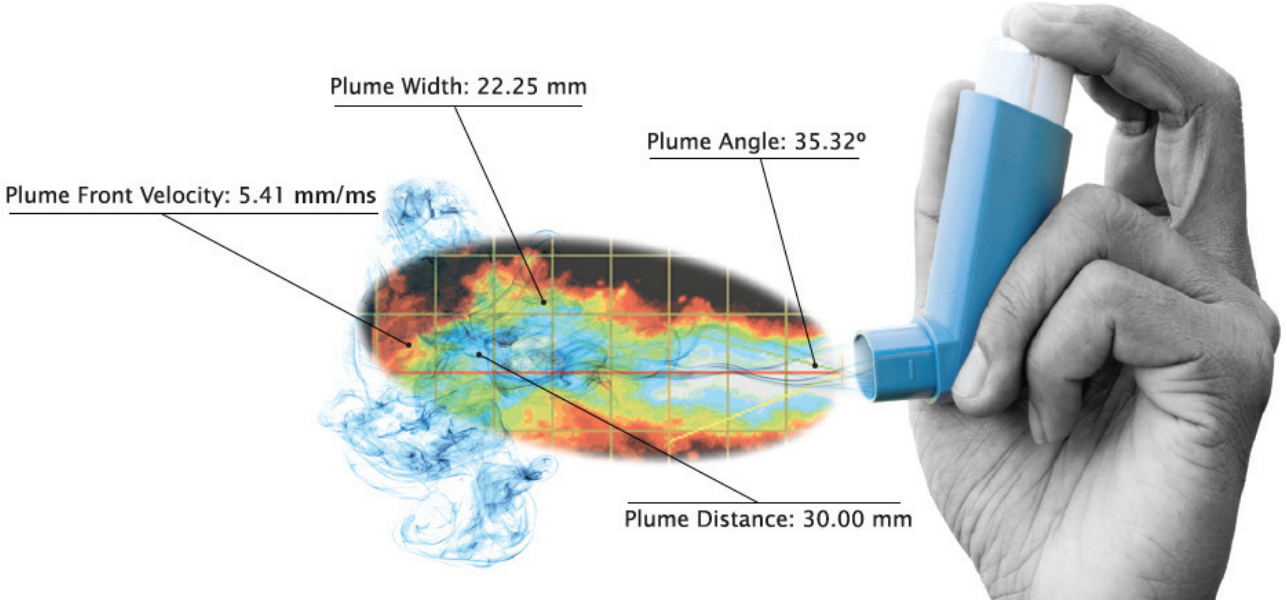
- accelerate successful product development and prevent late-stage development failures
- realize significant savings in time and resources by streamlining testing workflows
- evaluate the suitability of various OINDP delivery devices and optimize device parameters for maximum efficacy
- optimize testing variables to maintain batch-to-batch reproducibility, simplifying regulatory submissions

Proveris Instrumentation

Proveris Scientific manufactures a range of analytical instruments for spray and aerosol characterization, precision automated actuation for through-life testing, automated nasal spray collection systems for spraying, weighing and sample collection, automated shaking and actuation for wasting of pMDIs, as well as powerful software to preserve audit trail and manage your data efficiently.

Proveris Laboratory Services

Proveris Laboratories test service offerings include custom studies for method development, formulation and device screening, performance optimization, human usage studies, device robustness, stability testing, and rapid human-realistic testing for regional deposition and delivered dose of oral and nasal drug products.



REVOLUTIONIZING NASAL THROUGH-LIFE TESTING WITH AUTOMATION

Seconds to Weight: Vereo® SWC

Spray, Weigh, Collect

A benchtop nasal spray testing system providing automated actuation, sample collection, and weighing for dose uniformity testing.

Faster Batch Release

Increasing throughput by 2.5X means QC sign-off is never the bottleneck.

Operational Flexibility

FDA/EMA/JP/Anvisa/NMPA and USP 601a compliant. Ideal for all through-life testing workflows.

Reduce Risk of Non-compliance

Workflow automation eliminates manual errors and reduces OOS results.

Repeatability and Consistency

Industry standard Vereo NSx+ Actuator technology enables standardized methods for quick and efficient data transfers.

Data Integrity

Trusted traceability with Viota® software ensures compliance.

Environmental Containment

Small, enclosed benchtop design frees lab and fume hood space.

Increase Productivity

Increase lab efficiency by reducing analyst's workload.

All in-one-integration ideal for through-life testing and walkaway automated functionality

- Industry standard Vereo NSx Actuator technology
- Configured to collect up to 10 samples per nasal spray for through-life testing in a single run
- Reusable fire-down waste collector for priming and fire-down
- Integrated weighing module
- Dose collection into glass volumetric flasks
- Compatible with Multi-Dose, Bi-Dose and Unit-Dose Nasal Devices

proveris SCIENTIFIC®

LEARN MORE: www.proveris.com | contactus@proveris.com | +1 508 460-8822

KEEPING YOU CONNECTED TO YOUR TARGET AUDIENCE.

For more than 20 years, Drug Development & Delivery has successfully connected technology and service providers with R&D scientists, business development professionals and corporate managers working at pharmaceutical and biotechnology companies.

Marketing your technologies, services and products with Drug Development & Delivery keeps you engaged with your key audience.

Call us today or visit us at drug-dev.com and let us show you how.

- Print & Digital Editions
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- Email Campaigns
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- Exclusive Whitepaper & Webinar Marketing
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John Kiesewetter: 541-338-0022
jkiesewetter@drug-dev.com

Amy Nicklaus: 862-274-5872
anicklaus@drug-dev.com

Ralph Vitaro: 973-263-5476
rvitaro@drug-dev.com

drug-dev.com

Purisys is a proven leader in custom API synthesis and manufacturing. We bring more than 40 years of experience in commercial pharmaceutical production – everything you need to scale up quickly and smoothly, without delays.

Our extensive experience can help you reach your goals. We have experience working with emerging biotech companies looking for a skilled outsourcing partner to take your compounds to trial and with large pharma companies that want to outsource parts of their supply chain to increase efficiency and speed to market.

When you work with Purisys, you collaborate with a team that understands the specialized environment of the drug development process. We provide a CDMO offering that links route selection, process development services, analytical support, and manufacturing into one integrated process. We offer the people, the processes and the critical infrastructure to rapidly advance your projects.

Responsiveness is critical to our offering. We understand the tremendous timeline and financial constraints under which you operate. Our personnel bring decades of experience in the multiple disciplines required for rapid, successful drug development, having worked on bringing drugs to market themselves.

Manufacturing Excellence. Full-Service Support

Our flagship, 17,000-square-foot innovation center and manufacturing facility in Athens, GA, provides complex, high-barrier custom synthetic chemistry and manufacture of pharmaceutical APIs, as well as comprehensive controlled substance expertise featuring Drug Enforcement Administration (DEA)-secure manufacturing.

Development activities at Athens include process development and optimization, analytical method development, optimization and validation along with product design and development, formulation development and testing.

The facility also offers reference standard synthesis and qualification, small-scale Current Good Manufacturing Process (cGMP) clinical and commercial manufacturing, non-sterile, parenteral processing and milling, and custom packing. Purisys offers a fully operational global supply chain and exports to more than 40 countries – with full international regulatory compliance.

Via our parent company and external partners, our supply chain network has manufacturing capacity for clients in need of more than 180-360 MT of Active Pharmaceutical Ingredients (APIs). In addition, we hold our own commercial drug master files (DMFs) for several specialized compounds, and we maintain a 300+ compound commercial reference standard library, including APIs, synthetic impurities, degradation products, metabolites and more.

At Purisys, we offer proven technical and regulatory expertise to scientists and drug developers seeking to develop custom APIs for clinical and niche commercial purposes.

PURISYS
1550 Olympic Drive Athens, GA 30601
T: (706) 286-8263
W: Purisys.com

Quotient Sciences

Molecule to cure. Fast.™

Integrated drug development programs so molecules can become cures, fast.

Quotient Sciences is a drug development and manufacturing accelerator providing integrated programs and tailored services across the entire development pathway. Cutting through silos across a range of drug development capabilities, we save precious time and money in getting drugs to patients.

We bring together integrated contract research, development, manufacturing and clinical testing services for small molecules and synthetic peptide drug programs. We're a trusted partner to support:

- **Candidate development** – selecting the right molecules for development, offering expertise that shortens timelines to the clinic
- **Early development** – accelerating molecules from first-in-human (FIH) through to proof of concept (POC)
- **Late development** – scaling up molecules for registration/validation and commercial launch, at no expense to speed or quality

Quotient Sciences Translational Pharmaceutics®: Our flagship platform for drug development

For over 15 years and over 1,000 molecules, our Translational Pharmaceutics® platform for drug development has helped global pharma and biotechs accelerate molecules to market. Our flagship platform for drug development is Translational Pharmaceutics®. This platform integrates capabilities for on-demand cGMP drug product development and manufacturing with clinical testing, all within a single organization and program of work. Trusted for over 16 years and with more than 500 programs completed, Translational Pharmaceutics® provides flexible CMC and clinical strategies, enables better decision making based on emerging human clinical data, streamlines vendor management, and ultimately, accelerates drug development timelines by up to 12 months or more.

Our expertise in understanding dependencies between drug substance properties, formulation design, and clinical outcomes enables us to enhance development efficiency. Having both drug substance and drug product manufacturing activities under one organization allows us to deliver integrated chemistry, manufacturing, and controls (CMC) development activities for both pre-clinical and clinical studies in parallel, simplifying the supply chain and improving the likelihood of downstream clinical and commercial success.

Tailored Services

- **Drug substance synthesis and manufacturing** – we customize each program to help minimize chemistry costs and move your drug substance supply off the critical path
- **Formulation development** – leverage our expertise in complex formulation development in areas including modified release, solubility enhancement, and pediatrics
- **Clinical trial manufacturing** – a streamlined approach to drug product supply that reflects your clinical study design and timeline
- **Clinical pharmacology** – rapid study startup and recruitment through our clinical units in Miami, FL, US and Nottingham, UK
- **Data sciences** – providing fast access to reliable data to improve decision making during a study
- **Commercial manufacturing** – trusted, global services for reliable commercial supply, including support for high-potency compounds
- **Bioanalysis** – world-class expertise, delivering rapid bioanalytical data to support drug development milestones
- **Drug development consulting** – expertise at all stages of development, from candidate development through commercial launch
- **Modeling & Simulation** – PBPK modeling, FIH predictions, quality-by-design assessments, *in-vitro/in-vivo* correlations, bioequivalence assessments

QUOTIENT SCIENCES - US HEADQUARTERS - PHILADELPHIA, PA
3080 McCann Farm Drive - Garnet Valley, PA 19060
T: 1 800 769 3518 - W: quotientsciences.com
Linkedin: https://www.linkedin.com/company/quotient-sciences
Twitter: https://twitter.com/Quotient_Sci
Facebook: https://www.facebook.com/quotientsciences
Instagram: https://www.instagram.com/quotient_sci
Youtube: https://www.youtube.com/@quotientsciences

QUOTIENT SCIENCES
UK HEADQUARTERS – NOTTINGHAM, UK
Mere Way - Ruddington, Nottingham
NG11 6JS
T: +44 115 974 9000

Quotient Sciences

Molecule to cure. Fast.™

Accelerate Timelines. Reduce Costs. Minimize Risks.

Quotient Sciences is a drug development and manufacturing accelerator that is cutting through silos across the entire development pathway. With a full offering of tailored services and integrated programs for small molecule and peptide drug programs, our goal is to help you reduce costs and risks to get new medicines to patients, fast.

Integrated Programs

Candidate Development
Selecting the right molecules for development

Early Development
Accelerating molecules through to proof-of-concept

Late Development
Accelerating products through to commercial manufacture

Tailored Services

- Drug Substance
- Formulation Development
- Clinical Trial Manufacturing
- Commercial Manufacturing
- Clinical Pharmacology
- Bioanalytical Services
- Data Sciences
- Drug Development Consulting

→ quotientsciences.com/accelerate-timelines

RESILIENCE

RESILIENCE
3115 MERRYFIELD ROW, SUITE 200
SAN DIEGO, CA 92121
T: (888) 737-2460
E: CONTACT@RESILIENCE.COM
LINKEDIN: HTTPS://WWW.LINKEDIN.COM/COMPANY/WEARERESILIENCE
TWITTER: HTTPS://TWITTER.COM/INCRESILIENCE
W: HTTPS://RESILIENCE.COM

COMPANY DESCRIPTION

Resilience is a technology-focused biomanufacturing CDMO dedicated to broadening access to complex medicines (biologics, vaccines, nucleic acid, cell and gene therapy), from process development to drug substance and drug product manufacturing. Founded in 2020, the company is building a sustainable network of high-tech, end-to-end manufacturing solutions to ensure the treatments of today and tomorrow can be made quickly, safely, and at scale. By continuously advancing the science of biopharmaceutical manufacturing and development, Resilience seeks to free its partners to focus on the discoveries that improve patients' lives and protect biopharmaceutical supply chains against future disruptions.

COMPANY BACKGROUND

Resilience is leading the pursuit of novel medicines and large molecule drugs by remaking how they are developed and manufactured. The technology of manufacturing complex medicines hasn't kept pace with the wave of scientific discoveries fueling them.

Resilience has responded to two major problems — serving as a biomanufacturing powerhouse for process and analytical development, drug substance, and drug product across established (Biologics, Vaccines) to emerging (Cell and Gene Therapy) modalities, as well as focusing on the development of next-generation manufacturing technology platforms to keep up with essential product developments and increase access to complex medicines.

MARKETS/FACILITIES

Resilience serves global customers through its sites located in six states across the United States, as well as in Canada.

PRODUCTS/CAPABILITIES

With a current portfolio of 50+ clients across its network, ranging from large pharma to small and mid-size pharmaceutical and biotechnology companies, as well as government and NGOs, Resilience works across all stages of five primary modalities: Biologics, Vaccines, Nucleic Acids, Cell Therapy and Gene Therapy. Resilience offers several ways to engage, including incubation, collaboration, and manufacturing to support the development of 60+ molecules across its portfolio. The company's offerings include Platform Technology & Development, Process & Analytical Development, and Clinical & Commercial Manufacturing, geared toward increasing access to medicines around the world and democratizing manufacturing.

RESILIENCE

BALANCING CAPACITY AND COMPASSION

We hold a unique industry sweet spot: we're big enough to partner on your boldest projects, but small enough to provide the kind of service and agility that you wouldn't typically expect from a conventional CDMO.

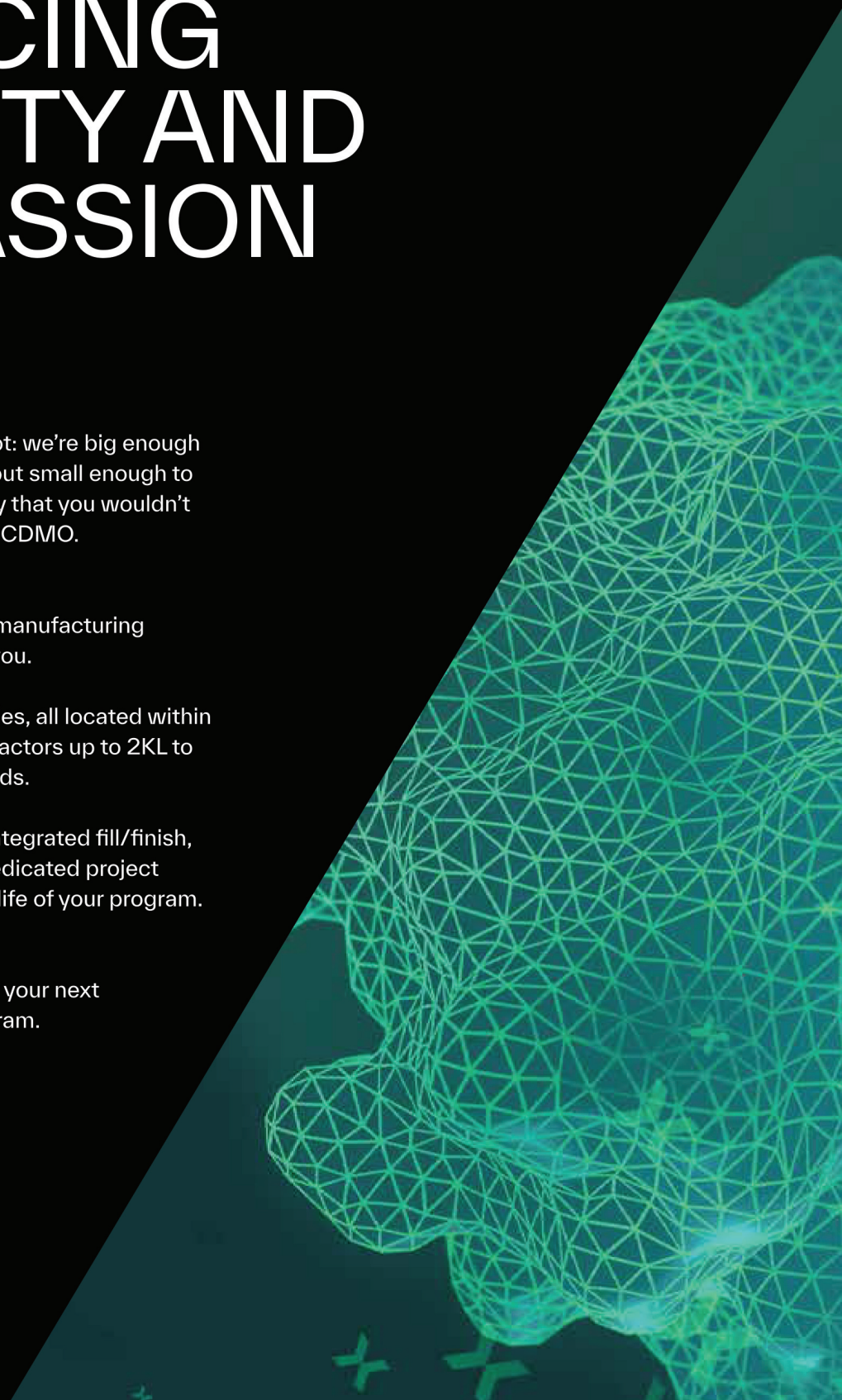
We build drug substance manufacturing programs that grow with you.

Our drug substance facilities, all located within North America, offer bioreactors up to 2KL to support your scale-up needs.

End-to-end capabilities, integrated fill/finish, regulatory support, and dedicated project management support the life of your program.

Discover if we're the right partner for your next development or manufacturing program.

Resilience.com



SERÁN BIOSCIENCE, LLC
63047 Layton Ave.
Bend, OR 97701
T: (541) 797-2148
E: Hello@seranbio.com
W: seranbio.com
LinkedIn: https://www.linkedin.com/company/seran-bioscience/

Serán BioScience, LLC is a science-based CDMO that specializes in a variety of drug delivery and formulation approaches suited to optimizing bioavailability. Serán's experienced formulation team will work with clients to identify an appropriate technology and formulation strategy to meet your program's unique needs. Our comprehensive approach to formulation design considers the physiochemical properties of the API, the target product profile, and your program's objectives and constraints to develop scalable formulations using efficient and material-sparing approaches.

Serán provides tablets (from minitablets to large format caplets), capsules (enteric or IR), multi-particulates (coated beads), and powder-in-bottle formulations. Our solid dosage forms are engineered for a wide range of formulation approaches such as overcoming solubility challenges and to enable extended-release.

OUR SERVICES

Preformulation & FIH Formulation Design

From discovery to commercial, our formulation design team has you covered. With the evolution of enabling technologies, low solubility no longer limits the advancement of molecules from discovery to clinical candidacy.

Formulation Development

For early discovery and toxicology studies, we utilize a variety of suspension and solution approaches to obtain desired *in vivo* exposure, especially at high doses. As you advance to the clinic, our solid dosage form approaches are designed to achieve your preferred performance and are engineered for scalability.

cGMP Manufacturing

Serán provides clinical manufacturing capabilities for a broad range of oral solid dosage forms including unit operations in particle size reduction, spray-dried dispersions, dry granulations, tablet compression, tablet coating, encapsulation, and clinical packaging and labeling.

Spray Drying & Particle Engineering

Serán has extensive spray drying capabilities. Our team has decades of experience developing spray drying processes, related formulations, and analytical methods and techniques. We have leveraged our core knowledge of particle engineering and formulation requirements to design and build optimum spray drying systems for pharmaceutical applications.

Solid Dosage Forms

Serán specializes in developing versatile solid dosage forms including tablets, capsules, and powder-in-bottle formulations, and a wide variety of other engineered solutions tailored for optimal *in vivo* exposure and scalability from discovery to clinical trials.

Analytical & Quality Control

At Serán, our culture of high quality science drives us to provide top-tier analytical services that meet the rigorous demands of our clients' projects. Our team, led by respected industry veterans, operates under a unified approach that de-risks each project from the outset. Our comprehensive suite of analytical services includes method transfer, development, qualification, and a cutting-edge QC lab designed to support cGMP release testing and stability assessment and storage.

Our deep scientific oral development expertise – integrated with rapid scale-up and manufacturing experience will accelerate your journey from clinical to commercial launch.

Serán's drug development approach begins with a thorough review of the drug's molecular properties and your development goals.
This helps us identify the best strategies to significantly reduce time to clinical trials and market launch.

- Delivery of soluble and insoluble compounds
- Tablets, capsules and powdered forms, orals solutions
- Spray drying, HME, milling, blends, granulation, coatings

Connect and Learn More

hello@seranbio.com 1+(541)797-2148 www.seranbio.com Bend, Oregon

Simtra BioPharma Solutions

Simtra BioPharma Solutions*
W: simtrabps.com

As a premier, independently owned CDMO with over 65 years of sterile injectable manufacturing experience, Simtra BioPharma Solutions (Simtra) offers world-class cGMP sterile fill/finish, technical expertise, quality service, and a uniquely collaborative approach. Pharmaceutical and biotech companies partner with Simtra when they face formulation challenges, clinical supply hurdles, surges in demand due to market fluctuations, or risk mitigation concerns.

With manufacturing sites located in Bloomington Indiana USA and Halle/Westfalen, Germany, Simtra BioPharma Solutions manufactures products which are distributed to over 120 countries across the globe. Simtra can help meet your sterile injectable drug product needs with a broad portfolio of sterile form/fill/finish production capabilities and other support services. Our delivery systems include prefilled syringes, liquid/lyophilized vials and diluents for reconstitution. Simtra can accommodate a variety of manufacturing requirements for an extensive selection of product types including biologics, cytotoxics, highly potent compounds, antibody drug conjugates (ADCs) small molecules, vaccines and diluents for reconstitution. From formulation and development, through commercial launch, our customized support services can help support your commercialization objectives.

*Simtra is a tradename of Baxter Oncology GmbH & Baxter Pharmaceuticals LLC

SIMTRA BIOPHARMA SOLUTIONS*
BAXTER ONCOLOGY GMBH · KANTSTRASSE 2
33790 HALLE/WESTFALEN · DEUTSCHLAND
BAXTER PHARMACEUTICAL LLC · 927 S CURRY PIKE
BLOOMINGTON · IN 47403 · USA
W: SIMTRABPS.COM

Where your product & our expertise **go further.**

At Simtra BioPharma Solutions, we're made for this. With 65+ years of sterile injectable manufacturing experience, we bring precision and transparency to every step of the production process, from product development through commercial fill and finish.
As a premier independent CDMO, we partner with pharmaceutical and biotech companies to help them realize their commercialization objectives for sterile injectables.

Whether you are looking to launch your innovation globally, improve your formulation, or proactively mitigate risk, Simtra can help you deliver on your commitments to patients.

Simtra
BioPharma Solutions

Made for this

Learn more: **simtra.com**

Stevanato Group

Founded in 1949, Stevanato Group is a leading global provider of drug containment, drug delivery, and diagnostic solutions to the pharmaceutical, biotechnology, and life sciences industries. Stevanato Group delivers an integrated, end-to-end portfolio of products, processes, and services that address customer needs across the entire drug life cycle at each of the development, clinical, and commercial stages. Stevanato Group's core capabilities in scientific research and development, its commitment to technical innovation, and its engineering excellence are central to its ability to offer value added solutions to clients.

Global Presence, Local Capabilities

Stevanato Group counts more than 5,600 people in 19 sites in 10 countries and generated around 1.1 billion euros of revenues in 2023. The global growth enabled Stevanato Group to serve customers with consistent and high-quality products and services close to their operations.

Advanced Drug Containment Solutions & Analytical Services

Stevanato Group boasts unique expertise in providing advanced pharmaceutical containers from glass tubing. Its comprehensive portfolio covers every customer need, from those related to small molecules to highly sensitive drugs. Stevanato Group produces vials, syringes, and cartridges for different applications, such as vaccines, RNA-based drugs, GLP-1 and peptides, and monoclonal antibodies (mAbs). Glass containers are available both in bulk and in EZ-fill®, the market-recognized ready-to-use configuration. Stevanato Group can also provide container closure and device characterization analytical services through its Technology Excellence Centers.

Offering Integrated Capabilities for Your Drug Delivery Devices Programs

Over the past few years, Stevanato Group has broadened its offering to include contract manufacturing of devices and proprietary drug delivery devices, including:

- Alina® a user-friendly, disposable pen injector platform for variable and multi-dose treatments.
- Aidaptus®, 2-step, single-use auto-injector accommodating both 1mL and 2.25 mL pre-filled glass syringes.
- Vertiva®, a pre-filled and pre-loaded on-body delivery system platform suitable for a wide range of therapies.

Vision Inspection, Assembly & Packaging Technologies: A Modular & Flexible Approach

Stevanato Group capabilities range from modular assembly platforms and packaging lines to advanced vision inspection machines, including manual, semi-automatic, and automatic. Stevanato Group equipment can inspect a wide range of liquid, emulsions, viscous, gel-like, powder, and lyophilized drugs, catering to the needs of both small firms or big pharma companies producing blockbuster drugs.

STEVANATO GROUP
Via Molinella, 17 35017 Piombino Dese, Padua, ITALY
W: www.stevanatogroup.com

DISCOVER OUR **INTEGRATED SOLUTIONS**

Analytical Services

Drug Containment Solutions

ADDRESSING **THE FULL VALUE CHAIN**

Inspection & Assembly Equipment

Drug Delivery Systems

- Reduced Time to Market
- Reduced Supply Chain Risk
- Reduced TCO
- Consistent Quality

Stevanato Group

MANAGING COMPLEXITY, DELIVERING VALUE

stevanatogroup.com

TERUMO

MEDICAL CARE SOLUTIONS

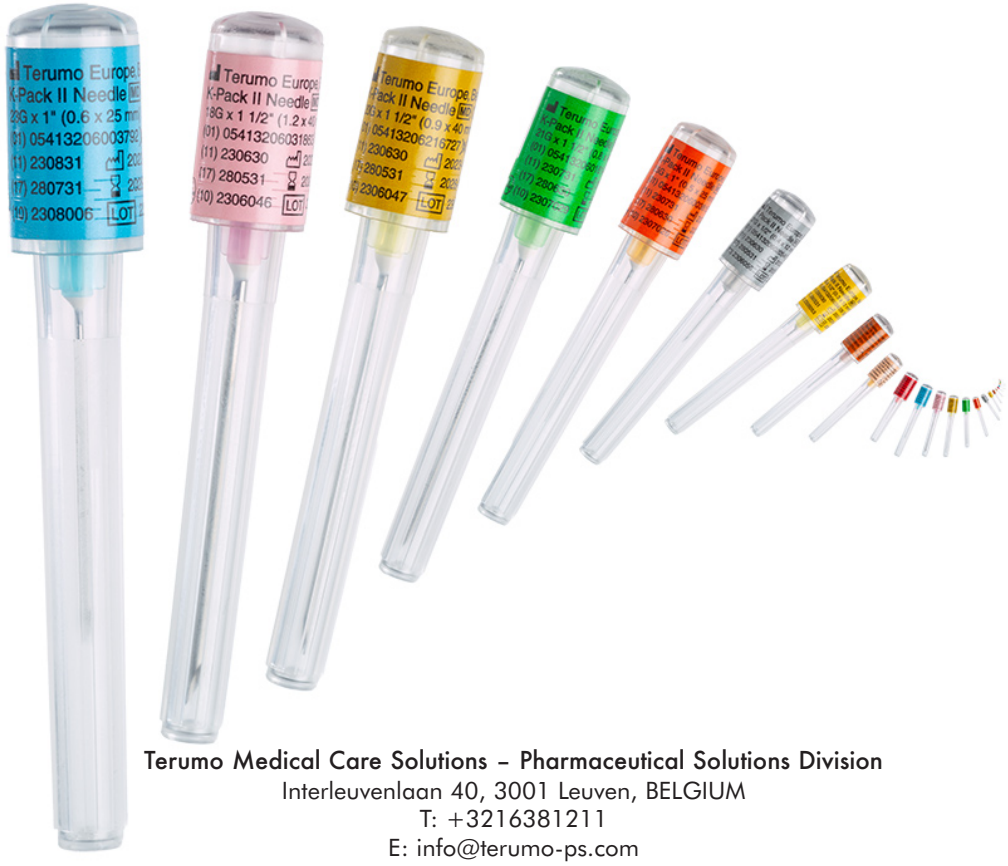
As Part of Terumo Medical Care Solutions, the Pharmaceutical Solutions Division develops patient-oriented arenteral delivery solutions for therapeutic performance and safety.

Globally trusted for quality and precision, we offer pharmaceutical and medical device manufacturers around the world comprehensive product design and development services.

We have decades of experience collaborating with pharmaceutical companies from the earliest phases of drug development to product commercialization to optimize critical aspects of parenteral drug delivery.

Innovation and creativity are central to our value proposition. Our expert teams lead the industry in developing and manufacturing advanced, high-performing infusion and injection technologies, including CDMO services for all parenteral applications.

We listen. We question. We deliver.



Terumo Medical Care Solutions – Pharmaceutical Solutions Division
Interleuvenlaan 40, 3001 Leuven, BELGIUM
T: +3216381211
E: info@terumo-ps.com
W: www.terumopharmaceuticalsolutions.com
Social Media: https://www.linkedin.com/company/92739322

Quality time for better care

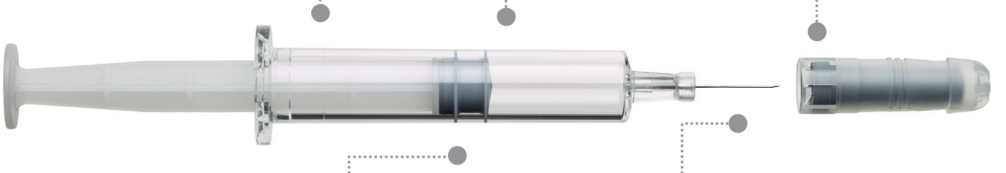
TERUMO
MEDICAL CARE SOLUTIONS

PHARMACEUTICAL

PLAJEX™ Ready-to-Fill Polymer Syringe for Biotech Formulations

Precisely engineered for today's challenging biotech formulations

- Durable COP syringe*
- Ready-to-fill format
- Tight dimensional tolerance*
- Rigid needle shield



- Device compatibility
- Silicone oil-free solution*
- Tapered needle
- Meets compendial requirements and ISO*

A simple formula for biotech success

PM-08754

Your trusted CDMO and CRO partner in drug development

Thermo Fisher Scientific

Thermo Fisher Scientific is the world leader in serving science, empowering customers to make the world healthier, cleaner, and safer. We accelerate life sciences research, solve analytical challenges, enhance lab productivity, improve patient health, and develop life-changing therapies. Our global team delivers innovative technologies and pharmaceutical services through trusted brands, including Thermo Scientific, Applied Biosystems, Invitrogen, Fisher Scientific, Unity Lab Services, Patheon, and PPD.

Our pharma services

Thermo Fisher Scientific serves the pharmaceutical, biotechnology, and life sciences industries as a strategic contract development and manufacturing organization (CDMO) and clinical services partner. Our end-to-end, integrated capabilities support every stage of drug development – from research and development and regulatory support to supply chain management and commercial manufacturing. Backed by an unmatched global network, we provide trusted solutions to help bring your treatments to market faster.

Accelerate small molecule drug development with Thermo Fisher Scientific

Oral solid dose (OSD) forms are the gold standard for efficient drug delivery, offering ease of administration, cost-effectiveness, and exceptional shelf stability.

We leverage innovative solutions, technological expertise, and a global network to streamline OSD development and manufacturing – saving time, money, and API.

The depth and breadth of expertise and experience to bring your vision to life

Early-phase offerings:
- Pre-formulation characterization: Analyze molecule properties
- Formulation development: Tailored to every clinical phase
- Bioavailability and solubility enhancement: Improve efficacy
- Digital modeling: Optimize outcomes with AI, reduce your risk
- Analytical and process development: Ensure quality and scalability

Late-phase capabilities:
- Packaging and labeling: Compliant for global distribution
- Total transportation support: Reliable, end-to-end logistics
- Scale-up and tech transfer: Transition to commercial production
- Regulatory support: Navigate requirements for market access
- Solid form development: Stable, patient-friendly formulations

Commercial services:
- Clinical manufacturing of investigational new drugs (INDs)
- Flexibility to support small- and large-scale manufacturing
- Qualified Person (QP) release: Always meet GMP requirements

A global network like no other

With nine state-of-the-art facilities across North America and Europe, we offer a global network of experts specializing in OSD development and manufacturing, including for high-potency APIs.

Together, let's bring your vision to life

THERMO FISHER SCIENTIFIC
168 Third Avenue Waltham, MA USA 02451
T: (781) 622-1000
E: pharmaservices@thermofisher.com

Thermo Fisher SCIENTIFIC

Oral solid dose solutions

Innovate and accelerate with Thermo Fisher Scientific

Small molecule drugs currently account for over 90% of approved medicines on the market, forming the foundation of the pharmaceutical industry.

At Thermo Fisher Scientific, we offer integrated, end-to-end CDMO and CRO services for oral solid dose (OSD) forms—the gold standard in drug delivery.

From early-phase drug formulation to late-phase process optimization, we help you save time, money, and active pharmaceutical ingredients (APIs).

And with nine state-of-the-art facilities worldwide, we provide global expertise in OSD development and manufacturing, including for high-potency APIs.

Let's turn your vision into reality.

Contact us to get started today **thermofisher.com/patheon**
or email us at **pharmaservices@thermofisher.com**
or call **+1 781-622-1000**




We place heightened focus on your success as your strategic partner.
Vetter produces aseptically prefilled syringes, cartridges, vials and dual-chamber systems as a globally operating CDMO partner. We are a reliable, family-owned, independent company rooted in 70+ years of history. We do not manufacture our own drugs. We support our customers from the initial phases of clinical drug product development and filling to commercial manufacturing, device assembly and packaging, and lifecycle management. Over 80% of our active projects are biologics.

We are reliable, responsive, and progressive partners for all stages of growth.
Our portfolio of services includes dedicated resources for drug product development, aseptic filling and visual inspection, device assembly and packaging, recently expanded analytical services, regulatory support and logistic services. We provide tailored solutions to meet your product's specific market needs.

Fast Facts: Vetter-at-a-glance

- Headquartered in Ravensburg, Germany
- Dedicated clinical production facilities in Rankweil, Austria, and Chicago, USA
- Commercial production sites in Ravensburg and Langenargen, Germany
- Branch offices for Asia Pacific in Singapore, Japan, South Korea, and China
- More than 6,600 employees worldwide
- Global specialist in the aseptic production of prefilled drug delivery systems
- International expertise with regulatory authorities including FDA, EMA, PMDA (Japan), and RP (Germany)
- Service offerings for pharma and biotech firms of all sizes and locations
- Numerous patents including technologies for protection against tampering and counterfeiting
- Lyophilization (freeze-drying) and siliconization specialist
- CO_2 neutral at all corporate sites since 2021

VETTER PHARMA INTERNATIONAL GMBH
Eywiesenstr. 5
88212 Ravensburg, Germany
T: +49-(0)751-3700-0
F: +49-(0)751-3700-4000
E: info@vetter-pharma.com (EU/APAC)
W: www.vetter-pharma.com

VETTER PHARMA INTERNATIONAL USA INC.
10 W. Algonquin Road
Des Plaines, IL 60016
T: (847) 581-6888
F: (847) 581-6880
E: infoUS@vetter-pharma.com (US)
LinkedIn: https://www.linkedin.com/company/vetter-pharma/
YouTube: https://www.youtube.com/channel/UCANcZrENXdzIusvN9Rapgqw

Unlock the full potential of your injectable product

Meet our experts @Pharmapack, Paris January 22–23, 2025

CDMO LEADERSHIP AWARDS 2024

BEST MANAGED COMPANIES GERMANY

GOLD | Top 5% ecovadis Sustainability Rating OCT 2024

Partner with a leading and independent global CDMO for aseptic fill & finish

For 40+ years, pharma and biotech companies around the world have relied on Vetter, a family-owned fill finish partner, to put their parenteral medications on a path to success. We're proud to help advance your innovative therapy with flexible, robust, scalable processes and services that set our partnership apart:

- Specialized support for your unique clinical development program
- High-quality aseptic filling at both clinical and global commercial scale
- Strategic packaging and device assembly solutions that span your product's life cycle
- Comprehensive technical, analytical, and regulatory expertise at every step

Rely on us.

vetter-pharma.com

VETTER

KEEPING YOU CONNECTED TO YOUR TARGET AUDIENCE.

For more than 20 years, Drug Development & Delivery has successfully connected technology and service providers with R&D scientists, business development professionals and corporate managers working at pharmaceutical and biotechnology companies.

Marketing your technologies, services and products with Drug Development & Delivery keeps you engaged with your key audience.

Call us today or visit us at drug-dev.com and let us show you how.

- Print & Digital Editions
- Website Marketing
- Email Campaigns
- Videos
- Exclusive Whitepaper & Webinar Marketing
- Online Company Profile
- eBooks
- eNewsletters

John Kiesewetter: 541-338-0022
jkiesewetter@drug-dev.com

Amy Nicklaus: 862-274-5872
anicklaus@drug-dev.com

Ralph Vitaro: 973-263-5476
rvitaro@drug-dev.com

drug-dev.com

Woodstock STERILE SOLUTIONS

Woodstock Sterile Solutions is a global provider of best-in-class sterile development and manufacturing solutions – with a decades-long track record of helping healthcare companies advance molecules through clinical development into full-scale commercial production.

Throughout our 50-year history, Woodstock has been a leader in developing and deploying advanced aseptic blow-fill-seal delivery products.

We recently completed the expansion of our QC analytical laboratory, doubling the size of our previous space, and building on to our analytical expertise. We have enhanced our formulation and method development capabilities to offer fully integrated drug development and manufacturing services. We have continued to expand our blow-fill-seal capabilities. Working extensively with customers in the respiratory and ophthalmic markets for years, our BFS packaging offers viable solutions for healthcare companies in the diagnostics market as it helps to minimize the risk of human contamination, allows for precise filling and can be easily customized to meet specific needs for diagnostics customers.

Today, Woodstock Sterile Solutions is a reliable partner in the development of complex, high-quality sterile products from ophthalmic and respiratory therapeutics to diagnostics and complex orals. Our experience with formulation and the development cycle is a core strength. Woodstock Sterile Solutions is at its best with complex solutions, suspensions, and emulsions, as well as biologics, sterile products, potent compounds, and sensitive APIs.

With us, your first delivery system can be your final delivery system

With decades of experience managing complex formulations, we have a track record of API stewardship, formulation optimization, effective clinical program support and seamless scale-up to commercial production – within stringent quality and regulatory environments. At each stage of the development process, we are committed to achieving the right quality-efficiently and with commercialization in mind.

Formulation

Our customers often come to us with just a molecule and an early formulation concept. Our experience with liquid formulations allows us to address challenges and make a robust, scalable product for clinicals that translates well for commercial manufacturing.

Clinical Supply

Woodstock is unique in the aseptic blow-fill-seal space in our ability to efficiently provide small-run prototypes using limited supplies of API material and then having the capabilities to seamlessly scale that to commercial production.

Manufacturing at Global Scale

Our manufacturing facility is one of the most comprehensive production environments supporting sterile and non-sterile liquid and semi-solid formulations in the world. We provide full-scale development to commercial solutions with customizable, specialty fill-finish solutions to ensure a reliable global supply.

Woodstock Sterile Solutions
2210 Lake Shore Drive
Woodstock IL 60098
T: (815) 338-9500
E: info@woodstocksterilesolutions.com
W: WoostockSterileSolutions.com

Contract Manufacturing

AbbVie Contract Manufacturing partners with companies across the globe to develop, scale and manufacture pharmaceutical products and bring them successfully to market. Drawing on more than four decades of success as the manufacturing division of AbbVie, we have the depth of experience and the technical knowledge to navigate issues and deliver the innovative solutions customers need. We are much more than a CMO – we are your partner for success. With foresight, scientific expertise and passion we anticipate the technical and compliance challenges along the entire pharmaceutical development journey through to commercialization. We see the complete picture to deliver our customer's vision. With full access to global state-of the-art facilities and world-class talent, our customers have come to depend on our service and quality to deliver real-world results. For more information, visit AbbVie Contract Manufacturing at **www.abbviecontractmfg.com.**

Lipid-Based Excipients

ABITEC manufactures lipid-based excipients to enhance the bioavailability of poorly water-soluble and poorly permeable APIs, in accordance with cGMP and IPEC guidelines in ISO-certified facilities. Lipids for LNP Therapeutics – With a catalogue of over 3000 lipid chemistries and the ability to customize and manufacture GMP lipids at scale. ABISORB-DC™ is ABITEC's co-processed excipient system for the direct compression of liquid lipids. The ABISOL™ Emulsion Preconcentrate Kit is a series of preconcentrates for the formulation of self-emulsifying drug delivery systems. CAPTEX medium chain triglycerides, CAPMUL mono- and diglycerides, and ACCONON pegylated esters formulate self-emulsifying drug delivery systems. ABITEC lipid excipients are the ideal starting point when formulating BCS Class II & IV (poorly water soluble) and BCS Class III & IV (poorly permeable) molecules. For more information, visit ABITEC at **www.abiteccorp.com.**

CDMO+CRO Services

Abzena is the leading end-to-end CDMO+CRO for bioconjugates, ADCs and complex biologics. From discovery through commercial, we support customers with integrated programs and individual services designed to de-risk and streamline the development of new treatments for patients in need. Our comprehensive services for biopharmaceuticals include antibody discovery & design, protein engineering & developability, lead candidate selection, analytics & bioassays, immunogenicity, mammalian cell line development, bioconjugation & complex chemistry, linker-payload design & synthesis, analytical method development, formulation development, process development & cGMP manufacturing, technology transfer & scale-up, master cell banking, and regulatory support. Discuss your program with our experts and discover how Abzena can help move your program forward faster. For more information, visit Abzena at https://www.abzena.bio/knownow or contact **info@abzena.com.**

Hybrid Supplier

Actylis is a leading global manufacturer of critical raw materials and performance ingredients serving the Life Sciences industry. Through our hybrid approach we provide combined capabilities in GMP manufacturing and global sourcing of raw materials and ingredients, offering flexibility and unrivaled choice to pharmaceutical and biopharmaceutical companies.Thanks to our hybrid manufacturing/sourcing model we can supply solutions for over 3,000 compounds, including excipients, cell culture ingredients, buffers, process solutions, PIs, APIs, Water for Injection, amino acids, nucleosides and nucleotides. We also offer GMP custom manufacturing, ingredient development, custom packaging, R&D and analytical services. All our products are backed by world-class quality, reliable delivery, and a strong regulatory record. Discover Actylis and explore our raw materials and ingredients portfolio. For more information, visit Actylis at **www.actylis.com.**

Specialty CDMO

Adare Pharma Solutions is a global technology-driven CDMO providing end-to-end integrated services, from product development through commercial manufacturing and packaging, with expertise in complex oral formulations. Adare's specialized technology platforms provide taste masking, controlled release, solubility enhancement, and patient-centric dosing solutions. With a proven history in drug delivery, Adare has developed and manufactures more than 45 products sold by customers worldwide. For more information, visit Adare Pharma Solutions at For more information, visit Adare Pharma Solutions at **www.adarepharmasolutions.com.**

Global CDMO

Agno Pharmaceuticals is a leading, global, small molecule Contract Development and Manufacturing Organization (CDMO), catering to the specific needs of the branded pharmaceutical, biotech, generic, and CDMO sectors. Agno Pharmaceuticals is a US-based, end-to-end premier service provider. We specialize in supplying Registered Starting Materials (RSMs), custom Chemical Intermediates, Active Pharmaceutical Ingredients (APIs), highly potent APIs, sterile APIs, and complex Drug Product formulations (including long-acting injectables/implants) to our valued clientele worldwide. Our US-FDA inspected cGMP compliant manufacturing facilities ensures that we are able to provide our services at a level of unparalleled quality and compliance to our customer base. For more information, visit Agno Pharmaceuticals at **www.agnopharma.com.**

Drug Development Services

ALMAC

Partnering to Advance Human Health

The Almac Group is a global leader in providing a range of expert services and support across the drug development lifecycle. We are trusted experts in R&D, diagnostic services, API manufacture, formulation development, clinical trial supply services and technologies through to commercial-scale manufacture and distribution. We are recognised as an industry leader in client service, providing understanding, experience and knowledge to our clients as we work together to advance human health. Almac is trusted by the leading global biopharma companies to provide crucial services across their drug development projects. In the last 5 years alone, we have contributed to over 50% of all FDA approved New Molecular Entities (NMEs) and are currently supporting 25% of EU approved /pre-registered Gene therapy products. For more information, visit The Almac Group at **www.almacgroup.com.**

Specialty CDMO

APRECIA™

THE 3DP PHARMACEUTICAL COMPANY

As a specialty CDMO, **Aprecia** is reinventing medicine so patients can live their best lives. Our life transforming innovations in 3D Printing (3DP) expand the possibilities for patient centricity in pharmaceutical product development. Agile production systems enable liberating formulation platforms that set a new standard in modern pharmaceutics, creating better products in better ways in less time. Aprecia is the only company in the world to scale-up manufacturing for a 3DP product, win regulatory approval, and reliably produce commercial supply. Our proven 3DP technology is taking existing medicines to their full potential and accelerating development for a new spectrum of early-stage product candidates. For more information, visit Aprecia at **www.aprecia.com.**

Primary Packaging & Closure Solutions

Aptar pharma

With the global rise of chronic diseases and the COVID19 outbreak, increasingly complex drug products are being tested and launched on the market. Choosing the right primary packaging and closure solution is essential to facilitating regulatory approval and fast time-to-market. Building on 70 years' experience in the development and manufacturing of drug packaging solutions, **Aptar Pharma** offers end-to-end services, accelerating and de-risking the choice of closure component. Our PremiumCoat® Service packages address key customer challenges at different stages of their drug development. Leveraging our state-of-the-art PremiumCoat® technology, internal capabilities, expertise, and knowledge of the drug development journey, Aptar Pharma offers three packages to support the validation of PremiumCoat® with your glass container (Platform Package) or your specific drug (E&L Package). The Development Package accompanies our customers through their validation process, to ensure their success. For more information, visit Aptar Pharma at **www.aptar.com/pharmaceutical/.**

Manufacturing Facility

Ascendia® Pharma's expanded state-of-the-art 60,000 sq./ft. R&D and manufacturing facility provides cGMP manufacturing formulation development, processing and scale-up along with toxicity and clinical trial materials with commercial supply for sterile and non-sterile dosage forms, including ophthalmic, parenteral, topical, and oral. Its facility includes the Netzsch Vakumix for state-of-the-art aseptic processing, and a complete suite of Precision NanoSystems equipment to provide comprehen-sive lipid nanoparticle manufacturing. For more information, visit Ascendia at **www.ascendiapharma.com.**

KinetiSol™ Technology

AUSTINPx™

PHARMACEUTICS / MANUFACTURING

AustinPx's KinetiSol™ Technology, offering superior sustainability, scalability, and performance, is revolutionizing amorphous solid dispersion development and manufacturing. A fusion-based, solvent-free process, KinetiSol rapidly transitions crystalline drug and polymer into an amorphous solid dispersion in as little as seven seconds. With its significantly smaller ecological footprint, broader formulation design space, faster processing times and wider application, KinetiSol is enabling the development of challenging APIs and setting new standards in sustainability, scalability, and performance. For more information, visit AustinPx at **www.austinpx.com.**

Quality Excipients & APIs

BASF

We create chemistry

BASF Pharma Solutions is a leading provider of innovative and high-quality excipients and APIs for the pharmaceutical industry. Our dedicated team of industry experts, supported by our cutting-edge digital solutions, works closely with customers to develop efficient and reliable formulations. Based in Florham Park, United States, our operations span across the globe, with production facilities that spread across multiple continents, we are able to provide support and solutions to pharmaceutical industries worldwide. At BASF, we prioritize the production of pharmaceutical ingredients in accordance with the highest quality standards. With over 75 years of experience, we offer the expertise and continuity necessary to meet the diverse needs of your pharmaceutical business. For more information, visit BASF Pharma Solutions at **https://pharma.basf.com/general-contact.**

Parenteral Delivery Devices

FOR BETTER TREATMENT OF CHRONIC DISEASES. Across the healthcare continuum, BD is the industry leader in parenteral delivery devices that help health systems treat chronic diseases. We not only continually advance clinically proven, prefillable drug delivery systems, we do so with a vision to help healthcare providers gain better understanding of how patients self-inject their chronic disease therapies outside the healthcare setting. This is why we partner with leading pharmaceutical and biotech companies worldwide to develop digitally-connected self-injection devices — including wearable injectors and autoinjectors — to capture valuable data that can be shared with caregivers. Discover how BD brings new ideas and solutions to customers, and new ways to help patients be healthy and safe. For more information, visit BD Medical – Pharmaceutical Systems at **bd.com/Discover-BD1.**

Global CDMO

BIOVECTRA
A part of Agilent

BIOVECTRA, now part of Agilent Technologies, is a global biotech and pharmaceutical CDMO that specializes in clinical-to-commercial-scale production capabilities for biologics, small molecules, bioreagents, pDNA and mRNA manufacturing, and fill/finish. Flexibility, creativity, process optimization, and compliance are at the heart of our method. With more than 50 years of experience and cGMP facilities in Canada we assure our programs advance on time and with the highest quality outcomes. Our teams leverage a proven track record of excellence to optimize, adapt, and perfect innovative technologies and drug substance development approaches to deliver world-class solutions for pharmaceutical manufacturing. Learn more at **www.BIOVECTRA.com.**

International CGMP CDMO

Bora Pharmaceuticals

Bora Pharmaceuticals is a global contract development and manufacturing organization (CDMO) specializing in complex oral solid dosage (tablet & capsules), biologics, liquids (solutions, suspensions, ophthalmics & nasal sprays), powders, semi-solids (creams, ointments & gels), and sterile injectables for pharmaceutical products for Clinical through Commercial manufacturing and packaging. Bora owns and operates sophisticated cGMP manufacturing facilities across North America and Asia (US, Canada, Taiwan), built to the highest international standards for development, manufacturing, packaging, and analytical testing. Our sites deliver to more than 100 markets around the world. We're proud to of the work we do everyday to help make success more certain. For more information, visit Bora Pharmaceuticals at **https://www.boracorpcdmo.com/.**

Lipid Nanoparticle R&D

Cayman CHEMICAL

Cayman is a US-based CRO and CRDMO supporting the research and development of lipid-based drug delivery systems. Cayman provides integrated solutions for custom lipid nanoparticle (LNP) development, combining our industry-leading expertise in lipid chemistry, synthesis, and analysis with proficiencies in bioanalysis and cell biology. With more than 40 years of experience, Cayman specializes in lipid synthesis and provides a comprehensive catalog of high-quality lipids for LNP formulation. Cayman also offers custom synthesis of novel lipids, CGMP lipid manufacturing, and LNP formulation, characterization, and screening services. For more information, visit Cayman Chemical at **www.caymanchem.com.**

Drug Delivery Platform

Celanese
The chemistry inside innovation™

Celanese corporation is a global leader in the production of differentiated chemistry solutions and specialty materials used in most major industries and consumer applications. With decades of experience in medical and pharmaceutical applications, we have earned our customers' trust us through providing unrivaled service, world-class expertise, and quality that improve product development, enhance manufacturability, and elevate patient experiences. Our VitalDose technology is a drug delivery platform providing controlled release either through local or systemic dosing in an implant or insert dosage form and is compatible with a wide array of drug molecule types. For more information on the VitalDose drug delivery technology, visit **vitaldose.com.**

Differentiated Injectable Delivery

Credence MedSystems is an innovator in drug delivery devices. Credence's philosophy of *Innovation Without Change* results in products that impress and protect end-users while preserving pharma's existing processes, sourcing strategies and preferred primary package components. The Companion® family of syringe systems includes proprietary integrated needle-retraction technology, reuse prevention, critical safety & usability features as well as sustainability advantages. The Dual Chamber platform offers simplified delivery for drugs requiring reconstitution or sequential injection at the time of delivery. The Credence Connect™ Auto-Sensing Injection System incorporates automatic real-time monitoring of critical injection data into a reusable ergonomic finger grip. Credence's Metered Dosing product line allows precise delivery of small volumes and a force advantage when viscosities are high. For more information, call +1 844-263-3797 (+1-844-CMEDSYS), email info@credencemed.com, or visit **www.CredenceMed.com.**

High-Performance Products

CRODA Pharma

SMART SCIENCE TO IMPROVE LIVES™

Croda's Pharma business is a leading partner for the development of excipients and the supply of high purity materials for pharmaceutical formulations, committed to enabling the next generation of drug delivery systems. The business is focused on empowering biologics drug delivery, through its adjuvant systems, small molecule, protein, and nucleic acid, delivery platforms. For more information, visit Croda at **www.crodapharma.com.**

CDMO Experts

curia

Curia is a contract research, development and manufacturing organization (CDMO) with over 30 years of experience, an integrated network of 20+ global sites and 3,000+ employees partnering with biopharmaceutical customers to bring life-changing therapies to market. Our offerings in small molecules, generic APIs and biologics span discovery through commercialization, with integrated regulatory, analytical and sterile fill-finish capabilities. Our scientific and process experts, along with our regulatory compliant facilities, provide a best-in-class experience across drug substance and drug product manufacturing. From curiosity to cure, we deliver every step to accelerate your research and improve patients' lives. For more information, visit Curia at **curiaglobal.com.**

End-to-End Development Services

douglas CDMO

Douglas CDMO, ibased in New Zealand, has a history dating back to 1967. We offer end-to-end integrated drug development services, specializing in high-potency small molecule softgels, liquids, semi-solids, new chemical entities (NCEs), and branded generics. Our capabilities extend to manufacturing prescription drugs across key therapeutic areas, including oncology, dermatology, the central nervous system, and immunity. Working with clients across the globe, we pride ourselves on delivering superior quality and excellent service, ensuring our partners achieve successful, timely outcomes. Our strategic location in Auckland, New Zealand offers our global customers with tax incentives and the ability to start first in human trials quicker than many other jurisdictions due to a streamlined regulatory process. For more information, visit Douglas CDMO at **www.douglascdmo.com.**

Testing Services

element

Element Materials Technology is at the forefront of the world's pharmaceutical and medical device testing services. We deliver trusted contract development and quality assurance to our clients across the globe, providing certainty to physicians and patients. Our Experts specialize in Trace Metals Analysis, Analytical Method Development and Validation, Extractable and Leachable Studies, CMC and Clinical Batch Manufacturing, and more. We surpass our client's expectations through unrivaled, tailored services, solid partnerships and our proven track record of helping our customers move their products to market faster. For more information, visit Element Materials Technology at **www.element.com.**

Delivery Design, Development & Manufacturing

flex

Flex helps a diverse customer base design and build products that improve the world. Through the collective strength of a global workforce across 30 countries and responsible, sustainable operations, Flex delivers technology innovation, supply chain, and manufacturing solutions to diverse industries and end markets. Flex's health solutions business focuses on medical device and drug delivery design, development, and manufacturing solutions for pharmaceutical and medtech companies. From pens and autoinjectors to wearable pumps and inhalers, Flex helps pharma companies by providing solutions wherever they are in the product lifecycle. Our approach is supported by FDA-registered and ISO 13485-compliant and ISO 11608-1-accredited facilities, with a world-class single quality system across sites. For more information, visit Flex at **www.flex.com.**

Hands-On Formulation Support

GATTEFOSSÉ

With application and R&D Centers in the United States, France, India, and China, the **Gattefossé group** is providing formulation support for oral, topical, transdermal, and other routes of administration. Equipped with state-of-the-art analytical and processing instruments, we stand to assist with your projects at all stages of development, from solubility screening to late-stage formulation and "proof-of-concept" studies. Moreover, we provide extensive regulatory support, sharing toxicological and safety data, and analytical/characterization methods. For more information, visit Gattefossé at **www.gattefosse.com.**

Pharmaceutical Services

Halo Pharma is a leading provider of pharmaceutical services, including contract dosage form development, commercial manufacturing and analytical services.Our capabilities in the areas of tech transfer, process and pharmaceutical product development, formulation development, production, scale-up and validation, and analytical method development allow us to partner with clients from development through commercialization or at any point along the way. Our expertise across many dosage forms, including complex oral solids, topicals, oral solutions and suspensions and the manufacture of controlled substances is unmatched in North America. Halo Pharma serves a growing global customer base across multiple regulatory environments. These attributes allow Halo Pharma to be a partner of choice for many of today's large pharma, generic pharma and biotech pharma companies. For more information, visit Halo Pharma at **www.halopharma.com.**

User-Friendly Oral Dosage Forms

HERMES PHARMA is the leading expert in developing and manufacturing user-friendly oral dosage forms, including effervescent and chewable tablets, instant drinks, lozenges, orally disintegrating granules, and the newly developed HERMES NutriCaps. As a CDMO, we offer customized services along the entire pharmaceutical value chain, from new product development and formulation to manufacturing and regulatory support. For more than 40 years, leading healthcare companies around the globe have worked with HERMES PHARMA to extend their pharmaceutical and nutraceutical product lines as well as to grow their brands. Our sister company HERMES ARZNEIMITTEL has a rich portfolio of successful OTC brands and a history of more than a hundred years in pharmaceutical excellence. This heritage makes HERMES PHARMA a reliable and experienced partner who truly understands the challenges of its customers. For more information, visit HERMES PHARMA at **www.hermes-pharma.com.**

Formulation & Manufacture

LATITUDE Pharmaceuticals delivers cutting-edge drug formulation development and GMP manufacturing and analytical testing services. For over 20 years, LATITUDE's extensive expertise has spanned a wide range of dosage forms, overcoming difficult formulation challenges such as solubility, instability, and bioavailability. Our scientists have particular expertise in complex injectables, including nanoemulsions, liposomes, microspheres, and nanoparticles. In addition, LATITUDE provides pre-clinical testing material and GMP-compliant manufacturing and analytical testing, focusing on quick client response and timely delivery for Phase 1 and Phase 2 clinical trials. LATITUDE's manufacturing capabilities include sterile injectables, ophthalmic, non-sterile oral, and topical dosage forms, tailored for GLP-tox studies or early-stage human trials. Renowned for proficiency in complex liquid formulations, LATITUDE is ready to meet your formulation needs. For more information visit LATITUDE Pharmaceuticals at **www.latitudepharma.com.**

Premier CDMO

LGM Pharma is a premier CDMO specializing in Active Pharmaceutical Ingredient (API) sourcing, analytical testing, drug product development and GMP commercial manufacturing for pharmaceutical, biotech, and compounding pharmacy industries. We support clients through every phase of drug development, from API sourcing to commercialization. Our global network of qualified API partners ensures optimized supply chain management and distribution. Core services include API procurement, formulation development, method validation, ANDA/NDA submissions, stability studies, and testing. With a strong regulatory track record and expert market intelligence, LGM Pharma delivers tailored solutions that reduce risk, enhance efficiency, and accelerate commercialization. Committed to quality and customer service, we partner with clients to meet their unique needs while driving innovation in pharmaceutical manufacturing. For more information, visit LGM Pharma at **lgmpharma.com.**

New Isolator Filler Capacity

Lifecore Biomedical is a fully integrated CDMO with differentiated capabilities in the development, fill and finish of sterile injectable pharmaceutical products. Proven capability with complex formulations and highly viscous products (>100,000 cP) highlights our ability to undertake challenges. With 20+ commercial products and a 40+ year regulatory track record, we are deeply knowledgeable on how to efficiently drive programs from clinical to commercial. No matter the size of your organization or the stage of your project, let's explore how Lifecore may be the right HOME for your molecule. For more information, visit Lifecore Biomedical at **www.lifecore.com.**

Global Development Partner

Lonza is a preferred global partner to the pharmaceutical, biotech and nutrition markets. We work to enable a healthier world by supporting our customers to deliver new and innovative medicines that help treat a wide range of diseases. We achieve this by combining technological insight with world-class manufacturing, scientific expertise and process excellence. Our business is structured to meet our customers' complex needs across four divisions: Biologics, Small Molecules, Cell & Gene and Capsules & Health Ingredients. Our unparalleled breadth of offerings across divisions enables our customers to commercialize their discoveries and innovations in the healthcare industry. For more information, visit Lonza at **www.lonza.com.**

Innovative Excipients

Lubrizol Life Science partners with pharmaceutical and nutraceutical companies to develop innovative solutions that improve patient outcomes and provide consumer benefits. We offer a portfolio of innovative and multifunctional excipients, encompassing our long-established Carbopol® polymers, Pemulen™ polymeric emulsifiers, and Noveon® polycarbophil, alongside our solubility-enhancing Apisolex™ and Apinovex™ novel excipients. In addition to our best-in-class pharmaceutical excipients and nutraceutical actives, our team leverages expertise from across formulation development, including oral, topical, ophthalmic, and parenteral dosage forms. Our deep industry understanding and unique capabilities can help you to differentiate your drug products and accelerate your innovations to market. For more information, visit Lubrizol at **https://lubrizol.com/Health.**

Lyophilization Services & Solutions

Founded 1992, **Lyophilization Technology, Inc.** is a Contract Development and Manufacturing Organization providing development services and technical support focused on lyophilized products. Experience with a wide variety of products, including small molecules, cytotoxics, biologics, highly potent compounds, vaccines, medical devices, and diagnostic agents, LTI has provided services and support spanning start-up, virtual, and multinational companies. A comprehensive range of services consists of product design, formulation development, process engineering, and clinical supplies manufacturing for pharmaceuticals, biologics, diagnostics, and biopharmaceuticals. Technical support encompasses consultation on technology transfer, validation, product and process evaluation, troubleshooting, streamlining operations, compliance auditing and training. When your needs are lyophilization, our focus is on your product. For more information, visit **www.lyotechnology.com** or call (215) 396-8373.

Medical Manufacturing

Medbio is a medical manufacturing partner like no other, with the broadest spectrum of solutions. From precision custom molding capabilities, full-service contract manufacturing and value-added services to a wide range of standard protective parts and medical packaging, Medbio is the one partner you need. Our in-house team of engineers is dedicated to deliver the most effective solutions to meet your needs. Our multiple state-of-the-art facilities include over 80,000 sq ft of cleanroom manufacturing, including custom built automation cells. We are ISO 13485:2016 certified and FDA registered. Together with sister company Caplugs, one of the world's leading plastic molders, we have worked with over 1,500 medical and biotech customers and look forward to putting our vast expertise to work for you. For more information, visit Medbio at **https://medbiollc.com/.**

Tailored Drug Delivery

Mikart, a CDMO specializing in pharmaceuticals, provides comprehensive solutions for formulation development, manufacturing, packaging, and regulatory support for solid oral dosages, liquids, semi-solids, and more. Mikart specializes in tailoring drug delivery technologies, optimizing processes, and ensuring compliance with industry regulations. Mikart operates from a state-of-the-art 150,000-sq-ft facility in Atlanta, GA, which boasts cutting-edge equipment and technologies for pharmaceutical development and manufacturing across various dosage forms. It includes specialized areas for formulation development, analytical laboratories, multiple manufacturing suites equipped for different types of drug products, packaging capabilities, and storage areas compliant with industry standards and regulatory requirements. Mikart's facility is designed to accommodate the diverse needs of clients in the pharmaceutical industry. Bringing innovative pharmaceutical products to market requires a reliable partner like Mikart. For more information, visit Mikart at **let-mikart-support-your-drug-development-and-manufacturing-needs**

Functional Chemicals

Mitsubishi Gas Chemical (MGC) is a leading company in the field of functional chemicals, such as oxygen barrier and absorbing polymers. MGC established the Advanced Business Development Division in 2015 for tackling a variety of today's problems, and the division created OXYCAPT™ Multilayer Plastic Vial & Syringe to solve some issues of existing primary packaging for injectable drugs. OXYCAPT Vial & Syringe consists of three layers. The inner and outer layers are made of cyclo-olefin polymer (COP), the most reliable polymer in the pharmaceutical industry. The middle layer is made of state-of-the-art polyester developed by MGC. The oxygen-barrier property is almost equivalent to glass and much better than COP. OXYCAPT also provides an ultra violet (UV) barrier. For more information, visit Mitsubishi Gas Chemical at **www.mgc.co.jp/eng/products/abd/oxycapt.html.**

Patient-Focused Delivery Devices

As a world-leading drug delivery device solutions provider, **Nemera's** goal of putting patients first enables it to design and manufacture devices that maximize treatment efficacy. Nemera is a holistic partner and helps its customers succeed in the sprint to market with its combination products. From early device strategy to state-of-the-art manufacturing, Nemera is committed to the highest quality standards. Agile and open-minded, the company works with its customers as colleagues. Together, they go the extra mile to fulfil its mission. For more information, visit Nemera at **www.nemera.net.**

High-Quality Reagents

Oakwood Chemical is a leader in selling high-quality reagents to academic, chemical, and pharmaceutical customers for over 30 years. Located in the South Carolina Lowcountry, we have over 10,000 square feet of laboratory space, as well as two large warehouses totaling 200,000 square feet with over 150,000 chemicals in stock. We offer benchtop to production quantities of inorganic and organic reagents, solvents, salts, catalysts, and biochemicals in numerous grades (reagent, anhydrous, ACS, HPLC, LCMS, NMR, USP) and in different amounts (from lab bench to industrial drum sizes). Let us help you in succeeding in this high growth industry. For more information, visit Oakwood Chemical at **www.oakwoodchemical.com.**

Injectable Drug Delivery

Owen Mumford Pharmaceutical Services is a specialist in the design, development, and manufacture of injectable drug delivery systems for the pharmaceutical, biotech, and generics industries. These include single-dose and multi-dose reusable and disposable auto-injectors, pens, and syringes for subcutaneous and intramuscular administration. Our innovative products are designed to meet both the need of our pharmaceutical partners and their patients by facilitating ease of use and improving safety and patient compliance. Our devices are also designed with the aim of reducing complexity and risk for the pharmaceutical and biotech industry in the development of their combination products. Our products are supported by our services, and we work with our partners every step of the way, supporting and guiding from initial concept stage through to taking the solution to market. For more information, visit Owen Mumford Pharmaceutical Services at **www.ompharmaservices.com.**

CDMO Services

Pace® Life Sciences provides a full suite of contract CMC development, CTM manufacturing, regulatory compliance, consulting, and facility support services to the pharmaceutical, biopharmaceutical, and gene therapy industries. Pace® Life Sciences operates from a network of CDMO sites, GMP analytical testing laboratories, and manufacturing support service centers across the United States. Our experienced, highly trained industry experts, and our investment in state-of-the-art development and manufacturing facilities emphasize our commitment to efficiently advancing client programs through the clinic to commercialization. We are dedicated to delivering the best and most reliable services with positive customer experiences across all channels of our business. For more information, visit Pace® Life Sciences at **www.pacelifesciences.com.**

A Leading, Global CDMO

PCI is a leading global CDMO, providing integrated end-to-end drug development, manufacturing and packaging solutions to increase product speed to market and opportunities for commercial success. PCI brings the proven experience that comes with more than 90 successful product launches each year and over 5 decades in the healthcare services business. We currently have 30 sites across Australia, Canada, US, UK, and Europe, with over 5,500 employees that work to bring life-changing therapies to patients. Leading technology and continued investment enable us to address global drug development needs throughout the product lifecycle, collaborating with our clients to improve patients' lives. For more information, visit PCI at **www.pci.com.**

Specialized Products & Services

Pfanstiehl is a leading cGMP manufacturer of parenteral-grade excipients and highly potent APIs. Pfanstiehl develops and manufactures high-purity, low endotoxin, low metals carbohydrates, such as Trehalose, Sucrose, Mannitol, Galactose, and Mannose, and Amino acids, such as Arginine, Histidine, Glutamine, and Methionine, along with Sodium Succinate and Sodium Gluconate utilized as injectable excipients for the stabilization of proteins, mAbs, and vaccines. These HPLEs are also used as supplements for cell culture, cell therapy, and cryopreservation media. Being in business for 104 years, Pfanstiehl is well-positioned to exceed the evolving needs of the industry and to help biopharmaceutical and vaccine manufacturers produce safe, effective, and high-quality products. Manufacturing & Development occur at Pfanstiehl's Waukegan campus near Chicago, IL. For more information, visit Pfanstiehl at **www.pfanstiehl.com.**

Sterile Solutions

Woodstock Sterile Solutions is a global provider of best-in-class sterile development and manufacturing solutions – with a decades-long track record of helping healthcare companies advance molecules through clinical development into full-scale commercial production. Throughout our 50-year history, Woodstock has been a leader in developing and deploying advanced aseptic blow-fill-seal delivery products. For more information, visit Woodstock Sterile Solutions at **www.woodstocksterilesolutions.com.**

Global End-to-End CDMO

With over 4300 customer-centric employees and commercial operations across the US, EU, and China, **Porton J-STAR** provides pharmaceutical and biotech companies with innovative, reliable, end-to-end process R&D and GMP manufacturing services for Drug Substance and Drug Product across Small Molecules, Tides, Biologics and Conjugates. Porton J-STAR is recognized for our process innovation, supply chain performance and compliance with global Quality and EHS standards. Constantly striving for excellence and enabling the public's early access to good medicines. Porton has steadily added and continues to expand in the areas of Process Chemistry, Analytical R&D, QC/QA, GMP delivery, Crystallization R&D, Solid State and Catalysis Screening, Enabling Technologies, High Potent Compound Handling (HPAPI), Impurity Isolation and Structural Elucidation, Pre-formulation, Drug Product Formulation R&D, and Oral Solid Drug Product GMP manufacturing. For more information, visit Porton J-STAR at **https://www.portonpharma.com/.**

Specialized CDMO

Since our founding 20 years ago, **ProMed Pharma** has endeavored to be your preferred development partner for long-acting injectable and implantable dosage forms. Our proficiency spans molding, extrusion, and microencapsulation techniques, leveraging polymeric excipients, including silicones, thermoplastics, and biodegradables. Key markets for our services include women's health, ophthalmology, oncology, and neurological disorders. Representative drug-device applications include steroid-eluting pacing and defibrillation leads, implantable sensors, antimicrobial eluting devices, and sinus stents. ProMed also supports pharmaceutical companies developing extended-release formulations utilizing subcutaneous implants, intratumoral pellets, intrauterine devices, intravaginal rings, and ophthalmic inserts. Whether you represent an emerging biotech venture or a global pharmaceutical entity, entrust us as your CDMO partner, as we diligently translate scientific concepts into finished dosage forms. For more information, visit ProMed Pharma at **www.ProMedPharmaLLC.com.**

OINDP Development Services

Proveris Laboratories offers Orally Inhaled and Nasal Drug Product (OINDP) expertise to pharmaceutical developers, including laboratories' services employing new innovative techniques. These include measuring plume front velocity, spray duration, evaporation rate, and quantitative/qualitative deposition of inhaled and nasal drug products using human-realistic models and nasal casts. Employing *in vitro* approaches that are human-realistic can enable companies to make data-driven decisions and expedite product development and approvals while saving time and resources. For more information, visit Proveris Laboratories at **www.proveris.com/proveris-laboratories/.**

Custom API Synthesis & Manufacturing

Purisys is a proven leader in custom API synthesis and manufacturing. We bring more than 40 years of experience in commercial pharmaceutical production – everything you need to scale up quickly and smoothly, without delays. Our extensive experience can help you reach your goals. We have experience working with emerging biotech companies looking for a skilled outsourcing partner to take your compounds to trial and with large pharma companies that want to outsource parts of their supply chain to increase efficiency and speed to market. When you work with Purisys, you collaborate with a team that understands the specialized environment of the drug development process. For more information, visit **www.purisys.com.**

Integrated Drug Product, Manufacturing, & Clinical Services

Quotient Sciences is a pharmaceutical development & manufacturing accelerator offering fully integrated programs and tailored services from candidate selection through commercial manufacturing. Our seamless integration of drug product development, manufacturing, and clinical testing services, results in a more efficient and accelerated development plan. Integrating all activities under a single organization in an entirely non-siloed way encourages close relationships between multidisciplinary experts, creating a more agile approach to pharmaceutical development. The ultimate benefit is a significant cost savings & shortening of the timeline from candidate selection to clinical development, which in turn allows us to get medicines to patients faster. For more information, visit Quotient Sciences at **www.quotientsciences.com.**

Technology-Focused Biomanufacturing

Resilience is a technology-focused biomanufacturing company dedicated to broadening access to complex medicines (biologics, vaccines, nucleic acid, cell and gene therapy modalities and drug product). Founded in 2020, the company is building a sustainable network of high-tech, end-to-end manufacturing solutions to ensure the treatments of today and tomorrow can be made quickly, safely, and at scale. By continuously advancing the science of biopharmaceutical manufacturing and development, Resilience seeks to free its partners to focus on the discoveries that improve patients' lives and protect biopharmaceutical supply chains against future disruptions. For more information, visit Resilience at **www.resilience.com.**

Why PharmaCircle?

Since 2003, PharmaCircle has been providing clients with the integrated data, powerful analysis tools and industry knowledge needed to solve complex, real world challenges in product development and innovation.

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SODIUM LAURYL SULPHATE (Core/Content)	7.58 mg
DIBASIC CALCIUM PHOSPHATE ANHYDROUS **(Core/Content)**	75.76 mg
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MICROCRYSTALLINE CELLULOSE **(Core/Content)**	75.76 mg
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POLYETHYLENE GLYCOL **(Tablet/Capsule coat)**	5.92 mg
TALC **(Tablet/Capsule coat)**	4.33 mg
FERRIC OXIDE YELLOW **(Tablet/Capsule coat)**	0.32 mg
TITANIUM DIOXIDE **(Tablet/Capsule coat)**	7 mg
FD&C RED NO. 40 **(Tablet/Capsule coat)**	
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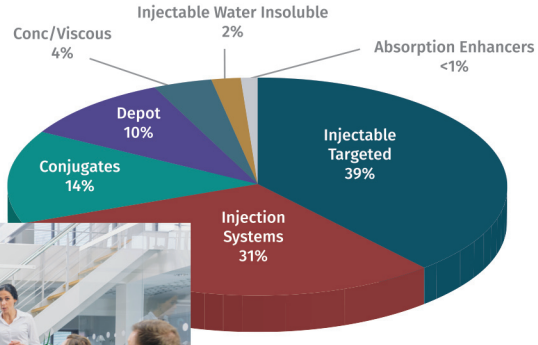
Evaluate New and Promising Technologies



Injectable Drug Delivery Technologies

Screen Potential Partnering and Investment Opportunities

Assess Development Pipelines and The Competitive Landscape

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Science-First CDMO

Serán BioScience is a science-based CDMO specializing in a variety of drug delivery and formulation approaches suited to optimizing bioavailability. Serán's experienced team works with you to identify an appropriate technology and formulation strategy to meet your program's unique needs. Our comprehensive approach to formulation design considers the physiochemical properties of the API, the target product profile, and your program's objectives and constraints to develop scalable formulations using material-sparing approaches. Serán provides capsules, tablets, multi-particulates (coated beads), and powder-in-bottle formulations. Our solid dosage forms are engineered for a wide range of formulation approaches, such as overcoming solubility challenges and to enable extended release. We complement industry-best production practices with the finest manufacturing equipment available to produce dosage forms that perform predictably and reliably. For more information, visit Serán Bioscience at **www.seranbio.com.**

Premier CDMO

As a premier, independently owned CDMO with over 65 years of sterile injectable manufacturing experience, **Simtra BioPharma Solutions** offers world-class cGMP sterile fill/finish, technical expertise, quality service, and a uniquely collaborative approach. Pharmaceutical and biotech companies partner with Simtra when they face formulation challenges, clinical supply hurdles, surges in demand due to market fluctuations, or risk mitigation concerns. With manufacturing sites located in Bloomington Indiana USA and Halle/Westfalen, Germany, Simtra BioPharma Solutions manufactures products which are distributed to over 120 countries across the globe. For more information, visit Simtra BioPharma Solutions at **simtrabps.com.**

Glass Primary Packaging & Analytical Services

Established in 1949, **Stevanato Group** is the world's largest, privately owned designer and producer of glass containers for the pharmaceutical industry. From its outset, the Group has developed its own glass-converting technology to ensure the highest standards of quality. The Group comprises a wide set of capabilities dedicated to serving the biopharmaceutical and diagnostic industries: from glass containers with its historical brand Ompi, to high-precision plastic diagnostic and medical components, to contract manufacturing for drug delivery devices, to vision inspection systems, assembly, and packaging equipment. For more information, visit Stevanato Group at **www.stevanatogroup.com.**

Parenteral Delivery Solutions

As Part of **Terumo Medical Care Solutions,** the Pharmaceutical Solutions Division develops patient-oriented parenteral delivery solutions for therapeutic performance and safety. Globally trusted for quality and precision, we offer pharmaceutical and medical device manufacturers around the world comprehensive product design and development services. We have decades of experience collaborating with pharmaceutical companies from the earliest phases of drug development to product commercialization to optimize critical aspects of parenteral drug delivery. Innovation and creativity are central to our value proposition. Our expert teams lead the industry in developing and manufacturing advanced, high-performing infusion and injection technologies, including CDMO services for all parenteral applications. For more information, visit Terumo Pharma Solutions at **www.terumopharmaceuticalsolutions.com.**

Accelerate Drug Development

Small molecule drugs currently account for over 90% of approved medicines on the market, forming the foundation of the pharmaceutical industry. At **Thermo Fisher Scientific,** we offer integrated, end-to-end CDMO and CRO services for oral solid dose (OSD) forms — the gold standard in drug delivery. From early phase drug formulation to late-phase process optimization, we help you save time, money, and active pharmaceutical ingredients (APIs). And with nine state-of-the-art facilities worldwide, we provide global expertise in OSD development and manufacturing, including for high-potency APIs. Let's turn your vision into reality. For more information, visit Thermo Fisher Scientific at **www.thermofisher.com.**

FULL-SERVICE CDMO

Vetter is a leading independent contract development and manufacturing organization (CDMO) that specializes in the clinical and commercial aseptic filling and packaging of syringes, cartridges, and vials. The company has extensive experience with biologics and other complex compounds. Collaborating with pharma/biotech clients worldwide, Vetter supports products from preclinical development through global market supply. Through its US and European facilities, Vetter Development Service provides state-of-the-art support for early-stage products, with transfer at Phase III to Vetter Commercial Manufacturing for large-scale production. For more information, visit Vetter at **www.vetter-pharma.com.**

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Douglas Pharma	84,85	enquiry@douglascdmo.com	www.douglascdmo.com
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