Drug Development & Delivery

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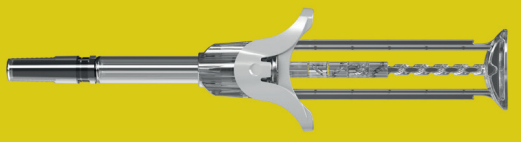

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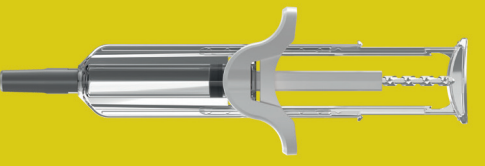

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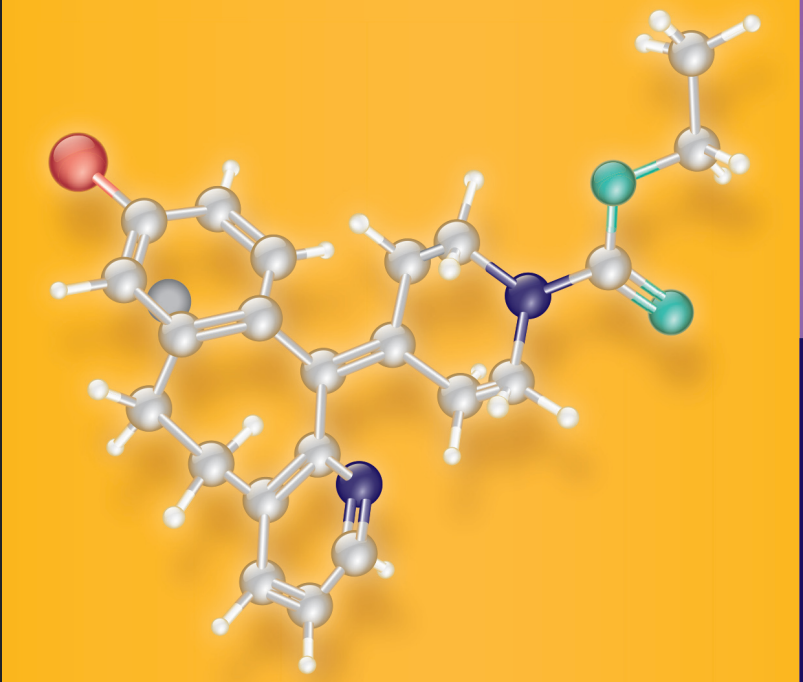

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Hovione Expands Nasal Drug Delivery Capabilities With Development of Nasal Powder Delivery Device Technology in Collaboration With IDC

Hovione recently announced an expansion of its nasal drug delivery capabilities with the addition of a family of innovative nasal powder delivery devices developed in partnership with IDC. Intranasal drug delivery is a good alternative to conventional delivery routes for both local and systemic drug delivery due to its simplicity, safety, and faster onset of action. Additionally, it is emerging as a promising pathway to deliver new drugs to the brain to treat diseases of the central nervous system (CNS).

Hovione and IDC have been working together to accelerate the development and commercialization of two new active nasal powder delivery devices, one single-use and one multidose. The devices enable broad and targeted nasal deposition flexibility while delivering maximum usability and reliability. By using standard capsules and filling equipment, they also have the potential to simplify drug product development and manufacturing.

"Intranasal drug delivery is gaining momentum across a number of applications, including mucosal vaccination and CNS treatments bypassing the blood-brain barrier", said Dr. Jean-Luc Herbeaux, Hovione's CEO. "Our partnership with IDC, a company with vast experience in industrial design, mechanical and electronic engineering of medical devices, enables Hovione to offer a complete solution for nasal powder delivery – covering Active Pharma Ingredients (APIs), formulation, filling, analytics and device design and manufacturing – that address the needs of pharmaceutical companies and patients."

"By combining Hovione's capabilities in pharmaceutical development, formulation and manufacturing with IDC's device development expertise, this partnership offers customers a nasal powder delivery solution which can be rapidly adapted to new pharma compounds and therapies," added IDC's Managing Director, Dr. Stephen Knowles. "Our joint development team has done incredible work to create unique, high performance nasal powder delivery devices."

Hovione will offer the new devices on an exclusive basis as part of its integrated offer for nasal drug development and manufacturing.

Hovione is an international company with over 60 years of experience in pharmaceutical development and manufacturing operations. As a Contract Development and Manufacturing Organization (CDMO) it has a fully integrated offering of services for drug substances, drug product intermediates and drug products. The company has four FDA inspected sites in the USA, Portugal, Ireland and China and development laboratories in Lisbon, Portugal and New Jersey, USA. Hovione provides pharmaceutical customers services for the development and compliant manufacture of innovative drugs, including highly potent compounds, and customized product solutions across the entire drug life cycle. In the inhalation area, Hovione offers a complete range of services, from API, formulation development and manufacturing, capsule filling and devices.

Dyadic Announces Top-Line Results From its Successful Phase 1 Clinical Trial for a First-in-Human Filamentous Fungal-Based Vaccine Candidate

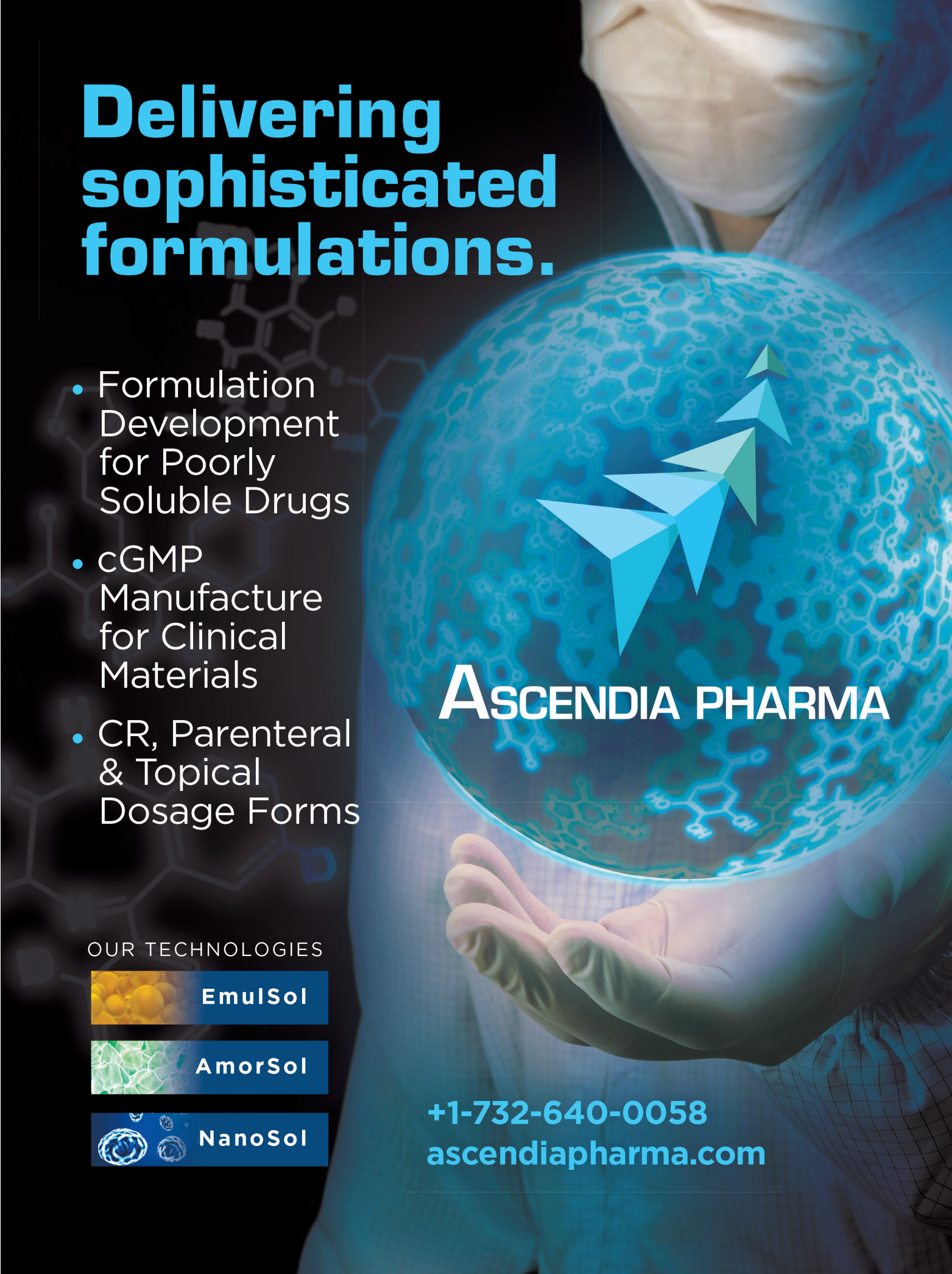
Dyadic International, Inc. recently announced successful top-line results for the Phase 1 clinical trial of its recombinant protein RBD vaccine candidate, DYAI-100. This marks the first-in-human use of a recombinant protein vaccine expressed by Dyadic's C1-cell expression platform.

The Phase 1 clinical trial was a double-blind placebo-controlled safety study of 30 healthy adults conducted in collaboration with Dyadic's South Africa licensee Rubic One Health (Rubic). In late 2022, Dyadic received regulatory approval of its Clinical Trial Application (CTA) from the South African Health Products Regulatory Authority (SAPHRA) to conduct the Phase 1 clinical trial for an antigen produced using its C1-cell protein expression platform. The primary endpoint of the study was to demonstrate the safety and reactogenicity of recombinant proteins. The C1 SARS-CoV-2 RBD single booster vaccine was administered at two dose levels. Top-line safety data confirmed that the study met its primary endpoint demonstrating that both dose levels are safe and well tolerated and that the vaccine produced immune responses at both dose levels.

"We are excited to share the top-line results from what we believe marks the first-in-human clinical trial for a vaccine antigen produced using a filamentous fungal cell line, such as our C1 platform," said Mark Emalfarb, CEO of Dyadic. "While vaccines and antibodies produced from our C1-cell protein production platform have previously demonstrated safety and efficacy in animal studies, this trial represents the initial evaluation of a C1-cell produced protein in humans and is clearly a key milestone for the company. Notably, no Serious Adverse Events were reported, and the clinical study successfully met its primary endpoint demonstrating that a C1 produced antigen was both safe and well-tolerated in both the low and high dose groups."

Mr. Emalfarb continued "The success of our phase 1 trial resulted in increased interest globally from academia, industry, government agencies, and non-profit vaccine development organizations that are considering leveraging our C1-cell expression platform for the development of vaccine antigens and therapeutic proteins."

Dr. Julian Naidoo, Chief Executive Officer of Rubic One Health, Dyadic's African licensee, added "We believe Dyadic's C1 technology is a game changer in the vaccine manufacturing space for not only the African population but also patients in countries across all income levels worldwide. Dyadic's successful DYAI-100 Phase 1 Clinical Trial results support our mission to bring much needed high demand vaccines that are safe, effective, and affordable to the African Continent. We believe that vaccines expressed from C1 are particularly well-suited for African conditions, as C1 produced recombinant vaccines do not need ultra-cold production or storage which can be distributed safely in remote and rural areas across the African continent."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Ardena's New Aseptic Fill-Finish Plant in Ghent Receives GMP License

Ardena, a leading Contract Development and Manufacturing Organization (CDMO) specializing in bringing molecules to clinic, has been granted a Good Manufacturing Practice (GMP) license by the Belgian Federal Agency for Medicines and Health Products (FAMHP) for its state-of-the-art aseptic fill-finish facility in Ghent, Belgium.

A significant step forward in Ardena's ability to provide full-service solutions for the development and clinical production of small molecules and large molecule biologics, the CDMO now has capacity for large molecule biologics, including proteins, next to oligonucleotides (DNA, recombinant RNA, synthetic RNA, RNA vaccines) and peptides.

The increased capabilities solidify Ardena's reputation as a trusted partner for drug development for clinical trials and complements Ardena's pre-existing strengths in drug substance development and manufacturing.

Harry Christiaens, CEO of Ardena, said "Receiving the GMP license for our new aseptic fill-finish facility is testament to our commitment to quality, compliance and dedication to navigating our customers through drug development. This milestone represents a significant step towards our vision of becoming a key CDMO for innovative drugs and is particularly vital when synergized with our existing nanomedicine development and manufacturing capabilities. We are proud to offer our clients a full-service solution, starting from formulation development and analytical method validation, all the way through to regulatory support and bioanalysis."

Ardena's cutting-edge aseptic fill and finish plant in Ghent is equipped with the latest technology, ensuring fast turnaround times, the highest quality standards, and a seamless experience for clients.

The facility uses ARaymond Life's RayDyLyo push-fit caps in the vial-capping process. This innovation simplifies the sealing process, resulting in greater efficiency, flexibility, and faster time-to-clinic. It addresses the growing need for aseptic manufacturing, especially for novel parenteral therapies, by enhancing drug sterility, quality, and reducing risks.

Christiaens added "Our flexible approach and focus on small batch sizes cater to the specialized needs of early-stage clinical development and personalized medicines. This flexibility means that we can efficiently handle small quantities. By eliminating the constraints of minimum batch sizes, we empower our customer to optimize their resources, reduce waste, and streamline the development process, ultimately accelerating the journey of innovative treatments from the lab to the clinic. We understand that in drug development one size does not fit all, and our commitment to adaptable manufacturing reflects our dedication to tailored solutions for every client's unique journey."

Ardena is a fully integrated Contract Development and Manufacturing Organization (CDMO) with a core focus on bringing molecules to the clinic. Our services include small and large API molecule projects, phase-appropriate drug product development and manufacturing, packaging and logistics for clinical trials, regulatory support, and leading nanomedicine development and manufacturing services. We are dedicated to seamlessly integrating our services to reduce development risks, ensure smooth project execution, and ultimately reduce time-to-clinic.

Ajinomoto to Acquire Forge Biologics for $620 Million

Ajinomoto Co., Inc. and Forge Biologics recently announced they have entered into a definitive agreement by which Ajinomoto Co., will acquire Forge, a leading manufacturer of genetic medicines, in an all-cash deal for $620 million.

Forge is a viral vector and plasmid contract development and manufacturing organization (CDMO) and clinical-stage therapeutics company, enabling access to potentially life-changing gene therapies by bringing them from concept to reality. All development and manufacturing is done at the Hearth, Forge's 200,000-sq-ft custom-designed cGMP facility in Columbus, OH, where the business has over 300 employees.

"Forge has had remarkable growth since our founding in 2020, and we're excited to join Ajinomoto Co., to continue to expand our global business of helping innovators manufacture much needed genetic medicines," said Timothy J. Miller, PhD, CEO, President, and Co-founder of Forge. "Our teams share a commitment to investing in innovation that helps our clients succeed in delivering therapies to patients in need. We set out to build a company with a mission to enable access to life-changing discoveries, and this transaction will support us in advancing that mission into our next global stage of development to expand our capabilities and platform for the benefit of our clients and their patients."

"Forge's unparalleled expertise in gene therapy development and manufacturing will be a transformative addition to our core growth area of Healthcare as part of our ASV Initiatives 2030 Roadmap. Forge brings to Ajinomoto an entirely new capability that will vitally enhance our Bio-Pharma Services business and help create new value through innovative solutions for communities and society," added Yasuyuki Otake, Corporate Executive, General Manager of Bio-Pharma Services Department of Ajinomoto Co. "We look forward to working with Forge's incredibly talented team and state-of-the-art specialized manufacturing facility to expand our platform technologies aimed to help realize Ajinomoto's 'Purpose' of contributing to the well-being of all human beings, our society, and our planet."

"This is a tremendous step to drive Forge's next phase of growth that will maximize the impact they have on their mission for clients and patients," said Chris Garabedian, Chairman and CEO of Xontogeny and Chairman of Forge's Board of Directors. "This acquisition in the current biotech market is a remarkable testament to the technical advancements, world-class facility, and experienced capable leadership at Forge."

The transaction, which is expected to be completed by the end of the fourth quarter of 2023, is subject to customary closing conditions, including regulatory approvals. Upon completion, Forge will become a fully consolidated subsidiary of Ajinomoto Co., Inc. Centerview Partners LLC served as lead financial advisor and Ice Miller LLP served as legal advisor to Forge in the transaction. Chardan Capital Markets LLC also provided financial advice.

Avidity Biosciences Announces Expansion of Cardiovascular Collaboration With Bristol Myers Squibb

Avidity Biosciences, Inc. recently announced a global licensing and research collaboration with Bristol Myers Squibb focused on the discovery, development, and commercialization of multiple cardiovascular targets with potential cumulative payments of up to $2.3 billion. Antibody Oligonucleotide Conjugates (AOCs) are designed to combine the specificity of monoclonal antibodies with the precision of oligonucleotide therapies to target the root cause of diseases previously untreatable with RNA therapeutics. This strategic collaboration broadens the reach of AOCs through the expansion of the existing relationship with Bristol Myers Squibb. Avidity continues to advance its internal research and development programs in rare cardiac indications.

Under the terms of the agreement, Avidity will receive $100 million upfront, which includes a $60-million cash payment as well as the purchase of approximately $40 million of Avidity common stock at a purchase price of $7.88 per share. Avidity is also eligible to receive up to approximately $1.35 billion in research and development milestone payments, up to approximately $825 million in commercial milestone payments, and tiered royalties up to low double-digits on net sales. Bristol Myers Squibb will fund all future clinical development, regulatory, and commercialization activities coming from this collaboration.

"We are excited to expand our collaboration with Bristol Myers Squibb, who are world leaders in cardiovascular drug discovery and development. This strategic collaboration solidifies our commitment in cardiology as we continue to advance our own research and development programs in cardiac indications," said Sarah Boyce, President and Chief Executive Officer at Avidity. "We look forward to broadening the utility of the AOC platform to address debilitating diseases previously unreachable with existing RNA therapies."

The collaboration with Bristol Myers Squibb is separate from Avidity's internal discovery pipeline consisting of research and development candidates to treat rare skeletal muscle conditions and rare cardiac muscle diseases. Avidity is currently advancing three distinct rare disease Phase 1/2 programs in the clinic: AOC 1001 for myotonic dystrophy type 1 (DM1), AOC 1020 for the treatment of facioscapulohumeral muscular dystrophy (FSHD) and AOC 1044 for the treatment of Duchenne muscular dystrophy (DMD) mutations amenable to exon 44 skipping (DMD44).

"This collaboration with Avidity represents an important part of our continued investment in innovative therapeutic approaches that have the potential to provide transformative outcomes to patients living with serious cardiovascular conditions," said Francisco Ramírez-Valle, MD, PhD, Senior Vice President and Head of the Immunology & Cardiovascular Thematic Research Center at Bristol Myers Squibb. "Aligned with our focus on causal human biology and efforts to successfully match therapeutic modalities to disease mechanism, our R&D organization will continue to leverage technologies like Avidity's AOC platform to identify meaningful

Oxford BioTherapeutics Announces Partner Boehringer Ingelheim Received Fast Track Designation for BI 764532 for the Potential Treatment of Advanced or Metastatic Large-Cell Neuroendocrine Carcinoma of the Lung

Oxford BioTherapeutics (OBT) recently announced the US FDA has granted Fast Track designation to BI 764532 for the potential treatment of advanced or metastatic large-cell neuroendocrine carcinoma of the lung (LCNEC-Lung) expressing DLL3 whose disease has progressed following at least one prior line of treatment including platinum-based chemotherapy.

BI 764532 is an investigational DLL3/CD3 IgG-like T-cell engager for potential treatment of patients with LCNEC-Lung that is being developed by Boehringer Ingelheim. The discovery of BI 764532 (OBT620) was enabled through a successful partnership initiated in 2013, leveraging OBT's proprietary OGAP drug discovery platform for identification of the DLL3 antigen and Boehringer Ingelheim's longstanding expertise in oncology and development of biotherapeutics.

As of November 2023, the FDA granted Fast Track designation to BI 764532 for the potential treatment of extensive-stage small cell lung cancer (SCLC) whose disease has progressed following at least two prior lines of treatment including platinum-based chemotherapy, and of advanced or metastatic extrapulmonary neuroendocrine carcinomas (epNEC) whose disease has progressed following at least one prior line of treatment including platinum-based chemotherapy.

BI 764532 was also granted Orphan Drug designation by the FDA for the treatment of SCLC, and is currently being investigated in a Phase 2 study, DAREON-5' (NCT05882058), in patients with relapsed/refractory extensive-stage SCLC and other relapsed/refractory NEC.

Christian Rohlff, Chief Executive Officer of OBT, said "We are delighted about the clinical development to help address unmet needs for people living with small cell lung cancer and other neuroendocrine carcinomas. This is an important milestone for our teams and exciting news for the community"

FDA's Fast Track designation is designed to facilitate the development and expedite the review of new drugs that are intended to treat serious or life-threatening diseases and that demonstrate the potential to address unmet medical needs.

Oxford BioTherapeutics is a clinical-stage oncology company with a pipeline of first-in-class immuno-oncology (IO) and antibody-drug conjugate (ADC) based therapies designed to fulfil major unmet patient needs in cancer therapeutics. These include bispecific, Chimeric Antigen Receptor T Cell (CAR-T), Antibody Drug Conjugate (ADC) and Antibody Dependent Cell-mediated Cytotoxicity (ADCC) therapeutics.

OBT's first clinical program, OBT076, initiated expansion in a US Clinical Trial in 2021 in patients with advanced or refractory solid tumors, including gastric, bladder, ovarian and lung cancer, where CD205 is overexpressed. Infiltration of tumors by immunosuppressive cells correlates with adverse outcomes (lower progression free and overall survival), suggesting that this process contributes to the progression of several cancers.

OBT's proprietary OGAP target discovery platform is based on one of the world's largest proprietary cancer membrane proteomic databases, with data on over 5,000 cancer cell proteins providing unique, highly qualified oncology targets, of which three programs are in clinical development in the US and Europe. OBT's IO discovery process provides unique insights into the cancer-immune cell synapse and has identified several novel IO monoclonal and bispecific antibody candidates for cancer therapies.

Mural Oncology Launches to Advance Pipeline of Novel Engineered Cytokine Immunotherapies

Mural Oncology plc recently launched as an independent, publicly traded, clinical-stage immuno-oncology company leveraging its core competencies in immune cell modulation and protein engineering to develop novel, investigational engineered cytokine therapies designed to address areas of unmet need for patients with a variety of cancers. Mural's ordinary shares will begin trading on the Nasdaq Global Market on November 16, under the ticker symbol MURA.

"Immunotherapies have made a tremendous impact on the treatment of cancers over the past decade," said Caroline Loew, PhD, the company's Chief Executive Officer. "Unfortunately, many patients either do not respond or do not have durable responses. We believe Mural Oncology can lead the future of immunotherapies for patients. Our protein engineering expertise allows us to reimagine the development of pro-inflammatory cytokine-based therapeutics that could address the key limitations with current cancer immunotherapies. I am thrilled to lead this company and am energized by the enormous potential of our lead clinical candidate, our preclinical programs, and our underlying protein engineering capabilities."

Mural Oncology's pipeline is built to address difficult-to-treat tumor types where checkpoint inhibitors are not effective. The Company's lead product candidate, nemvaleukin alfa (nemvaleukin), is an investigational, engineered interleukin-2 (IL-2) cytokine designed to capture and expand the therapeutic benefits of high-dose recombinant human IL-2 (rhIL-2), while mitigating the hallmark toxicities of native IL-2 in difficult-to-treat cancers with high unmet need. Nemvaleukin is currently in two potentially registrational studies: one for the treatment of mucosal melanoma as a monotherapy and one for the treatment of platinum-resistant ovarian cancer (PROC) in combination with pembrolizumab.

In addition to nemvaleukin, Mural Oncology has discovery-stage programs in IL-18 and IL-12, focused on proinflammatory cytokines that leverage the Company's immune cell modulation expertise and protein engineering capabilities. This multi-faceted approach to cytokine engineering is aimed at maximizing the utility of identified cytokines and includes binding selectivity, tumor-targeting, half-life modification, and stable fusion proteins.

"We believe nemvaleukin has the potential to reduce native IL-2's toxicities, potentially allowing greater tolerability and efficacy than other IL-2 molecules have shown in the past," Dr. Loew continued. "We plan to report top-line results in each of mucosal melanoma and PROC in the first quarter of 2025 and declare product candidates across both of our other discovery-stage programs in 2024. We are building on years of foundational work from which our engineered cytokines may lead to new therapies for significant patient populations where checkpoint inhibitors either failed to achieve a response or produced a limited response. We believe these new therapies could be effective either as monotherapies or in combination with a range of other therapeutics."

To advance the company's pipeline and capitalize on its protein engineering capabilities, Mural has assembled an experienced and highly accomplished executive team and board of directors.

Formulation Forum

Nanosuspensions- A Enabling Formulation for Improving Solubility & Bioavailability of Drugs

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

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INTRODUCTION

In the recent past, the industry is adapting innovative technologies as more new chemical entities (NCEs) coming out of discovery are poorly soluble, and hence, enhancing their performances, solubility, permeation, and bioavailability remain at the forefront of development.[1] By utilizing new approaches like amorphous solid dispersions, such as spray drying, hot melt extrusion, co-precipitation, among others, a considerable number of the NCEs have been marketed in the past decades.

Nonetheless, utilization of the most classical methods like nano-milling, complexation, and salt formation has also yielded a number of drugs to market as innovation and more NCEs continue to fill the pipelines.

Nanosuspensions are colloidal dispersions composed of nano-sized drug particulates stabilized by suitable stabilizers.[2] Nanosuspension formulation technology has overcome many of the challenges posed by insoluble molecules stemming from high melting and/or higher logP. In spite of all of these enabling technologies, the nanosuspension is ideally relevant for poorly soluble drugs with high crystal energy in lipids or aqueous solutions. The nanosizing by homogenization or milling results in drugs with reduced particle size, which allows higher per volume loading, thereby making them ideal for depot delivery via the subcutaneous route for long-acting injectable or oral administration of insoluble molecules.[3] Examples of drugs marketed as nanosuspensions include griseofulvin, fenofibrate (Tricor®), megestrol acetate (Megace® ES), sirolimus (Rapamune®), among others that utilize one or more excipients, polymers, and/or surfactants to stabilize these nanoparticles by minimizing the electrostatic interactions, thereby preventing flocculation and enhancing long-term stability in the crystalline state.[4] Unforeseeable challenges could stem from maintaining the supersaturation of drugs, especially from those in amorphous states. However, nanosuspensions are proven to be ideal when administered, eg, IV, IM, or SubQ as the macrophages act as the reservoirs for slow release of the molecules, resulting in prolonged pharmacokinetics profiles while maintaining the therapeutic's concentration and minimizing the drug's systemic toxicity, and enhancing the efficacy at higher dosing levels. Likewise, the oral administration of nanosuspensions resolves many challenges stemming from dose dumping and variabilities, faster onset, and minimizing the food effects in fed and fasted states. Nanosuspensions can also be sterilized by filtration, dry heat, steam, and radiation.[3]

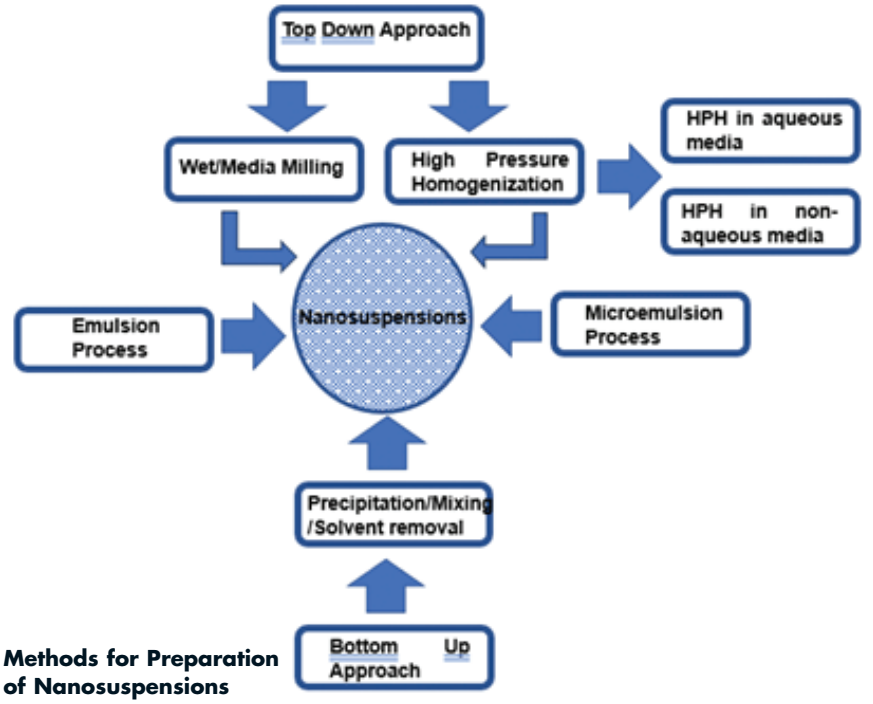
The following focuses on the role of excipients and methods for preparation and application of nanosuspensions in injectable, ocular, topical, and oral drug delivery.

ROLE OF EXCIPIENTS IN NANOSUSPENSIONS

Stabilizers

Povidone, Polysorbate 80, synthetic and natural lipids, cellulosic ingredients (MC, HPMC, EC, HEC, HPC, CMC), Soluplus®, Poloxamer 188, Poloxamer 407, sodium lauryl sulfate, polyvinyl alcohol, vitamin E TPGS, polyethylene glycols, among others are commonly used stabilizers for nanosuspensions. They play an important role in nanosuspensions for stabilization of high energy nano-sized crystals prepared via milling or homogenization. One stabilizer is preferred over others depending upon the nature of administration routes, such as oral versus injectable. In certain cases, a mixture of two or three stabilizers are used. The mechanism by which these particles are stabilized is wetting of the particle

FIGURE 1



Methods for Preparation of Nanosuspensions

size, thereby preventing agglomeration by steric repulsion barrier around and minimizing Ostwald's ripenings. The chemical nature and composition of the stabilizers have pronounced effects on the physico-chemical stability and *in vivo* performance of nanosuspensions.[5]

Organic solvents and lipid-based surfactants/co-surfactants are also predominantly used when using microemulsions for formulation of nanosuspensions. These include bile salts, transcutol, and solvents like glycofurol, ethanol, and isopropanol.

PREPARATION OF NANOSUSPENSIONS

For preparation of nanosuspensions, top-down and bottom-up approaches are commonly used, as shown in Figure 1.[6-8] In addition, there are other ways to prepare nanosuspensions, such as emulsion and microemulsion processes.

TOP-DOWN PROCESS FOR NANOSUSPENSIONS

Wet/Media Milling

Nanosytems originally developed wet/media milling technology, which involves the use of high-shear milling of drug, stabilizers, and water.[5] The high-shear grinding results in breaking down large particles into nano-sized crystals under controlled temperature until a desired unimodal particle size distribution of 200 nm is obtained. This process is simple and results in a desired particle size of drugs. For instance, after high-shear wet milling, the particle size of naproxen is reduced to a mean particle size of 0.147 microns (D_{90} 0.205 microns) from a mean particle size of 24 microns (D_{90} 47 microns) within 30 minutes.[9]

The advantages of high-shear wet milling involve include easy scalability, less variations from batch to batch, drugs compatible to 1organic or aqueous milling, and milling flexibility with handling of drug concentrations as high as 400 mg/ml in nanosuspensions.

High-Pressure Homogenization

This method requires high-pressure, high-shear homogenization using microfluidization, Disso Cubes technology, or Avestin's piston gap homogenization. This homogenization process requires the fracture of drug particles by cavitation, high-shear force collision of particles against each other. The collision of the particles at high speed helps break the particles into smaller particles to achieve nano-sizing. In some cases, increasing the viscosity of media helps enhance the nano-sizing efficiency by increasing the powder density within the dispersion media. Usually, multiple homogenization cycles (5-10 cycles) are used to achieve the desired unimodal particle size distribution with a narrow polydispersity index. Similar to wet-milling technology, the advantages of high-shear homogenization include easy scalability, compatible to drugs in organic and aqueous solutions, flexibility for higher drug loading (>400 mg/ml), and suitability for aseptic production of parenteral nanosuspensions.

BOTTOM-UP PROCESS FOR NANOSUSPENSIONS

The bottom-up method involves a number of processes, including precipitation, microemulsions, among others as described further. This method requires the dispersion of drug dissolved in organic solvent to aqueous solution containing a suitable solubilizer/co-surfactant followed by agitation to yield precipitates/emulsions. Following evaporation of solvent, the drug immediately precipitates into aqueous phase, resulting in surfactant-stabilized nanosuspensions. Organic solvents, such as methylene chloride, chloroform, ethyl acetate, ethyl format, ethanol, among others, are used in preparation of nanosuspensions via precipitates/emulsions. These solvents can also control the emulsion droplets, which in turn

control the particle size of nanosuspensions. In some cases, a hybrid process combining bottom-up and top-down is utilized to ensure better control of size distribution.

Microemulsions are thermodynamically stable, clear dispersions of two immiscible liquids (oil and water), which are stabilized by interfacial films of a surfactant and co-surfactant. They offer advantages of easy scale up and manufacturing, high levels of solubilization and drug loading, and long shelf-life. Griseofulvin, an anti-fungal drug, for example, has been investigated as a microemulsion in nanosuspensions showing a 3-fold faster dissolution compared to a marketed drug, suggesting the co-surfactant caused faster dispersion of drug from nanosuspensions.[10]

CHARACTERIZATION OF NANOSUSPENSIONS

Particle Size Distribution (PSD)

The mean particle size of nanosuspensions is a key governing factor for saturation solubility, wettability, and dispersion ability and physical stability. In general, large particle size dispersibility is much slower compared to smaller particle nanosuspensions, which dictates the performance of drugs. There are several methods to measure the PSD, including photon correlation spectroscopy (PCS) or dynamic light scattering (DLS), which are used to measure rapid and accurate PSD and polydispersity index (PDI) of nanosuspensions. PDI is an important parameter that dictates the unimodal (PDI 0.1-0.25) or multimodal distribution (PDI > 0.5) of the particulates and governs the physical stability of nanosuspensions. With its limited ability to measure the particle size in the range of 3 nm to 3 microns, PCS may not be applied to large particulates of the suspensions for contaminants averaging particle size > 3 microns. In those cases, the laser diffraction (LD) technique is used. It has the ability to measure particle size in the range of 0.05-80 microns or much higher (2000 microns). The samples are diluted to measure the PSD by LD or PCS, and both use different principles to measure the particle size, eg, LD measurement is volume based, whereas PCS is light-intensity weighted size. Therefore, measurement from each differs considerably, and LD often yields higher values than PCS.[11] In other techniques, for example, Coulter counter gives more precise measurement for PSD per volume unit compared to LD and/or PCS, which is important to identify the contamination with lager particles of nanosuspensions intended for IV administration.

Zeta potential of nanosuspensions is an important attribute for physical stability and performance of drugs. A zeta potential of ±30 mV is required to electro-statistically stabilize nanosuspensions. In some cases, a zeta potential of ±20 mV is desirable for better stability and preventing aggregation of nanosuspensions.[12] In addition, morphological and surface properties, rheological properties, and solid state characterization methods, such as DSC, XRPD, and FTIR and Raman spectroscopy, are used to characterize nanosuspensions.

Solidification & Stability of Nanosuspensions

Nano-sized drug suspensions are in a kinetic stable state. In spite of a range of polymers and solubilizers used to stabilize these particulates in nanosuspensions, it is often impossible to inhibit the nucleation of nano-sized particles. To alleviate these challenges, in addition to stabilizers, other methods, such as drying or lyophilization of the formulation, is necessary for long-term stability-enhanced shelf-life and avoiding aggregation and degradation by hydrolysis. Matrix former water-soluble cryoprotectants, such as mannitol, sucrose, glucose, dextran, and trehalose, are commonly used to preserve the physio-chemical properties of nanosuspensions in lyophilized or freeze-dried forms.[13] Spray drying can also be used to preserve the physio-chemical stability of drugs in nanosuspensions.[14]

APPLICATION OF NANOSUSPENSIONS IN DRUG DELIVERY

Oral Drug Delivery

Nanosuspensions have been used in formulation of several marketed drugs with the aim to improve solubility and bioavailability of poorly soluble molecules. Nano-sizing helps increase the surface area, enhances wettability and hence the dispersibility in aqueous medium, and significantly increases kinetic solubility, permeability, and absorption of drug molecules. A few examples of orally marketed drugs includes the following:

- Atovaquone, an antibiotic for treatment of viral infection in HIV patients, with bioavailability 10%-15%, improved the oral bioavailability by 2.5-fold by nanosuspensions compared to the marketed drug Wellvone®.
- Danazol, a poorly soluble and bioavailable drug, showed a significant increase in oral bioavailability of 82% in nanosuspensions with respect to 5.2% of the marketed drug Danocrine. In addition, it also minimized the dose variability and food effect in fed/fasted states when dosed at 200 mg.[15]
- In naproxen's case, when this drug was administered as a nanosuspension, it enhanced faster absorption, reduced the tmax to half, increased 2.5- to 4.5-fold AUCs during the first hour of intake compared to suspension (Naprosyn) and tablet (Anaprox) formulations. In addition, it also minimized food effect in fed/fasted states and reduced the dose variability.[9]

Like several marketed drugs, a number of drugs have also been investigated in oral nanosuspensions.[16] Nanosuspensions are ideally dosed as liquid capsules in hard gels and/or soft gels because many of the poorly soluble drugs require technologies for immediate delivery of molecules, and formulation of these molecules for oral sustained or controlled release may be challenging due to risk of dose dumping and poor *in vivo* performances. However, finding the appropriate excipients that could incorporate nanosuspensions as tablets or fast melt caplets might be advantageous for prolonged delivery, reduced food effects, and inter-subject dose variability. Ketoprofen, for example, has been successfully incorporated into pellets for sustained release of drug over 24 hours.[17]

Parenteral Drug Delivery

A range of molecules in several marketed drugs have been investigated as nanosuspensions in injectable formulations.[16] Parenteral routes of administration (especially, IV, IM, or SubQ for nanosuspension) offer a limited choice of excipients not only in selection of key ingredients, but also the amounts used in such formulations often dictated by the FDA' s inactive ingredient database. This database also creates a bottleneck of finding the appropriate excipients for such use, primarily driven by lack of safety data and bioburden for a particular ingredient. Furthermore, stringent requirements for aseptic processing, concerns of cross-contamination, safety and foreign particulates in manufacturing and, on the other hand, the lack of patient compliance and concerns of allergic reactions and any adverse effects, all impede the development of injectable formulations. In spite of all the hurdles, the injectable route, though is invasive, remains widely used for potent and high-valued drugs for quick onset for regular and emergency use and reduces dosing frequencies for long-acting injectables and for targeted

Ascendia's cGMP wet-milling equipment - Netzsch SystemVita DV600GV25/100 for top-down nano-sizing, micromilling, and preparation of sterile NPs.

delivery. Nanosuspensions offer solutions to all the challenges due, in part, to low-volume administration especially via IM and SubQ, reducing dose frequencies and maintaining the drugs over extended periods by the lymphatic system.[18] It is therefore ideal for drug delivery of small and large molecules. Sequestered by mononuclear phagocytic systems (MPS) upon IV administration, nanosuspensions offer higher efficacy of anti-biotics and anti-infective drugs for which they can be targeted by macrophages leading to prolonged and sustained release.[19] Unlike IM and SubQ administration, IV administration of nanosuspensions may cause incontrollable dissolution rates, leading to accumulation of drugs in the reticuloendothelial system or macrophage systems (MPS) in liver and spleen, with increased risk of organ damage and unpredictability in safety and efficacy of drugs.[20] These challenges have resulted in the launch of several oral and IM drugs to the market, and fewer by IV route.[21]

Pulmonary Administration of Nanosuspensions

Pinar et al 2003, describe a number of drugs in pulmonary applications. Increasing the surface area to improve bioavailability by reducing particle size of nanocrystals with prolonged residence time in lungs provides a better strategy for achieving the desired efficacy though inhalation. It can lead to rapid onset, thereby avoiding systemic toxicity in the mouth and/or pharynx by unwanted drug accumulation. This is achieved by using nebulizers (jet or mesh) or aerosol meter dose or powder inhalers. In such cases, the particle size of nanocrystals and their controls with aerodynamic diameter of 1-5 microns are critical for optimal pulmonary delivery.

Ocular Drug Delivery

Ocular drug delivery via nanosuspensions remains at the forefront of treatment of eye diseases for both hydrophobic and hydrophilic drugs across the ocular mucosa.[22] These formulations are designed to permeate the corneal membrane with controlled-release excipients for sustained and prolonged release with their abilities to enhance the absorption and bioavailability of drug molecules and with intent to reduce toxicity, side effects, and drug dosing. Treatments for eye diseases, such as diabetic retinopathy, glaucoma, macular degeneration, conjunctivitis, proliferative vitreoretinopathy, among others, are within reach due in part to formulation of drugs in nanosuspensions composed of solubilizers, viscosity enhancers, charge modifiers, stabilizers, and polymeric excipients to achieve optimal retention, permeation, and tolerability at the ocular site.[23]

SUMMARY & FUTURE PERSPECTIVES

As more insoluble NCEs are discovered, nanosuspensions have become a popular choice to enhance the solubility and bioavailability of BCS II and IV drugs, driven by their low solubility and permeability. Nanosuspensions containing nano-sized crystals and stabilized with polymeric solubilizers and permeation enhancers leverage added benefits for screening of a broad range of NCEs across all modalities via oral, injectable (IV, IM, and SubQ), ocular, pulmonary, and topical routes of administration. Evidently, this has resulted in the launch of many drugs over the years, and as the new molecules continue to be discovered, the industry is open to adapt all the classical and non-classical technologies to bring NCEs to the pipeline, clinical development, and commercialization. The advent of antibody drug conjugates (ADCs) for delivery of high-concentration monoclonal antibodies (mAbs) will open doors for SubQ administration of nanosuspensions.[24]

Ascendia remains at the innovation front of utilizing its enabling platform technologies to screen, formulate, and manufacture NCEs for its clients. Nanosuspensions applicable to molecules across all dosage forms can easily be adaptable via seamless transition from the early research phase to clinical manufacturing of new drug candidates. With Ascendia's expertise in top-down and bottom-up (solvent inversion) approaches coupled with its cGMP sterile and non-sterile capabilities and state of-the-art facility and equipment, our team is ready to handle small molecules and biologics across all modalities for oral, injectable, ocular, and inhalation delivery in nanosuspensions. ◆

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Drug Development
EXECUTIVE

Jan Vertommen

Vice President,
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Development

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Small Molecules

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Lonza Small Molecules: Facing up to the Challenges of Drug Development

In recent years, there has been a significant growth in the proportion of the pharmaceutical development pipeline that originated in small and emerging companies. These businesses rarely have their own capabilities for scale-up and manufacture, and adding to the challenges they face is the increasing likelihood they will retain the assets in-house until the later stages of clinical development. CDMOs such as Lonza are therefore key partners for emerging companies in the pharma-biotech sector as they look to progress their promising molecules through the development pipeline and on to the market. As an integrated CDMO, Lonza is also well placed to assist in overcoming a wide range of issues that might arise, from complexity to capacity. *Drug Development & Delivery* recently interviewed Jan Vertommen, Lonza's Head of Commercial Development (Small Molecules), to discuss some of the challenges facing the sector and how his company is looking to address them.

Q: It's no secret CDMOs working in the pharma/biotech sector are facing multiple challenges, whether from the molecules they are asked to make or the wider business environment. Let's start with the molecules. What's getting harder?

A: It all boils down to increasing complexity, in all of its forms. With so many of the "easy wins" having already being met in terms of therapeutic targets, pharma and biotech companies are increasingly working on targets that are more difficult to address, if not previously thought undruggable. As a result, the molecules now entering their development pipelines are more likely to be difficult to make, difficult to formulate, or both.

The difficult-to-make aspect might be that the molecule itself is complicated; it might also mean the synthetic route to make it is long-winded. On the formulation

side, in recent years, the molecules heading into the clinic have become increasingly likely to be insoluble, with knock-on effects on their bioavailability. All of these challenges can usually be overcome, but it takes expertise – and experience.

Q: What are you doing to try and address these complexities?

A: One way Lonza Small Molecules is trying to address the difficult-to-make problem is by applying artificial intelligence (AI) to find shorter, more efficient synthetic routes. The lab-scale routes used to make drugs entering the pipeline are getting ever longer, but the more steps a synthesis has, the more likely it is to have a low overall yield, and take longer to complete, not to mention generate more waste. Our new Route Scouting offering combines our in-house database of reactions, reagents, and raw materials with AI tools that suggest potential synthetic routes, and these can be tested in an automated system. It provides a great support for our process chemists as it is able to evaluate and check a route far more quickly than they could do on their own.

The likelihood of a molecule being deemed highly potent is also increasing, not least because of the continuing interest in antibody drug conjugate (ADC) molecules that combine a targeting antibody with a highly potent API. These require very careful handling, and the right equipment must be in place to ensure both plant operators and the wider environment are effectively protected from these drugs, as they have pharmacological effects in extremely small doses. The ongoing growth in this market means we have made strategic investments in capabilities and capacity to ensure we can keep up with demand.

We've also made significant investments in our solid form services. The right tactic varies from one molecule to the next, clearly, but it may involve finding a more stable crystal form. To tackle the solubility challenge, spray drying to create an amorphous form often comes into the picture.

Q: Away from the nuts and bolts of manufacturing, the Covid-19 pandemic caused significant disruption to our lives and businesses, and the world is still recovering from its impacts. How is it continuing to affect pharma?

A: One notable way is the decline in biotech funding that we've seen over the past couple of years. Funding – rightly – spiked very significantly in 2020 and 2021, as the world searched for drugs to treat and vaccines to prevent Covid-19 infections. Venture capital investments, financing rounds, and IPOs hit record levels in 2021 as a result.

However, since these huge peaks, funding availability has now declined once more, returning far closer to the levels we saw before Covid-19 turned our lives upside down. And, as a result, small and emerging biotech businesses are feeling the squeeze. Significant funding is only likely to be available if a company has an exceptionally promising pipeline, backed up by a sound business model and an experienced, proven management team.

Unsurprisingly, this has led to companies being far more careful in their spending decisions. Companies are becoming far more selective in their progression decisions as they look to ensure only the most likely to succeed are pushed forward.

Equally unsurprisingly, this is having a knock-on effect on the CDMO world. Existing customers, we have found, are starting fewer new projects, although we have seen an increase in new customers committing their business to us.

Q: What sort of impact is this having on project timelines?

A: It is clear companies are now more likely to delay the start of a manufacturing campaign rather than risk resources being wasted on a project that might not progress after all. In the past, in the interests of speed, they might press on with the next part of a manufacturing campaign after a positive signal was seen in a trial. This financial risk might be avoided by waiting until the trial's full results are available, albeit with the knock-on risk the timeline might be pushed back as a result. It's a real balancing act.

There is another knock-on effect for CDMOs here, too – capacity availability is currently significantly better than it has been in recent years because fewer projects are competing for it. Biotechs may believe they don't need to rush to tie down capacity well in advance, believing that it's likely to be available when they actually need it. It remains to be seen how capacity availability will trend in the coming years. It all goes back to the availability of funding, and if that spikes upward again, there will likely be an uptick in demand for manufacturing capacity. ◆

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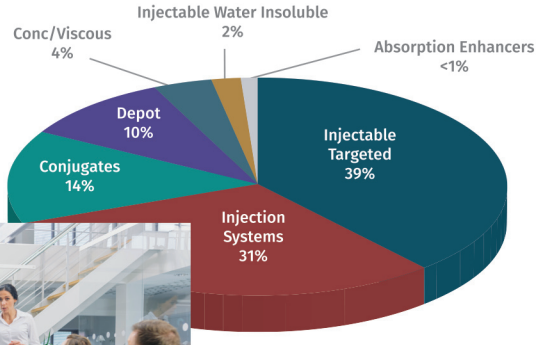

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PHARMACEUTICAL GLOBALIZATION

Navigating Opportunities & Obstacles

By: Jürgen Hönig, PhD

INTRODUCTION

There are many reasons to celebrate the globalization of the pharmaceutical industry. It brings with it access to medicinal products for far more patients, as well as greater commercial opportunities for pharmaceutical companies.

At the same time, globalization adds complexity. Companies must navigate ever-changing regulations and government policies that differ across jurisdictions. They must consider cost constraints or expectations at the local and regional levels that can affect market access. And they must consider heightened consumer demands.

This environment means companies must plan strategically, drawing on good regulatory intelligence, before launching their products. This need is further accentuated by the fact that drug development, particularly for innovative products, can span 8 to 15 years, meaning it's a significant challenge for companies to predict the global regulatory landscape at the time of submission or even being granted marketing authorization.

Companies should consider early market access strategies, carefully selecting which markets to pursue first and how to repurpose a regulatory submission to best effect, taking into consideration economic factors, in particular the relationship between expected profitability and investment in research and development. They should seek to gain insights into the market and regulatory dynamics in each region and have on-the-ground expertise in all markets they plan to target. And they must ensure they understand the patient population and medical need in each market.

MAKING THE MOST OF HARMONIZATION

The most notable regulatory harmonization initiative is that of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), which works collaboratively across regulators and industry to develop uniform guidelines and technical requirements. ICH members adopt those guidelines, helping to:

- create greater uniformity around quality, safety and efficacy criteria
- support the electronic transfer of regulatory information
- adopt a common format for information sharing
- use standardized medical terms to enable regulatory information to be shared internationally

Certainly, COVID-19 helped to accelerate the level of collaboration between regulators. As highlighted in a Lancet paper, there was unprecedented convergence in regulatory requirements to support vaccines and therapeutics for COVID-19, enabling developers to set development plans without significant hurdles.[1]

Propelled, in part, by the urgent need for more agile regulatory processes during the pandemic, a number of harmonization initiatives have developed between regulatory authorities. Most notable are the Access Consortium and Project Orbis.

The Access Consortium was established to promote collaboration among regulators across different geographic regions, as well as better alignment of requirements for assessment and approval of medicinal products. Its members include the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), Health Canada, Australian Therapeutic Goods Administration (TGA), Swissmedic, and Singapore's Health Sciences Authority

(HSA). The goal is to work toward a goal of improving cooperation, reduce regulatory duplication, and increase each agency's capacity to ensure consumers have timely access to safe and effective medicinal products.

In its strategic plan overview, the consortium noted "Greater regulatory agility and international alignment by sharing of scientific resources and expertise, while at the same time maintaining independent regulatory decision-making within each authority, will reduce a product's time to a wider market. Exploring collaboration with national health technology assessment organizations (and similar) by Access countries also serves to improve patient access to safe and effective health products."[2]

Project Orbis, meanwhile, was established in 2019 as a collaboration between the US FDA, the TGA, and Health Canada. Since its initial launch, several other regulatory authorities have joined: Brazil's Health Regulatory Agency (ANVISA), Israel's Ministry of Health Pharmaceutical Division, HAS, and the MHRA. The aim of Project Orbis is to cut cancer drugs' review time across country borders, facilitating concurrent submissions by sponsors and collaborative reviews between agencies.

Project Orbis is a model for regulatory collaboration that is taking shape around the world and a reminder that collaboration is the key to improving the review process and access to life-changing medicines.

For its part, the UK's MHRA has been taking broad steps to streamline and harmonize processes, recently announcing plans for a new international recognition framework.[3] The MHRA adopted the European Commission Decision Reliance Procedure (ECDRP) after Brexit, extended to the end of 2023, which allowed the UK agency to fast track any products managed by the European Medicines Agency (EMA) and granted marketing authorization by the EC. From the start of 2024, MHRA will introduce the new framework, which will consider decisions by EMA and some other regulators, enabling a simplified, more harmonized route to market in the UK.

There are also initiatives to improve regulatory harmonization to enable better access to medicines in the developing world. Led by the World Health Organization (WHO) and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), efforts have focused on a drug classification system, International Pharmacopoeia and standards for pharmacovigilance through the WHO Program for International Monitoring, and a medicines prequalification program to facilitate the distribution of drugs to developing nations.

EARLY ACCESS HARMONIZATION

Important early access initiatives in the EU, UK, and US are also starting to see greater harmonization. Recently, the EMA introduced several important changes to its PRIority Medicines (PRIME) scheme, which seeks to speed the development of life-changing medicines.

Changes to the scheme include a roadmap to assist innovator companies when compiling information, expedited scientific advice, and submission readiness meetings a year ahead of submitting a marketing authorization application.

These changes bring PRIME into closer alignment with the UK's Innovation Licensing and Access Pathway (ILAP) program, which provides tools to support companies through the development

process. ILAP is similar to the FDA Fast Track process, which enables rolling reviews and allows applicants to submit completed sections for review rather than waiting until the entire application is complete.

With the PRIME changes, developers of innovative products can take advantage of greater harmonization between the three regions with regard to scientific advice and regulatory support.

Early access or accelerated access programs, such as for orphan drug products, can guide market decisions. If navigated effectively, making use of scientific advice offered by many regulators, companies may be able to design strategically considered dossiers that might then be leveraged for easier transfer to other markets.

NAVIGATING DIFFERENCES

While there is fairly seamless harmonization between some authorities, for example, the FDA and Health Canada, that is not always the case. Some emerging markets have not only tightened their regulatory requirements but also have some region-specific expectations. For example, in some Asia-Pacific markets, high-level knowledge of the regulation is not sufficient. Rather, companies must have access to the local health authorities through face-to-face interactions to understand and interpret what they want and expect.

It is important to understand regulators in many developing countries must balance public health requirements with cost, while responding to rapid change as these markets open up and expand. After all, there are currently 300,000 manufacturing facilities in 150 countries – countries that are not only producing products but also seeing increased demand for medical goods and services.[4]

Different approaches to the regulation of medicines can also occur in regions where there is, ostensibly, full harmonization. In the EU, despite efforts by the EMA to ensure consistency across member states, there are varying requirements and expectations in various countries when it comes to specific tasks that must be carried out at the national level.

One notable example is advertising of prescription medicines. The principles that underpin responsible advertising and promotion often get fleshed out in detail on a national level through self-regulation and adherence to industry codes of practice, reflecting the norms, lifestyles, and societal preferences of those local markets.

The supply chain is another market difference that is often poorly understood. When seeking global launches, companies need to know whether the product or active pharmaceutical ingredients and excipients can be imported from the country of origin. If not, they must ask themselves some critical questions, such as: What are the logistical challenges with building a manufacturing site in the target markets? Is there potential to partner with third-party manufacturers? What are the regulatory requirements to register those sites? Can increased demand in a certain country/region be managed by importation?

LOCAL & GLOBAL REGULATORY INTELLIGENCE

Local regulatory intelligence and on-the-ground expertise in all the markets a company operates in are imperative for that adherence to local requirements and for interacting effectively with health authorities. As an example, in the area of pharmacovigilance, most regulators require a local contact person who is a citizen of and physically located in that country.

Good regulatory intelligence is also important if companies are to streamline their submission processes, such as leveraging a submission with a reference country – in other words, countries or regions with trusted regulatory authorities, such as the US or EU or a comparable health authority – when seeking to bring those innovations to other markets.

Regulations and legislation are constantly evolving, and companies must deploy regulatory intelligence – internally or externally – to stay on top of these. As an example, the European Commission recently submitted a proposal for a new Directive and a new Regulation to the European Parliament and Council for consideration.

The new legislation seeks to drive innovation, to ensure the safety, quality, and efficacy of medicinal products for EU patients, and to harmonize the supervision and control of such products. In particular, the legislation will repeal and replace general and specific legislation, such as the Orphan Regulation and the Paediatric Regulation, with legislation that applies to all other products. The new EU legislation incorporates specific requirements that apply to these products in the new regulation and the directive "in order to ensure clarity and coherence of all the measures applicable to these products."[5]

This puts everything in a consolidated legal document that provides more precise guidance, enabling more strategic planning for companies, ensuring they have clear guidance in one place to support

them from early development and to understand what regulators expect.

PREPARING FOR REIMBURSEMENT

As complex as the regulatory landscape is, an even greater source of uncertainty for the industry is market access and reimbursement. To gain market access, developers must be able to demonstrate clinical and economic evidence to providers, healthcare decision-makers, and payers – be these insurers, government programs, or health technology assessment bodies (HTAs).

They must not only show the efficacy and safety of their product, but also its effects on healthcare outcomes and resource utilization. To effectively demonstrate their product's value to payers, developers must be able to show how their product improves patient outcomes or reduces the burden on the patient and the healthcare system. That means having good real-world evidence to provide a better value proposition to decision-makers.

Too often, given the time span for development and not always knowing the intended markets early on, this process only begins later in product development, by which time it is too late to determine if the clinical trial and clinical data fits the needs of the HTA.

Early phase modelling, which evaluates costs and expected outcomes of new and current treatments using assumptions and extensive sensitivity analysis, should be performed as soon as possible in the product development process when there is a need to understand opportunities and challenges from a health economic perspective.

The importance of early discussion, particularly for novel therapies, is again underscored with the UK's ILAP program, which is a collaboration between the MHRA, the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC), and the All Wales Medicines Strategy Group (AWMSG).

As Daniel O'Connor, Deputy Director of Innovation Accelerator and Regulatory Science in the Scientific Research and Innovation Group at the MHRA, has noted "If a company wants to do something novel or if it wants to try to push the boundaries on the acceptability of the data or think about different managed access approaches, then having those early discussions with both the medicines regulator and the HTA bodies is key."[6]

CAUTIOUS PROGRESS

Globalization has brought with it numerous issues to consider at every stage of the journey – whether bringing an innovative product to market or planning expansion initiatives. Yet, it has also created new opportunities to bring products to more people in more markets.

From important cooperative programs, such as the Access Consortium and Project Orbis, to efforts by global organizations, such as ICH, WHO, and IFPMA, there are growing opportunities to streamline global regulatory processes. Differences remain – and likely will continue, due to the needs and expectations of each market – but by taking advantage of important programs and staying on top of market dynamics through regulatory intelligence, companies can enjoy greater success globally. Most importantly, increasing numbers of patients in developed, emerging, and developing countries that will enjoy access to these medicines.

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6. Science Huddle – Small Data, Big Outcomes, Biopharma Excellence. https://www.biopharma-excellence.com/insights/whitepapers/strategies-for-achieving-statistical-significance/.

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CLOUD COMPUTING

Revolutionizing Antibody Discovery: The Role of Cloud Computing

By: Suhani Nagpal, PhD, Laura Spector, PhD, and Frank Erasmus, PhD

INTRODUCTION

Antibody therapies are an important class of drugs that have exhibited outstanding efficacy and safety in the treatment of many major diseases, including cancers, auto-immune, hematological, and infectious diseases, including COVID-19. Considerable progress has been made in the global research and development of antibody therapies in the past decade.

The antibody market is also the fastest growing class of therapeutics, with 9 of the top 20 best-selling drugs, and is projected to grow from $178.50 billion in 2021 to $451.89 billion in 2028 at a CAGR of 14.1%.[1,2] According to the Umabs-DB, 162 antibody therapies have been approved by at least one regulatory agency in the world, including 122 approvals in the US, followed by 114 in Europe, 82 in Japan, and 73 in China. While the US and Europe have led the way in antibody drug discovery for decades, Japan and China have made significant strides in the past decade.[3]

Traditional methods of antibody discovery using random colony screening and low-throughput Sanger sequencing are inefficient and incomplete. Due to the inherent limited sampling in this approach, understanding the complete binding diversity is nearly impossible at a reasonable cost, which makes it difficult for many small biotech companies to compete. Further, such traditional approaches only capture a fraction of the diversity, lowering the potential to find antibodies with desired specificity or biophysical properties.

The advent of next-generation sequencing (NGS) and high-throughput computing have revolutionized antibody discovery, making it faster, more efficient, and cost-effective. Cloud computing has further improved this process by reducing overhead costs as well as significantly simplifying the process. The following discusses the role of cloud computing in antibody discovery, its benefits, and its potential applications in the field of biotechnology.

ANTIBODY DISCOVERY

Antibodies are essential tools in diagnostics, therapeutics, and research. Antibody discovery, most often using *in vitro* (phage or yeast) or *in vivo* (hybridoma) technologies, is a crucial step to identify leads that bind specifically to target proteins.

The massively parallel sequencing

technology known as NGS includes several high-throughput approaches to DNA sequencing and provides extremely high throughput, scalability, and speed. NGS parallelization of sequencing reactions generates hundreds of megabases to gigabases of nucleotide sequence reads in a single instrument run. This has enabled a significant increase in available sequence data and fundamentally changed genome sequencing approaches in the biomedical sciences.[4]

Applying NGS to antibody discovery pipelines allows for more comprehensive coverage of output populations at substantially reduced costs. Further, advances in high-throughput computing and computational tools have simplified the handling of the large amount of data generated. This not only allows the expansion of diversity from any given selection campaign, but also reduces biases, such as favoring only the most abundant clones. The underlying statistics collected from NGS outputs enrich datasets, providing information that significantly improves ranking criteria for potential leads. Most importantly, the greater number of unique antibodies identified allows the use of unsupervised clustering to obtain diverse clones. This improves screening efficiency by eliminating redundancy arising from screening antibodies in the same cluster with similar binding properties.

The advent of NGS, high-throughput computing, and computational tools have elevated the need for cloud computing, before which companies had to rely upon the expertise of highly technical staff supported by computational overhead, making it challenging for organizations with fewer financial resources. Cloud computing involves the use of remote servers to store, manage, and process data, democratizing access to computational tools and computing power/compute resources across a broad spectrum of companies from small to larger biotech.

THE ROLE OF CLOUD COMPUTING IN ANTIBODY DISCOVERY

The emergence of cloud computing has revolutionized the field of biotechnology. In the case of antibody discovery, cloud computing enables the storage and analysis of large volume of data, particularly DNA sequencing data, leveraging sophisticated algorithms residing on remote servers, rather than on-premise. This allows screening of target antibody populations, derived from large antibody library selections or animal immunization, by rapidly performing complex calculations on massive amounts of data, making the process more efficient and cost-effective.

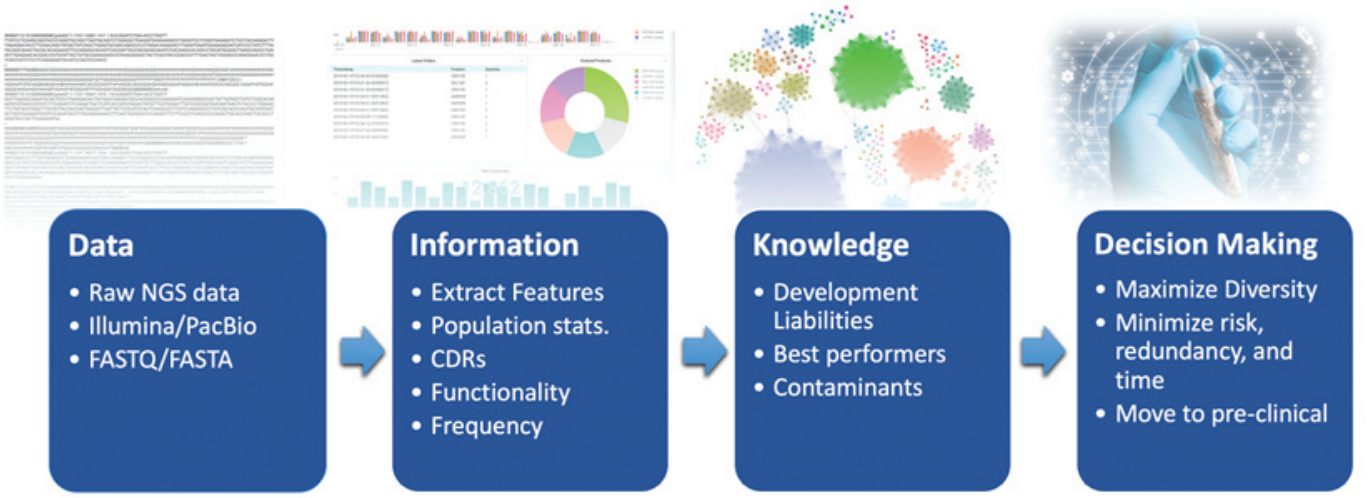
BENEFITS OF USING CLOUD COMPUTING IN ANTIBODY DISCOVERY

Other benefits to cloud computing are that it helps overcome any data sharing limitations, and empowers teams with easy access to software and computational resources. Data sharing, in turn, promotes collaboration and enables researchers to identify, visualize, and prioritize leads across distinct discovery campaigns through a cloud interface in real time.

Finally, as an increasing number of machine learning solutions are applied to the antibody space, the need to scale computational power poses a serious challenge. Before cloud computing, users were restricted to in-house hardware, requiring frequent updates and significant support from overhead informatic technical staff. Cloud computing reduces overhead and staffing needs by providing scalable access to computational power. Cloud-based antibody discovery platforms provide the flexibility to scale up or down depending on the needs of the project. Companies can easily access the computing resources they need to run their discovery programs, without having to invest in expensive hardware and infrastructure.

CLOUD COMPUTING BEST PRACTICES FOR ANTIBODY DISCOVERY

A key element of cloud computing best practices for antibody discovery includes benchmark datasets and validation studies. Benchmark datasets are compiled to compare the performance of a model against an industry standard, while validation studies test the performance of a particular tool against empirical performance metrics. This in turn allows for automating the workflows with tested parameters and simplifies the overall pipeline by uploading the sequencing data and inputting the desired number of leads. This creates a "plug and play" to run the calculation on the cloud. The best cloud computing platforms also provide adequate technical support and training, secure and reliable data management, and compatibility for various computation tools.



Cloud-based Discovery Platform Automates Antibody Lead Selection from Next-Generation Sequencing Data

CASE STUDY: SUCCESSFUL APPLICATIONS OF CLOUD COMPUTING IN ANTIBODY DISCOVERY

Selection campaigns from the Specifica Generation 3 antibody platform were conducted against three SARS-CoV-2 targets. Unique NGS sequences identified by the AbXtract module in the cloud-native Orion® Antibody Discovery Suite were compared to random colony screening for the same selection outputs. Antibody sequences were clustered by unsupervised machine learning, and genes corresponding to representative cluster antibodies were synthesized, expressed as IgG and experimentally tested for epitope binning by surface plasmon resonance (SPR).

As expected, this study showed that antibodies within clusters recognized identical epitopes, while antibodies recognizing distinct epitopes belonged to distinct clusters. This study validated Specifica's bioinformatics pipeline and clustering method to prioritize leads for experiments.

THE FUTURE PROMISE OF ANTIBODY DISCOVERY WITH CLOUD COMPUTING

The future of antibody discovery with cloud computing is promising, particularly by enabling the efficient deployment of artificial intelligence (AI) to this field at large scales. AI is composed of a wide variety of subfields, whereby machine learning, particularly deep learning (DL) and natural language processing (NLP), show great promise within the antibody discovery space.

Many recent advances in DL, particularly through the increasing use of transformers, are enhancing NLP capabilities within the antibody discovery space. Some active areas of AI in the antibody discovery space include: 1) de novo antibody design, 2) developing AI-enhanced library formats, 3) improving the probability of success of lead candidates from in-vitro discovery campaigns, 4) paratope and epitope prediction, 5) structural homology modeling and docking, and 6) identifying and ranking developability issues in antibodies.[5-10]

While many of these applications continue to show real improvements in antibody discovery, it is unclear whether de novo design, which holds the greatest potential to disrupt the field, will match the hype. For instance, a recent study on de novo design employed generative AI to produce a wide array of leads to a known binder, but still required construction of a library followed by the screening of leads.[11] While the employment of AI for library construction is novel here, it begs the question of whether that is an improvement to existing capabilities or shows true cost savings over some of the latest discovery technologies.[12]

While we hold high hopes for de novo antibody lead generation, it will be important for these technologies to show clear improvements in time, cost, diversity, and developability over existing state-of-the-art display technologies.[12] One limitation of the de novo effort may be the available datasets used to train AI models, which may fall short of comprehensively capturing the latent patterns within protein-protein interaction networks, understanding the biophysics driving these interactions, or the sequence or structural properties implicated in developability. Of course, this is not necessarily a limitation in AI, but high-throughput experimental technologies, cross-institutional data silos, and/or in silico modeling (homology models and

docking), which may be required to enable these AI models to fulfill its promise, particularly in de novo design.

To overcome this limitation for effective AI training, not only large amounts of data but appropriate processing and storage requirements will be required. Cloud computing offers immediate solutions to these hurdles by allowing ready access to a vast computing network, which enables researchers to scale their needs to process these large datasets at the push of the button. Furthermore, cloud infrastructure allows for the testing of a large array of AI models and the fine-tuning of hyperparameters in a massively parallel fashion, enabling more automated selection of models and hyperparameters suited to a given task. Streamlining of these processes is a major advantage of cloud computing, ultimately facilitating better decisions on lead prioritization and reducing costs.

SUMMARY - THE IMPACT OF CLOUD COMPUTING ON THE FUTURE OF ANTIBODY DISCOVERY

Cloud computing has transformed the field of antibody discovery, making the process faster, more efficient, and cost-effective. The use of cloud computing tools and algorithms has enabled the rapid screening of large antibody libraries, leading to the identification of high-affinity antibodies with high specificity. Overall, antibody discovery is a complex process and leveraging cloud-based platforms provides a centralized location for researchers to store, share, and analyze data, facilitating collaboration and development of new antibody discovery methods. ◆

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Dr. Laura Spector is a Bioinformatics Scientist at Specifica, a Q2 Solutions Company in Santa Fe, NM, where she interfaces between the Discovery and Bioinformatics teams to conduct next-generation sequencing and data analysis for antibody discovery campaigns. In developing new AbXtract workflows for OpenEye's Orion Antibody Discovery Suite and validating them using in-house data, she contributes to tools that accelerate the identification of clonotypes of interest. Prior to joining Specifica, she earned her PhD in Genetics at Stanford University, where she studied genomic factors influencing a virus-mediated gene therapy platform.

Dr. M. Frank Erasmus is Head of Bioinformatics at Specifica, a Q2 Solutions Company in Santa Fe, NM. He has more than 15 years of experience in antibody therapeutics, with several patents and publications contributing to the advancement of the field.

DIGITALIZATION STRATEGIES

The Era of Technological Transformation in Pharma: Digitalization's Role in Future-Proofing the Pharma & Biotech Industries

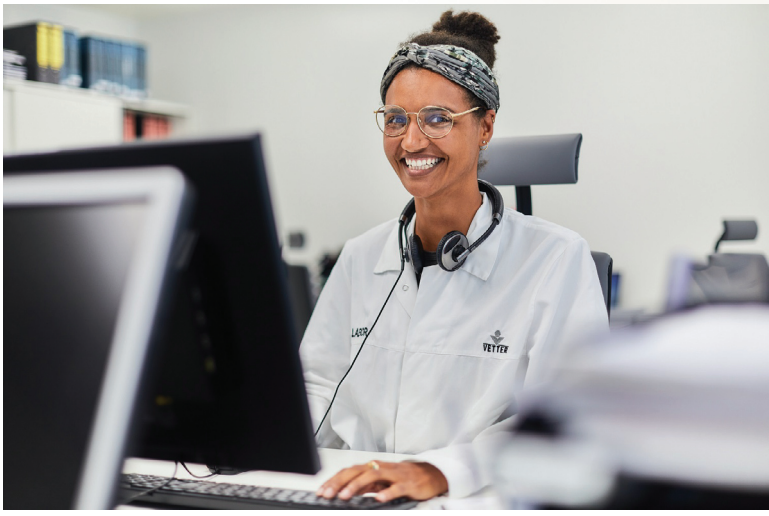
By: Kai Vogt

INTRODUCTION

The world is experiencing a technological transformation, which the World Economic Forum has dubbed the fourth Industrial Revolution. As a result, jobs in nearly every industry are experiencing a ground-up metamorphosis to adhere to the digitalization of processes, systems, and skillsets. As a globally operating contract development and manufacturing organization (CDMO), we are not exempt from the impacts of this transformation. CDMOs that embrace digitalization will be better equipped to meet the evolving needs of their customers with minimized human error compared to those who avoid change. Though many may see digitalization as a threat to job security, we are valuing the nexus between human-driven innovation and the support of improved digital processes. Through this embrace, we enhance our business's capabilities to produce life-saving medications for patients around the world.

As digitalization becomes a cornerstone for businesses that will see success in the future, our customers have expressed gratitude for our reliability and up-to-date nature. Although digitalization is a worldwide trend, the way it is implemented in the pharma and biotech industry is unique. In addition to the complex requests and expectations of our customers, the requirements to protect the sensitive and fragile nature of high-value molecules are also increasing. Together, this results in a highly volatile environment amidst the evolution of the industry.

Organizations that keep up with the technological transformation and incorporate employees in new digitalization strategies can likely achieve the greatest-possible success. This can be driven by the ability to produce high-quality drug products, and the commitment to reskilling employees, bringing human-centric value to an increasingly tech-driven industry. We, among many other CDMOs and pharma/biotech companies, are adapting to digitalization in several ways that not only adhere to our models but enhance our capabilities.



OPTIMIZATION AS AN IMMEDIATE UNDERTAKING

As referenced by the World Economic Forum, digitalization is happening now, with an estimated 1 billion jobs expected to be transformed by technology by 2030. Companies that strive to

be progressive, a foundational value at our company, are seeing this change and making internal adaptations accordingly. CDMOs, in particular, have several areas where digitalization improves processes, from administration, to production, quality control to logistics, and more. As with any transformation, digitalization is an ongoing evolution, and as such, companies must commit to making constant changes – this change will not happen overnight and will not stop at one or two changes. Rather, it will be a continuous process that could likely go on for decades.

We place a strong focus on the quality and success of our projects in Production, Quality Control, and Industry 4.0, all of which are managed by a digitalization strategy that is several years in the making and continuously adapted as necessary. To further enhance our digitalization, technologies like the Internet of Things (IoT), virtual reality (VR), and autonomous, collaborative robots have been incorporated into our approach. For example, Helmo and YuMi, two kinds of robots that we have integrated into our production processes, have improved the time and quality of tedious work, allowing human employees to redirect their focus to process steps where the work of employees creates a higher impact. Helmo is a mobile robot system that works autonomously and can navigate diverse working environments to successfully complete technical tasks, for example, the thawing of previously frozen drug solutions.

Similarly, YuMi (aka You and Me) serves as a partner to add flexibility to assembly processes for individualized products, enhancing workflow precision. Although many view robots as a risk for heightened job displacement, we have experienced and clearly communicated the opposite right from the start. Robots serve to improve the work outputs of humans, by taking on repetitive tasks and allowing more time for people to focus on specific conceptional work. In addition, YuMi must be trained by humans to adequately be able to accomplish packaging tasks, leaving room for technology and humans to collaborate side by side.

THE HUMAN ELEMENT OF TECHNOLOGICAL TRANSFORMATION

Although the result of digitalization appears to be less of a need for human support, achieving this result requires the opposite. Our digitalization strategy is built on the foundation that people drive the evolution of processes. Transforming to adapt to new technologies requires human understanding of complex and highly regulated production processes to find proper technological solutions that enhance them, without negating the high levels of quality that our customers expect.

For us, digitalization is truly human-driven. Our colleagues evaluate current processes for gaps or areas of improvement and in turn, find new appropriate technologies that solve these problems without sacrificing anything from the resulting injectable drug product. The result is a seamless collaboration between people and supporting technology.

Additionally, we have developed a Digital Transformation strategy to define

the guard rails for digitalization across our global company.

NAVIGATING NEW CHALLENGES

As with any industry-wide change, and in particular, global revolutions, digitalization does not come without its challenges. Though positive results are already proven, and the potential of these new digital processes are seemingly limitless, navigating this new, tech-driven work environment brings unprecedented obstacles. All employees must be aware of these obstacles so they can address them in an efficient and timely manner.

By incorporating the teams that will work with new technology into the planning and strategic development process, companies can proactively address concerns and instill a sense of collective responsibility for the success of these processes. Further, this early inclusion allows company leadership to address fears of job displacement head-on, and to provide assurance that digitalization is a tool to support employee success.

THE PATH FORWARD

Digitalization is already underway in nearly all industries around the globe. As a leading CDMO, we have chosen to accept this transformation with open arms to evolve with the times and continue striving to provide our customers the highest quality, best time-to-market, and most effective processes for manufacturing their life-saving drug products. This flexibility to adapt to new innovations is engrained in our company culture, in which we want to serve as a reliable, progressive, and responsive partner to small and large renowned pharma and biotech companies producing life-enhancing medicines. While digitalization is not the answer to every process within our company, it does serve several purposes where we see added value. It is in those spaces where we are integrating new technology to support sustainable growth for years to come.◆

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BIOGRAPHY

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REGULATORY AFFAIRS

Rethink the Regulatory Dynamic: A Better Approach for Being Your Product's Best Advocate

By: Nick Smalley

INTRODUCTION

Technology is always moving forward, its momentum maintained by a series of inorganic micro- and macroevolutions. While 100 years ago, patients were likely to receive medication by ingesting a tablet or getting an injection, alternative routes of administration have ballooned, greatly increasing the complexity of drug-device combination products, defined for our purposes here as products composed of both a drug and a device that facilitates its delivery. The pressurized metered-dose inhaler (pMDI) and the autoinjector, two of Kindeva Drug Delivery's early industry-leading innovations, are prime examples of this increased complexity. In both instances, the need to safely deliver the right dose of a drug to the right place necessitated the creation of very complicated, very precise devices.

Understandably, this complexity will continue to grow as each innovative idea branches to the next. And for combination products, even as the devices become more complex, so too do the drugs themselves, including the development of features that allow more control over the release timing and positioning of a drug substance. This side-by-side evolution in dosage form and device functionality raises both engineering and chemistry challenges.

As drug-device combination products grow more complex, regulations increase commensurately. However, to implement and enforce appropriate regulatory standards and truly ensure product safety, regulators must understand what it is they are regulating. Given that both halves of drug delivery combination products are concurrently evolving on an incline, this is a tall task. How do you address it? That involves a lot of collaboration and education.

DUELING REGULATIONS

With combination products, there are regulatory requirements related to the drug, and there is another set of requirements for the device. In many regions of the world, these two regimes are often incompatible, rarely communicating with one another. On the drug side of the regulatory equation, safety and efficacy take focus. With device regulatory review, a key focus is on manufacturing quality systems and ensuring adequate control of highly engineered components. While there are standards for quality and effectiveness on both sides, these differing outlooks can lead to conflicting guidance.

For drug delivery combination products, which fit squarely in both regulatory regimes, there is a need to untangle and work through potential complications. As a simplistic hypothetical example, imagine that a medicinal regulator is requiring a warning on your product's label while the device regulator is requesting contradictory language. By clearly understanding the regulations of both agencies, you can help align this sort of diverging guidance.

THE TERMINOLOGY GAP

Remember that you are the expert on your technology, not the regulators. There is no way for anyone to appreciate the details of a novel device prior to its explanation. A key focus of any regulatory agency is protecting patient safety while ensuring efficacy, so appropriately explaining how a new device meets those requirements can keep all parties on the same page.

Available routes of administration have ballooned, greatly increasing the complexity of drug delivery combination products. Even as the devices become more complex, so too do the drugs themselves, including the development of features that allow more control over the release timing and positioning of a drug substance.

For many developers, the issue is really one of terminology, as an entirely new device improperly explained offers false or insufficient understanding for regulators. Providing thorough and complete details about the new device helps ensure regulators apply the appropriate guidelines and standards. While drawing comparisons may be important to illustrate your product's functionality, it is vital you also explain everything that makes your product different from others. By relaying those unique elements, you help ensure regulators judge the device as truly innovative.

Highlighting the safety and patient-centric features of any new device gives regulators a solid foundation from which to review the product. Regardless of your final approach, be sure to consider the best way to explain the product in advance of needing to do so. The clearer the explanation, the easier it is for regulatory agencies to review and hopefully approve the new product.

TAKE A SEAT AT THE TABLE

Don't miss an opportunity to sit down with regulators. Many regulatory bodies have pre-submission or pre-development meetings, which are excellent venues in which to explain your new technology or new drug and highlight the potential patient benefit. This is a surefire way to strengthen the regulatory partnership. Even if you don't get the exact results you hope for, discussing study design, device manufacturing, or the intricacies of submission itself offers insight into the thought process of regulators, as well as an understanding of how you can better communicate with them. This early and regular engagement also gives you a seat at the table in the discussion of how to protect public health while bringing the most effective product to patients as quickly as possible. You will have further opportunities to educate regulators throughout the process, but it is best to begin the process prior to the submission of data or, even better, before the generation of that data, so start early.

This is a practice particularly recommended for combination products because regulatory bodies worldwide tend to impose regulations that may not apply to the product or technology in hand. By discussing your product with regulators throughout development, you increase the odds of it being understood and regulated accurately with the correct set of regulatory requirements appropriate to its functionality and use.

PRIORITIZE THE PATIENT

From ideation to commercialization, the entire process of creating a drug-device combination product is risky. Will the device work? With the drug formulation? Can it be scaled? In fact, the risk of not addressing an unmet patient need is often

"As drug device combination products grow more complex, regulations increase commensurately. However, to implement and enforce appropriate regulatory standards and truly ensure product safety, regulators must understand what it is they are regulating. Given that both halves of drug delivery combination products are concurrently evolving on an incline, this is a tall task. How do you address it? That involves a lot of collaboration and education."

the drive behind discoveries. So, the risk is baked into each step, and as your product proceeds along the pipeline into patient use, those risks quickly become regulatory concerns.

Among the most important aspects of healthcare is minimizing the risk to the patient, so in the struggle to balance conflicting requirements, the soundest position from which to start is with a patient-centric approach. If you can justify a deviation from a stated requirement because you can show it is in the best interests of the patient to do so, you stand a much better chance of getting a regulator agreement and, in turn, aligning the stated requirements for your combination product more closely with its actual use.

In the face of guidance that often seems based more on history than on a patient-centric evaluation of the specific combination product at hand, it is vital the regulators understand why your viewpoint is the right one for the patient. The explanation of this falls to you. As discussed, there is no way for the regulatory regime to completely understand your combination product if you do not provide that information. Developing your patient-centric rationale for regulators requires you to ask yourself some questions: Am I creating a quality product? Will it be safe for patients? Will it be effective?

GUIDE YOUR GUIDANCE

Once you've examined these questions for yourself, you can better determine how far away what you are doing is from what regulators are expecting. Then the question becomes, "How do I justify that difference?" Commencing from this vantage point gives you a place from which to start developing a patient-centric rationale that helps regulators better understand your product and which guidance to apply. Given the high level of many regulations versus the more specific guidelines that try to explain how to meet the regulation, there is often room for interpretation so long as you provide sound reason for it. This is a strategy that is particularly necessary for combination products because of the dual regulatory bodies overseeing the invention, for which a justified shift in effective guidance could remedy any clashing requirements. Your role in keeping your combination product on track is ensuring it is understood, which means bringing a clear, patient-centric discussion to the regulatory table. ◆

BIOGRAPHY

Nick Smalley is Vice President, Regulatory Affairs, where he leads Kindeva Drug Delivery's Global Regulatory Affairs Organization. He has held previous positions in regulatory at 3M Health Care, Perrigo, UCB, and Norton Healthcare Limited. He earned his BSc (Hons) in Chemistry from Loughborough University.

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Kerstin Pohl

Senior Manager, Cell & Gene Therapy & Nucleic Acids

SCIEX

Scott Ripley

General Manager, Nucleic Acid Therapeutics

Cytiva

PRECISION NANOSYSTEMS
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SCIEX

Precision NanoSystems Inc. (part of Cytiva) & SCIEX: Lipid Impurities Within mRNA-LNPs

New, exciting research shows a novel, developing multivalent flu vaccine against all 20 known influenzas (A and B virus subtypes/lineages). This could be a breakthrough as current flu vaccines only treat a few strains, and each year, it's an educated guess for which flu strain will dominate. This prevalent research comes as a new class of impurities within mRNA drugs has been detected by advanced and highly specific analytical tests being conducted on existing mRNA-lipid nanoparticle (LNP)-based therapeutics and vaccines. These new impurities are typically undetectable by traditional mRNA purity analytical techniques based on gel electrophoresis. Given these findings, it is essential researchers and manufacturers have the tools and know-how to assess the full range of potential lipid impurities and differentiate them in order to ensure mRNA-LNP vaccines are effective and safe.

Drug Development & Delivery recently spoke with Kerstin Pohl, Senior Manager of Cell & Gene Therapy & Nucleic Acids at SCIEX, and Scott Ripley, General Manager of Nucleic Acid Therapeutics at Cytiva, to dive into the detection of these impurities and the impact it has on manufacturing.

Q: Could you tell me more about how new classes of impurities within vaccines development have been detected?

Scott Ripley: Although LNP (Lipid Nanoparticle) technologies have existed since the late 90s, the success of the two COVID-19 mRNA vaccines and subsequent rapid expansion of the LNP delivery technology have resulted in the evaluation of countless new lipid compositions and LNP designs. Therein, ionizable lipids, the enabling technology for LNPs, and proprietary PEGylated lipids have radically changed in design and complexity, yielding new classes of impurities in mRNA-LNP vaccines. Such impurities are increasingly detected as more detailed and sensitive analytical technologies, such as high-resolution mass spectrometry (HRMS), capillary electrophoresis (CE), and ion pairing high-performance liquid chromatography (IP-HPLC), are applied within the LNP field. Consequently, LNP drug manufacturers and regulatory agencies are increasingly expecting careful assessment for impurities.

Q: What would the consequences be for the effectiveness and safety of mRNA-LNP vaccines if researchers and manufacturers don't understand or have the tools to assess and characterize potential impurities and address them?

Kerstin Pohl: In general, there are three main risks resulting from a failure to detect LNP impurities: changes in LNP structure and manufacturability, reduction of vaccine potency, and direct immunologic or toxicologic concerns. In the former, low lipid purity or mRNA purity equates to changes in the LNP composition, affording unstable or un-manufacturable drug product. In the second case, there is a growing acknowledgement specific lipid impurities directly react with the mRNA payload, thereby inactivating the vaccine. In the latter, incomplete or ineffective purification of lipids and mRNA can result in unexpected synthetic reagents and compounds making their way into LNP vaccines. These species can potentially elicit a range of immunogenic and toxicological effects.

Q: What is the future for advanced analytical tests in enabling the safe and effective development of innovative healthcare technologies and vaccines? How can they ensure the next flu vaccine, COVID-19 booster, and mRNA therapies are effective?

Scott Ripley: In contrast to the revolution in technologies enabling robust and high-capacity manufacturing of LNP-based drugs, such as Precision NanoSystem's NanoAssemlr® platform, LNP analytics remains an adapting and evolving field. Fortunately, several key players in the lipid and LNP manufacturing space are recognizing the necessity of developing and adopting cutting-edge technologies and heavily investing in the area. Consequently, advanced analytics are being applied throughout the design, process development, and manufacturing stages of the next generation of LNP vaccines. The result will be threefold. Adoption of HRMS will yield higher potency due to the early identification of detrimental impurities. CE, IP-HPLC, and HRMS will enable unprecedented mRNA characterization affording lower batch-to-batch variability. Finally, field flow fractionation (FFF) – multi-angle laser light scattering (MALLS) systems will enable unparalleled analysis of intact LNP properties, such as size, polydispersity, mRNA loading, shape, and density, enabling a deep understanding of how composition impacts both manufacturability and potency. Overall, advanced analytics will ensure a faster and smoother path of LNP drugs from concept to the clinic.

Q: Where do these new lipid impurities come from, and how do they arise?

Kerstin Pohl: The new lipid impurity of key concern was first described by Dr. Meredith Packer and her team at Moderna in 2021 (Packer et al, 2021. Nat. Comm.). Therein, the mRNA payload in LNP was found to inactivate following the reaction with a lipid impurity resulting from the degradation of an ionizable lipid. Subsequently, the industry has discovered that in fact, all ionizable lipids will undergo a similar reaction, albeit at a wide range of rates. Mechanistically, impurities are likely caused by the oxidation of tertiary amine to N-oxide species

Q: In your experience, how commonly do these impurities arise in LNPs for mRNA-LNP vaccines?

Scott Ripley: The significant growth and diversity of applications for mRNA-LNP vaccines have resulted in a wide range of ionizable lipid structures whose susceptibility to oxidation varies significantly. Furthermore, some reagents employed in the synthesis of ionizables lipids may elevate N-oxide levels. Therefore, differences in vendors, manufacturing, storage, and other parameters can radically, and unpredictably, impact the N-oxide levels. In general, N-oxide levels above 1% abundance will result in the complete inactivation of an mRNA vaccine; however, even trace amounts can be problematic. Consequently, careful quantitation of N-oxide content in all ionizable lipid lots is recommended.

Q: What are the three key things manufacturers and researchers should do to optimize mRNA-LNP vaccine design and development, and stringent manufacturing controls to manage these impurities and ensure mRNA stability?

Kerstin Pohl: Three approaches to minimize the risk of mRNA adducts are (1) adopt careful analytics on incoming raw materials, (2) take a Quality by Design (QbD) approach to mRNA adducts in manufacturing processes to limit conditions by which N-oxides form and react, and (3) carefully monitor the mRNA-LNP vaccine for signs of adduct formation. In the former, the use of state-of-the-art HPLC-HRMS, such as the ZenoTOF 7600 system (SCIEX), by both the lipid vendor and LNP manufacturer, enabling the differentiation of problematic N-oxides from other impurities and the determination of levels, is recommended. In the second, limiting exposure to oxygen and heat as well as storing material under cryogenic conditions will limit N-oxide formation. In the latter, monitoring for signs of adduct formation on the mRNA payload by IP-HPLC or leveraging robust in vitro potency assays to identify inexplicable drops in potency will afford early recognition and hopefully illuminate the causative agent. Overall, analytics should be a key consideration throughout the LNP vaccine manufacturing process to mitigate these mRNA adducts as well as countless other challenges. ◆

LIPOSOMAL PEPTIDE THERAPEUTICS

Revolutionizing Oncology: Unleashing Innovative Strategies to Tackle Challenging, High-Value Drug Targets

By: Natalia Zisman, Krishna P. Allamneni, MS/PhDDABT, and Stacy W. Blain, PhD

INTRODUCTION

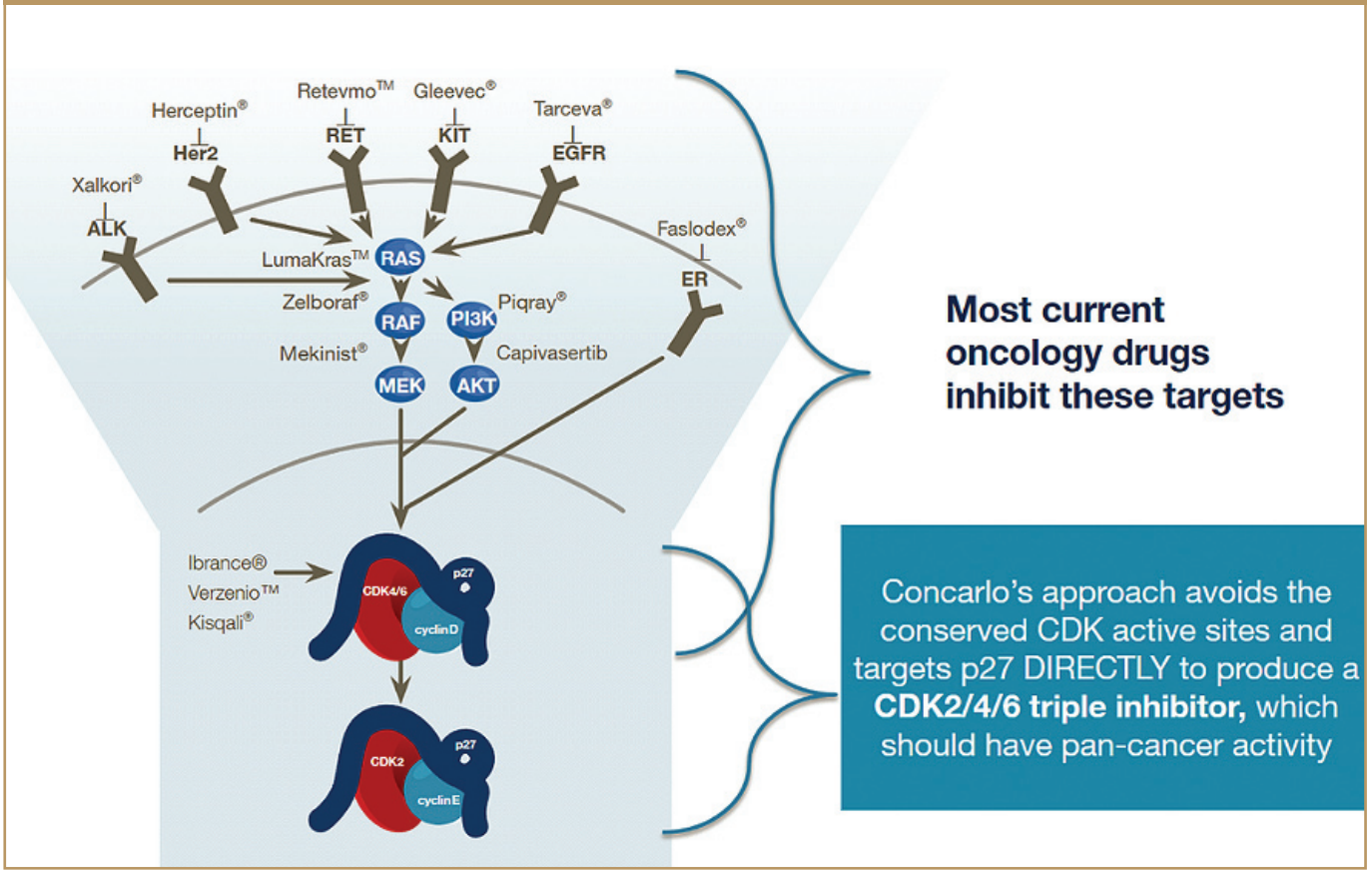
The past 40 years in oncology have been dominated by the development of precision oncology approaches, or the idea that if one can identify the particular genetic perturbation that drives a patient's cancer, one could design a medicine to target that particular mutation to stop cancer growth. The growth-promoting signals driving cancer proliferation flow from the cell surface through the cytoplasm to the nucleus, a type of oncogenic funnel so to speak (Figure 1), and as a field, we have attempted to stop that signaling flow by the development of monoclonal antibodies or small molecule kinase inhibitors to inhibit the cell surface receptors, such as the Epidermal Growth Factor Receptor (EGFR), or small molecule kinase inhibitors to block the activity of the cytoplasmic signal transduction molecules, like RAS or MEK, that carry those oncogenic signals from the cell surface to the nucleus.

While this approach has transformed the oncology space, significantly expanding our clinical toolkit and decreasing adverse effects for our patients, we now understand one of the liabilities of this approach. When we target the top or the middle of the oncogenic funnel, there is just too much residual opportunity for the tumor cell to evolve away from the blockade that was imposed on the cell. For example, Trastuzumab (Herceptin®), which targets one form of the EGFR oncogene (Her2) in breast cancer and one of the first targeted therapies approved in 1998, has transformed Her2+ breast cancer. In the metastatic setting, the addition of Trastuzumab to chemotherapy has increased overall survival (OS) to more than 4.5 years, compared to a life expectancy of 1.5 years seen in the 1990s. However, up to 30% of these patients develop resistance to these therapies, due to increased activation downstream of the imposed EGFR blockage. While efforts to develop better Her2-targeting therapies are ongoing, such as the approval last year of ENHERTU® (fam-trastuzumab-deruxtecan-nxki), these observations reinforce the idea we need to inhibit the bottom of the oncogenic funnel with more mutation-agnostic drugs, to inhibit the common factors at the end of the signal transduction cascade that drive the response to most if not all growth- promoting signals.[5] Targeting downstream signaling proteins offers a promising approach to effectively mitigate the emergence of drug resistance that precision oncology therapies leave behind.

THE ONCOGENIC FUNNEL & CDK INHIBITORS

The bottom of the oncogenic funnel encompasses five cell cycle proteins that are members of the G1 CDK families (CDK4/6-cyclin D and CDK2-cyclin E) along with their unique regulator, p27Kip1 (Figure 1). Significant R&D resources have been dedicated to inhibiting CDK4/6 and CDK2, resulting in commercially successful CDK4/6 inhibitors (CDK4/6i), such as palbociclib, abemaciclib, and ribociclib.[2] These are approved for treating metastatic hormone receptor+ (HR+) breast cancer and, more recently, as adjuvant therapy for high-risk non-metastatic HR+ patients. While these medicines have improved the progression-free survival rate, the development of resistance to these

FIGURE 1



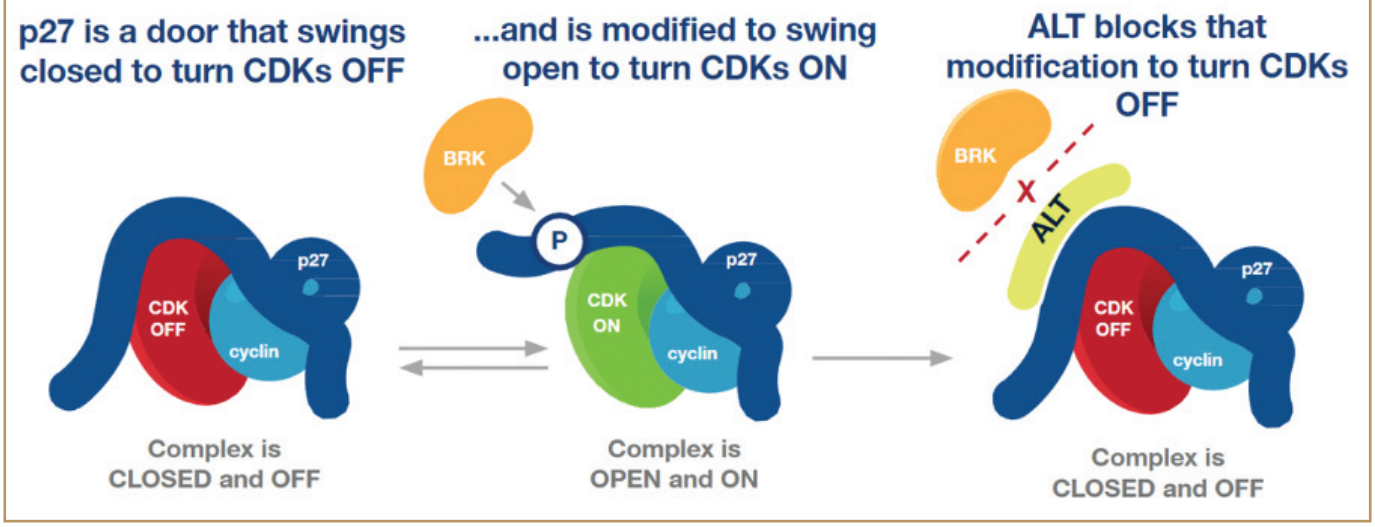
drugs remains a significant concern for almost all patients, resulting in a more modest OS and >40,000 patients in the US continuing to lose their lives to metastatic breast cancer each year.

The issue is that CDK4/6 is not the final player in the oncogenic signaling cascade. CDK2 can increase its activity and compensate for the loss of CDK4/6, driving the tumor out of remission and into a resistance state. CDK4/6 and CDK2 can be likened to a see-saw, where the effects of CDK4/6 on the left side can be counterbalanced by CDK2 on the right side. Therefore, instead of viewing CDK4/6 and CDK2 as distinct entities, it might be beneficial to think of them as a hub with the need to target both CDK4/6 and CDK2 simultaneously. Developing CDK2 single inhibitors (CDK2i) has presented challenges due to off-target toxicities, as the ATP binding pocket in CDK2 is structurally related to that of other essential CDKs, such as CDK1. Several promising CDK2i candidates, such as Pfizer's PF-07104091, Blueprint Medicine's BLU-222, and Incyclix Bio's INX-315, are currently being investigated in Phase 1 clinical trials. Only time will determine if these novel CDK2i have achieved the necessary specificity for a favorable therapeutic margin. Notably, Nuvation Bio and Pfizer previously pursued the development of triple CDK4/6/2 inhibitors, but both of these programs were terminated due to unmanageable adverse effects.

P27 AS NOVEL TARGET FOR CDK INHIBITION

Concarlo Therapeutics has embraced a unique approach, by shifting its focus away from the conserved CDKs and instead targeting the master regulator of these kinases: p27 (Figure 2). p27 binds with high specificity to these complexes and ignores most of the rest of the kinome. Its endogenous function is to turn these kinases on and off, a function required during the cell's natural cycling between proliferative and quiescent state. One way to think about p27 is to compare it to a door controlling access to activity of these kinases. When the key or the phosphorylation modification is present on p27 itself, the door swings open and CDK4/6 and CDK2 are on, but when the key is absent, the door slams shut, blocking the activity of these kinases. This dynamic opening and closing of the door is the way that CDK4/6 and CDK2 are regulated normally and p27 acts as the conduit between the left and right half of the see-saw, linking the activation or inhibition of CDK4/6 and CDK2 together.

FIGURE 2



We hypothesized that blocking the protein-protein interaction between p27 and its modifier Breast tumor-Related Kinase (BRK) would lock p27 into the door closed/off conformation. Furthermore, p27 is an intrinsically disordered protein, which means it only has structure when bound to its substrates, and traditional ATP-binding pockets, such as seen in kinases, are not present. Our hypothesis led us to develop a series of p27 inhibitors aimed at firmly shutting the door, effectively turning these three kinases CDK4/6 and CDK2 off in concert. By simultaneously inhibiting CDK4/6 and CDK2 via p27, our approach could address the tumor resistance seen in the presence of palbociclib, abemaciclib, or ribociclib. What sets our approach apart is that by targeting the bottom of the oncogenic funnel, our p27 inhibitors hold the potential to be more perturbation and tumor-type agnostic. This means they could effectively tackle resistance associated with various therapeutic antibodies against cell surface receptors, and the small molecule kinase inhibitors of the RAS/MAPK pathway, including Sotorasib, Cetuximab, etc. It is this innovative concept that gave birth to Concarlo Therapeutics, as we strive to harness the full potential of this groundbreaking approach.

THERAPEUTIC PEPTIDE FOR INHIBITION OF P27

Targets such as p27 may be more amenable to peptide approaches. Peptide drugs can effectively block protein-protein interfaces that are relatively featureless, can offer advantages related to specificity, and reduce the potential for off-target liabilities. Several high-value targets, such as Beta-catenin, Myc, or p53, have not been accessible by traditional small molecule approaches but newer traction has been achieved with peptide-based drugs (FOG-Pharma, Sapience Therapeutics, and PeptoMyc).

Initially, we took our lead from nature: a small protein called ALT (an alternative splice variant of BRK), which can bind to p27 and act like a blanket to block the door to keep it shut (Figure 2). *In vitro*, ALT expression resulted in its binding to p27 and inhibition of its phosphorylation, thus turning CDK4/6 and CDK2 off and blocking tumor cell proliferation. ALT cleared faster from non-tumor cells than from tumor cells, thus favoring longer inhibition of tumor cell- versus normal cell-proliferation. Expression of ALT in animal models of treatment naïve and CDK4/6i-resistant breast cancer caused tumor regression and increased OS. We screened variants of ALT based on an evolutionary informed approach of conserved sequence across species and nominated a lead therapeutic candidate peptide to progress into early nonclinical development. Additional optimization was undertaken, via protein engineering for modifications to enhance the peptide's properties, including potency, selectivity, stability, manufacturability etc, and a lead peptide candidate, CCL20, was chosen for further development.[4]

One of the key challenges in manufacturing a peptide via chemical synthesis is both the cost and duration of the manufacturing process and low process yields, as well as the increased possibility of multiple process-related impurities. Concarlo approached this problem by investing in several proof-of-concept studies, comparing different peptide manufacturing techniques, such as Linear automated/manual

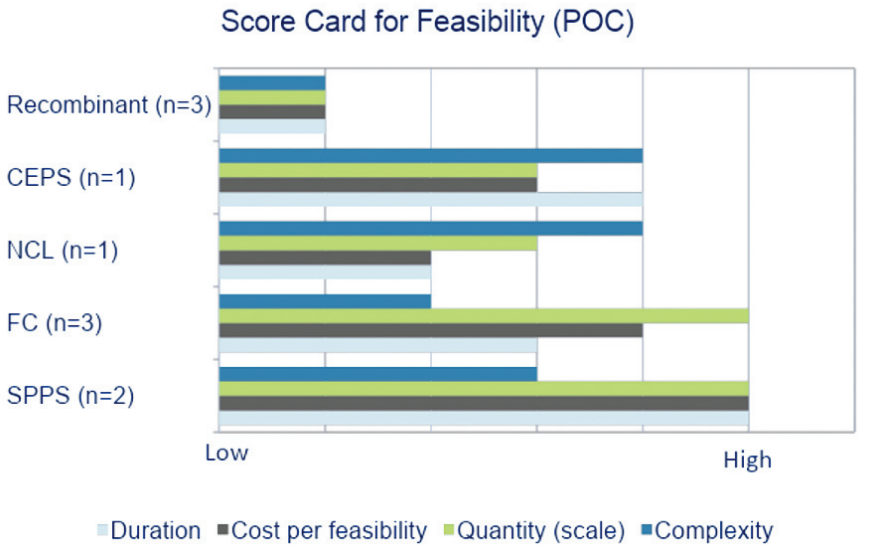
Solid Phase Peptide Synthesis (SPPS), Fragment Condensation (FC) of several smaller peptide fragments, Native Chemical Ligation (NCL), and Chemoenzymatic Peptide Synthesis (CEPS) of main fractions using proprietary ligation conditions (Figure 3).

One of the critical components of peptide manufacturing is the development of proper analytical tools for assessing peptide purity. While it is a common industry practice to use generic HPLC-based methods for assessing purity of novel peptides, in the case of Concarlo's peptide, it became clear this approach (even coupled with Mass Spectrometry) was incapable of separating multiple smaller impurities and providing accurate purity readout. By switching to a UPLC method early in development and paying additional attention to in-process impurity characterization, Concarlo was able to significantly improve the overall purity of CCL20.

DELIVERY OF A THERAPEUTIC PEPTIDE TO TUMOR SITE

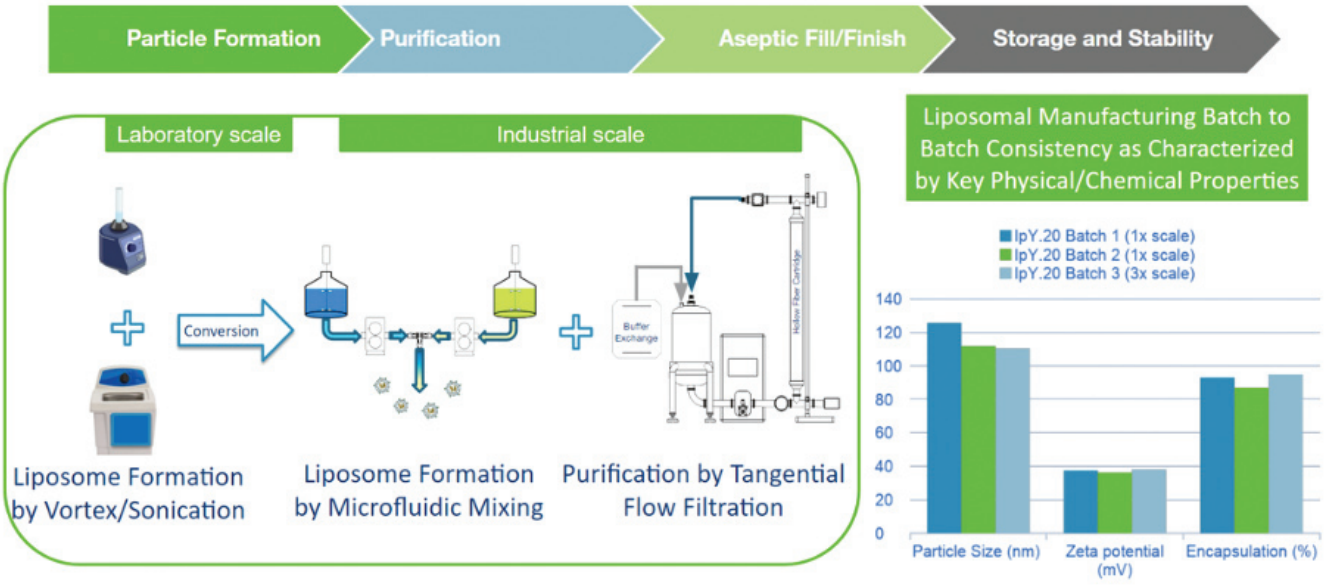
One of Concarlo's challenges was delivery of its therapeutic peptide effectively to the tumor and into tumor cells, as the p27 protein is found intercellularly. Lipid nanoparticles (LNPs) are an attractive vehicle for delivery of different types of active pharmaceutical ingredients (APIs), such as small molecules, peptides, and nucleic acids.[1] LNPs have a proven clinical safety record and have been successfully utilized in injectable formulations. Nucleic acid containing LNPs, similar to those used in COVID-19 vaccines, rely on delivering their cargo intercellularly by fusing with the target cell membrane and releasing their cargo into the endosome. This fusion is achieved through interaction of an ionizable cationic lipid of the LNP with the target cell membrane. These types of delivery systems are typically used for localized delivery (such as vaccines) or systemic delivery of gene therapies that benefit from ApoE-mediated uptake of lipoprotein particles. Delivery to extrahepatic tissues still remains one of the main challenges of LNP-based delivery systems.[3] Conventional Liposomes, on the other hand, rely on the ability of small vesicles to extravasate at the tumor site following systemic administration, due to "leaky" tumor vasculature, that allows particles of up to 150 nm to penetrate into tumor tissue. This preferential accumulation of small LNPs into tumor has been called "enhanced penetration and retention" (EPR) effect, and in combination with long circulation times of liposomal drugs, was able to improve tumor delivery of known small molecule cytotoxic drugs, while reducing their known side effects. Since the approval of the first liposomal drug Doxil™ for breast cancer treatment in 1995, several other conventional liposomal drugs have been approved for other cancer indications (for example, Vyxeos® approved in 2017 for treatment of AML).

FIGURE 3



Concarlo's approach to drug delivery is to utilize the best of both worlds by combining features of conventional liposomal formulations and nucleic acid LNPs. We need to ensure our delivery vehicle is able to fuse with the tumor cell membrane and release the cargo intercellularly. Cationic lipids historically used for nucleic acid delivery have been known to promote membrane fusion and allow for efficient transfection of the target cells. Although Concarlo's peptide is significantly smaller than mRNA, it is as highly negatively charged as nucleic acids and relies on the same intercellular delivery principles as nucleic acids do. During liposomal particle formation, it complexes with the cationic lipid, and this charge/charge interaction ensures high loading efficiency of the peptide into the lipid nanoparticle. The presence of other lipids in the formulation, such as cholesterol helper lipid and PEG lipid, ensures both stability and long circulation half-life of peptide- containing liposomes.

FIGURE 4



MANUFACTURING OF LIPOSOMAL PEPTIDE THERAPEUTIC CANDIDATE

The ability to scale-up production of liposomal formulations remains one of the key aspects of successful liposomal product development (Figure 4). Although the advancement of off-the-shelf microfluidic instruments has enabled research scientists to produce small batches of liposomal formulations with relative ease, further scale-up required to support preclinical and clinical product demands can pose a significant challenge. Typical steps required for LNP manufacturing include LNP formation, solvent removal by buffer exchange, and product concentration by ultrafiltration, followed by aseptic filtration through 0.2-μm sterile filters. The LNP formation step involves microfluidic mixing of solvent stream containing lipids with aqueous stream containing the payload, such as peptide, small molecule, or nucleic acid. Consistent and reproducible LNP formation across different scales is the key to successful scale-up of LNP formulations, as this step controls both the particle size and encapsulation efficiency of the resulting LNPs. Typically, conditions for LNP formation do not scale-up linearly, and therefore, conditions developed during discovery phase using laboratory scale equipment likely will not be directly transferable to a larger scale production.

WHERE ARE WE NOW WITH CMC PROCESS & PRODUCT DEVELOPMENT?

At Concarlo, we successfully manufactured our peptide drug substance as well as our liposomal formulation using a scalable and controlled process. We were able to establish feasibility of several manufacturing routes for production of our peptide. We have invested in extensive physical/chemical characterization of key peptide properties, such as solubility, conformation assessment, and salt form impact. We transitioned from a laboratory scale process for making LNPs to an industry-standard process capable of supporting clinical development. We are currently gearing up to optimize our liposomal formulations for the best encapsulation efficiency, strict particle size specifications, and optimal stability to support nonclinical studies. The extensive in vitro screening of the formulation variants for enhanced cellular uptake of our therapeutic peptide would allow further improvement in *in vivo* efficacy and tolerability. Simultaneously, we developed key phase-appropriate analytical assays for lipid and peptide analysis to support our future IND-enabling stability program. We are scaling up the manufacturing process of our drug product in preparation for *in vivo* pharmacokinetic/pharmacodynamic testing and indication expansion while supporting an accelerated nonclinical safety assessment toward submission of an IND application for initiation of first-in-human Phase 1 clinical trials.

Rather than persistently seeking a me-better variation of existing targets at the upper or middle regions of the oncogenic funnel, we hope the field will continue to exploit novel approaches to target intracellular proteins that are known high-value oncology targets at the bottom of the oncogenic funnel. Moreover, the oncology

field could draw inspiration from the vaccine and gene therapy sectors and embrace innovative strategies in manufacturing formulations that enable the systemic and safe delivery of peptides across the cell membrane and efficient release of peptides from the endosome to maximize their intracellular effectiveness. This cross-pollination of knowledge between fields has the potential to revolutionize the delivery of therapeutic peptides in oncology, fostering advancements and offering new possibilities for effective treatment options. Through our commitment to innovation and scientific excellence, we invite potential development partners to join us in our pursuit of advancing liposomal peptide therapeutics and making a positive impact on patients' lives. ◆

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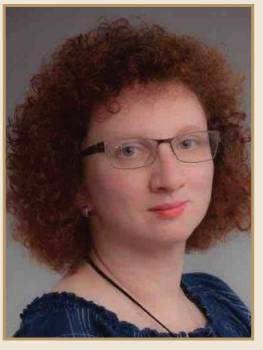
BIOGRAPHIES

Dr. Stacy Blain is Co-Founder and Chief Scientific Officer of Concarlo Therapeutics. She is an internationally known expert in cell cycle and cancer biology, and is one of the world's experts on p27Kip1. She has been studying cell cycle regulation for more than 25 years as an NIH-funded investigator and tenured Associate Professor at the SUNY Downstate Medical Center. She founded Concarlo, capitalizing on discoveries she made and patented. She was trained at Princeton, Columbia, and the Memorial Sloan-Kettering Cancer Center.

Dr. Krishna Allamneni is Chief Development Officer at Concarlo Therapeutics. She is a biopharma R&D expert with almost 20+ IND/IMPD submissions, 6 NDA/MAA approvals, and a track record of efficiently developing therapeutic candidates of various modalities. A forward-thinking leader in R&D strategy and tactical planning, and a highly regarded operational manager for key R&D functions, she has impactful global regulatory interactions with FDA, MHRA, BfArM, ANSM, PMDA, Health Canada, TGA etc. during clinical development, partnership, and commercialization. She was formerly with Turning Point, Jazz Pharmaceuticals, and Genentech.



Natalia Zisman is Director, Chemistry, Manufacturing and Controls at Concarlo Therapeutics, specializing in liposome and lipid nanoparticle drug delivery systems. Prior to her current role, she held various positions at Evonik Vancouver laboratories, facilitating transition of customer projects through various stages of development, from proposal scoping to formulation development to early clinical manufacturing. She has over 20 years of experience in the lipid nanoparticle drug delivery field and has been involved in all aspects of liposome manufacturing, starting from early stage formulation design, process development, scale-up, and early clinical manufacturing. Prior to Evonik, she worked at a number of Vancouver-based drug delivery companies (CDRD/adMare, Celator/Jazz, Inex), focusing on liposomal products. She earned her undergraduate degree in Chemistry from University of British Columbia.

CARBOMER CHEMISTRY

Breaking Ground in Controlled Release

By: Nicholas DiFranco, MEM

INTRODUCTION

Controlled-release medicines are increasingly in demand, with market share forecasted to more than double by 2032.[1] This growth is driving a need for techniques that can optimize the properties of controlled-release medicines. Active pharmaceutical ingredients (APIs) that are challenging to formulate often require multiple doses, leading to a high pill burden for patients. Improving patient comfort, convenience, and compliance are therefore key motivators for developing controlled-release drugs. As they maintain release of the API over a defined period from a single dosage form, these products can often be administered less frequently – a significant benefit for patients.

The need for controlled-release drugs is further fueled by the increased prevalence of chronic diseases and the global aging population. It is estimated the number of people in the US alone aged 50 years and older will increase by 61.11% from 2020 to 2050.[2] Of the population 50 years and older, the number with at least one chronic disease is estimated to increase by 99.5% in that same period.[2]

Chronic diseases, such as diabetes, can be a daily inconvenience for a patient's foreseeable future, so innovations in controlled-release dosages that can reduce administration frequency promise to improve patients' quality of life and increase compliance with prescribed medication. Meanwhile, elderly patients often have complex medication regimens and a lower tolerance to high dosages, and can also suffer from dysphagia, or difficulty swallowing.[1] As such, the geriatric population in particular stands to benefit from reduced administration frequency and dosage form improvements through advancements in sustained release.

In addition to the important patient-centric drivers, controlled release is also commercially valuable to pharmaceutical companies as a lifecycle management tool. For some novel immediate-release products nearing the end of patent protection, leveraging the 505(b)(2) pathway with an extended-release version can extend the lifetime of a drug, differentiating from generic competition, and protecting the developer's investment.

Innovative excipient technologies are key to accommodating the growing demand and enabling more patients to benefit from controlled-release dosage forms.

FACTORS TO CONSIDER WHEN SELECTING AN ORAL EXCIPIENT FOR CONTROLLED RELEASE

A variety of factors influence excipient choice for controlled-release drugs. The first step when selecting an excipient is often to look at precedence of use, with the aim of repeating previously successful methods for achieving controlled release. As a result, it is common for existing products to make use of grades of hydroxypropyl methylcellulose (also known as HPMC or hypromellose). This ubiquitous cellulosic polymer forms a gel layer around the API, which subsequently erodes to achieve extended release.

However, the success of previously implemented approaches is not guaranteed. For example, in some cases, formulators are unable to achieve a high enough drug loading or are unable to exercise the desired control over release within a given therapeutic window. There could even be compatibility issues between the specific API and the chosen excipient – particularly with formulations containing multiple APIs.

In addition, it is necessary to consider compliance with GMP standards and scalability at the formulation stage and choose an excipient that will be compatible with mainstream manufacturing techniques at scale later down the line.

When challenges arise with excipients that are already widely used commercially, it is necessary to look beyond precedence of use to new solutions.

METHODS TO ACHIEVE CONTROLLED RELEASE & ASSOCIATED CHALLENGES

The most straightforward method to produce controlled release is through a matrix tablet. This typically involves granulating the API with the chosen controlled-release excipient and forming the material into a tablet, following which controlled release is achieved out of the matrix.

Recently, direct compression has also gained interest as a manufacturing technique for matrix tablets. Utilizing free-flowing ingredients and bypassing several manufacturing steps associated with granulation, direct compression can reduce manufacturing time and costs. While granulation is still the dominant technology in the controlled-release space, direct compression is expected to grow in popularity in the future.

In addition to matrix forming, there are also companies that utilize coating technologies to provide a layer for sustained release. More complex approaches are typically used when there's a challenge with the API that makes it difficult to formulate a simpler matrix or coated tablet, such as strong hydrophilicity. This leads to the API being highly soluble and dissolving quickly in solution, making it difficult to control release through traditional systems. Additionally, if it is necessary to achieve a high dose of API, it can be difficult to then control release.

Alternative systems for APIs that are challenging to formulate often rely on technologies, such as multi-particulate systems and osmotic pumps, to control release. This lengthens processing time and would only be used when more simple approaches, such as coating and matrix tableting, have failed.

When it comes to excipients for sustained release, one of the biggest challenges formulators experience is usage levels. It is common for a large amount of excipient to be needed to control release of an API – for example, using HPMC by itself – especially for hydrophilic or high-dose APIs.

The excipient polymer could comprise as much as 30% of the tablet, leaving less flexibility for adding different excipients to provide other much-needed properties. It also leaves less space to incorporate a high-dose API and may lead to large pill sizes that are challenging for some patients to swallow.

SEEKING OUT PROVEN INNOVATIONS

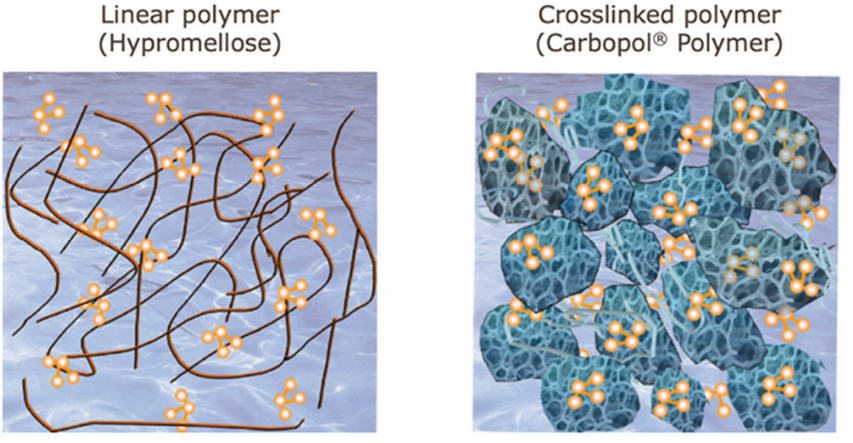
In response to controlled-release formulation challenges and the associated need for simpler, effective solutions, tried and tested excipients like carbomer polymers can come into play.

When carbomer tablets are placed in contact with dissolution media, the external surface of the tablet becomes hydrated. It then swells and forms a gel layer that efficiently controls the release of the drug from the tablets.

Due to the crosslinked nature of the polymer, the hydrogel is not composed of single entangled chains of polymer (as in the case of the water-soluble polymeric matrix), but discrete microgels made up of many polymer particles, in which the drug is dispersed (Figure 1). Because the carbomer is not water soluble, it does not dissolve, and erosion in the manner of linear polymers such a HPMC does not occur. Rather, when the hydrogel is fully hydrated, osmotic pressure from within may break up the structure, essentially by sloughing off discrete pieces of the hydrogel.

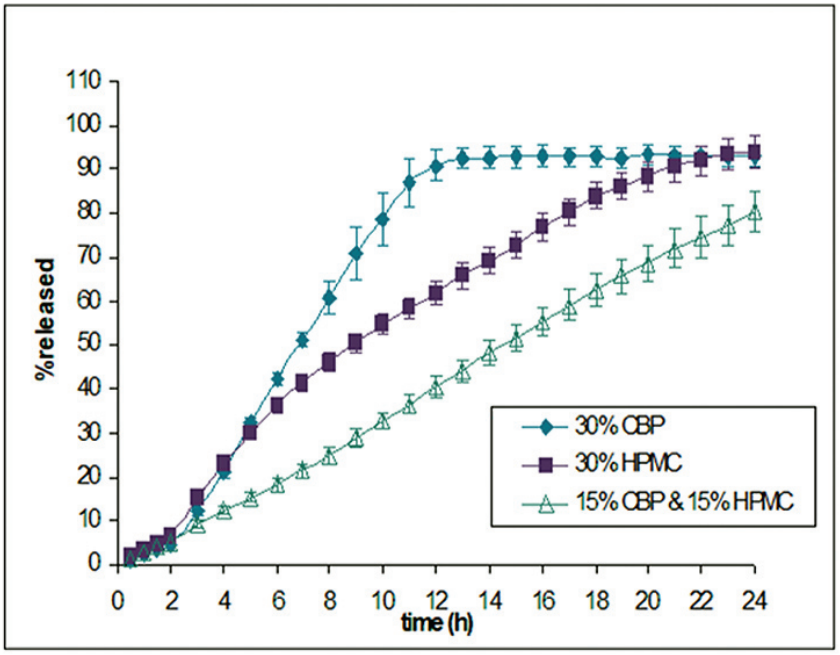
Carbopol® polymers are an example of carbomer chemistry that has been successfully leveraged in controlled-release formulations. These are efficient matrix-forming excipients that are highly effective at low concentrations – indeed, more effective than linear (cellulosic) materials such as HPMC in sustaining drug release. Chemically, Carbopol polymers are high

FIGURE 1



3D Structure of Linear & Crosslinked Polymers

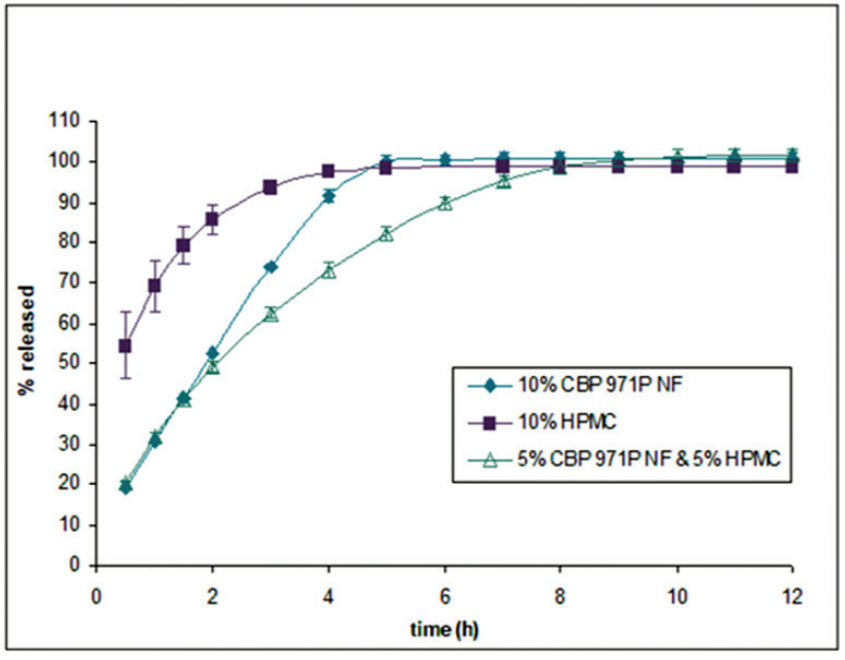
FIGURE 2



Ketoprofen release (USP method for modified release) from tablets (50 mg) with 30% polymer (direct compression)

Carbopol® polymer combined with HPMC results in a stronger extended-release matrix and improved control over Ketoprofen release.

FIGURE 3



Guaifenesin release in pH=6.8 buffer from tablets (100 mg) with 10% polymer (wet granulation)

Carbopol® polymer combined with HPMC results in a stronger extended-release matrix and improved control over Guaifenesin release.

molecular weight polymers of acrylic acid, with a 3D structure that enables efficiency in controlled/extended release.

Drug-release rates are affected by differences in the rates of hydration and swelling of the polymer hydrogel, which are dependent on the molecular structure of the polymers, including crosslink density, chain entanglement, and crystallinity of the polymer matrix.

Generally, increasing the level of Carbopol polymer in a formulation leads to slower and more linear drug release, with a stronger gel layer, fewer regions of low micro viscosity, and fewer interstitial spaces between microgels.

Powder grades of Carbopol polymers, such as Carbopol 971P NF polymer and Carbopol 974P NF polymer, are amenable to traditional wet and dry granulation processes. These grades can achieve robust control over drug release at usage levels as low as 5%. There is also a granular form of carbomer called Carbopol 71G polymer, which is free-flowing and directly compressible, leading to simplified processing.

In addition, all these grades of Carbopol polymers are IID-listed ingredients used in FDA-approved oral drug products. Their strong precedence of use in the oral space facilitates their use in novel extended-release tablets and 505(b)(2) products.

One of the most important features of Carbopol polymers is they can help reduce tablet size and control release of a high-dose API. As a result, Carbopol polymers can enable formulators to bypass complex processing techniques, such as an osmotic pump or multi-particulate system. It is possible to continue working with more simple matrix tablets using Carbopol polymers and still achieve control over release.

As a result of their useful characteristics, carbomer polymers have been used as controlled-release excipients for several decades now. Commercial examples include Lyrica CR, the extended-release version of Lyrica for the management of chronic pain, which utilizes carbomer polymers. Mucinex, an expectorant that relieves symptoms of the common cold, delivers controlled release in a bilayer format, utilizing Carbopol polymer in the extended-release layer to enable the drug to be delivered for up to 12 hours.

The applications of Carbopol polymers even extend to metformin, the frontline treatment for type-2 diabetes. Case studies show Carbopol polymers can be of great benefit for conferring sustained release to metformin formulations, as well as reducing tablet size by 20%-30%, potentially improving the quality of life for millions of patients worldwide.[3]

COMBINING EXCIPIENTS TO FACILITATE IMPROVED PROPERTIES

Carbopol polymers are a strong first-choice alternative to HPMC, one of the most widespread excipients for controlled release on the market. It is possible to apply Carbopol polymer as a stand-alone excipient or supplement an HPMC formulation with Carbopol polymer as a co-excipient.

Carbopol polymer combined with other controlled-release excipients results in more efficient extended-release tablets with improved performance, as illustrated in Figures 2 and 3. As the data shows, whether HPMC or carbomer performs best as a stand-alone matrix former, the combination of both excipients provides the best control over drug release. This "synergistic" effect can be a valuable tool for formulating challenging APIs into extended-release formats.

With carbomer chemistry, a full reformulation may not be necessary to formulators struggling to achieve release targets using HPMC alone. Simply adding Carbopol polymers to cellulosic-based formulations may solve the problem.

UNLOCKING CONTROLLED-RELEASE MEDICINES FOR PATIENTS

Patients stand to benefit greatly from controlled-release treatment options that reduce administration frequency, especially those with chronic diseases or complex drug regimens. Innovative, commercially proven excipients such as carbomers are key to both unlocking patient-friendly formulations and helping pharma companies extend the lifetime of their portfolios.

By working alone or alongside other well-established excipients for controlled release such as HPMC, the power of carbomer chemistry can help drug developers to overcome common challenges associated with controlled-release formulations without resorting to more complex techniques. Patient-centric, formulator-friendly carbomer polymers offer a long runway for innovation for small molecule formulations, enabling a new wave of controlled-release medicines that can be streamlined to the market and improve patients' lives. ◆

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BIOGRAPHY

Nick DiFranco is the Global Market Segment Manager for Oral Treatments at Lubrizol Life Science Health (LLS Health). In his role, he coordinates a multi-disciplinary team offering excipients and services for controlled release and solubility enhancement in oral solids and liquids, including Carbopol® and Apinovex™ polymers. Prior to this role, held positions as an Applications Scientist and Market Manager at Lubrizol supporting long-acting drug delivery and CDMO services. He earned his BS in Biomedical Engineering (Biomaterials focus) and a Master of Engineering and Management degree from Case Western Reserve University.

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Facebook: www.facebook.com/AjiBioPharma
LinkedIn: www.linkedin.com/company/ajibio-pharma-services/
Twitter: twitter.com/AjiBioPharma W: www.AjiBio-Pharma.com

Company Description

Ajinomoto Bio-Pharma Services is a fully integrated contract development and manufacturing organization, with sites in Belgium, United States, Japan, and India, providing comprehensive process development services, cGMP manufacturing, and drug product fill finish services for small and large molecule APIs and intermediates.

Ajinomoto Bio-Pharma Services offers a broad range of innovative platforms and capabilities for pre-clinical and pilot programs to commercial quantities, including Corynex® protein expression technology, oligonucleotide synthesis, high potency APIs (HPAPIs), continuous flow manufacturing, and more. Ajinomoto Bio-Pharma Services is dedicated to providing a high level of quality and service to meet our client's needs.

Ajinomoto Bio-Pharma Services is your trusted manufacturing partner providing a broad range of capabilities, regulatory excellence, and extensive experience, helping you navigate production challenges, providing solutions to your development process, and delivering your new therapies to patients who need it most.

MARKETS SERVED

Our integrated global network for large and small molecule development and manufacturing has sites in Europe, North America, and Asia, providing the infrastructure and local support to meet your drug process development and manufacturing needs.

SERVICES & CAPABILITES

Phase-Appropriate Services: Our complete range of process and analytical development capabilities offer the tools to address your needs, whether it is producing small quantities for early testing or in developing robust, reliable, and scalable processes that will enable a strong commercial advantage.

Broad Range of Capabilities: Over 40 years of CDMO experience providing a range of manufacturing capabilities enables us to deliver the flexibility and guidance to meet different drug product needs from emerging therapeutics to life cycle management.

- Drug product aseptic fill finish
- Small molecule manufacturing
- Large molecule manufacturing
- Oligonucleotide and peptide synthesis

Advanced Technologies: Our services are enhanced by a portfolio of innovative and advanced technologies that enable robust, scalable, cost- and time-efficient processes for large and small molecule manufacturing. We are continuously developing new solutions to improve manufacturing processes.

Regulatory Support: With an impressive and successful track record, we are well positioned to advise you on regulatory strategies and navigate hurdles to achieve your program goals. We provide strong, yet flexible quality management to ensure continued program success.

EXPERIENCE THE POWER TO MAKE

We have the capacity and know-how to manage projects from preclinical stage to commercialization successfully, but what truly differentiates us is our dedication to quality and our commitment to fostering trusted partnerships. We're looking forward to hearing from you.

LET'S MAKE A HEALTHY WORLD

WITH AJINOMOTO BIO-PHARMA SERVICES, YOU HAVE THE POWER TO MAKE.

To make your vision a reality. To make your program a success. To make a positive difference in the world.

Your programs deserve the most comprehensive suite of CDMO services available, and Ajinomoto Bio-Pharma Services has the Power to Make your therapeutic vision a reality - from preclinical through commerical production.

CDMO SERVICES:

- Small Molecules
- Large Molecules
- Process Development
- Oligos & Peptides
- Aseptic Fill Finish

WHAT DO YOU WANT TO MAKE?

www.AjiBio-Pharma.com

AJINOMOTO BIO•PHARMA SERVICES | THE POWER TO MAKE®

Alcami provides customizable and innovative solutions for analytical development, clinical to commercial sterile and oral solid manufacturing, packaging, microbiology, cGMP biostorage, environmental monitoring, and pharmaceutical support services.

Partnering with Alcami as your contract development and manufacturing organization connects you to a US-based team of dedicated professionals with over 40 years of experience advancing products through every stage of the development lifecycle. Whether you are a virtual start-up or a large organization, you and your patients deserve subject matter experts who take ownership of your program from clinical trials through commercial supply.

- **Analytical Services**
  - Small and large molecules
  - Solid State Chemistry
- **Drug Product Development & Manufacturing**
  - Formulation Development
  - Sterile Fill-Finish
  - Oral Solid Dose
  - Packaging & Labeling
- **cGMP Biostorage**
  - Cryoboxes to pallets
- **Pharma Support Services**
  - Environmental Monitoring
  - Commissioning, Qualification and Validation (CQV) Solutions
  - Metrology & Calibration
  - Product Rental & Sales

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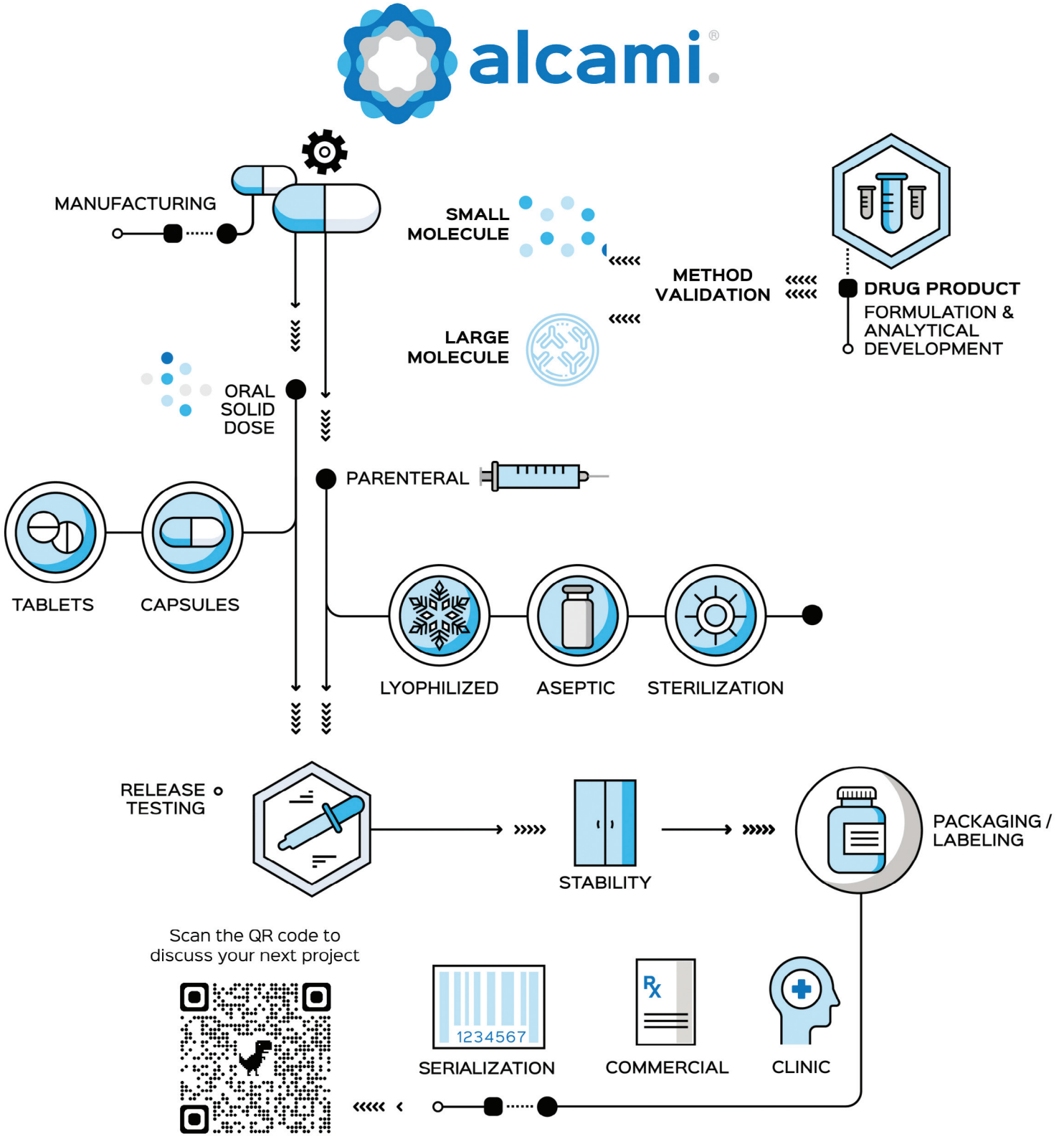
W: alcaminow.com



Solutions, Delivered.

alcaminow.com |

COMPANY PROFILE

APRECIA™

THE 3DP PHARMACEUTICAL COMPANY

VISION

Aprecia is the global leader in new pharmaceutical technologies that address unmet healthcare needs.

LIFE TRANSFORMING INNOVATIONS

As a specialty CDMO, Aprecia is redefining 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.

Scan to schedule a meeting with our formulation experts.

ADVANTAGE

- Differentiating oral formulations
- Enabling innovation
- Extended exclusivity

SPEED

- Accelerated drug development
- Streamlined clinical trials
- On-Demand cGMP production

QUALITY

- FDA approved product
- cGMP operations since 2016
- FDA registered and inspected

FUTURE

- Distributed/decentralized manufacturing
- Innovation partnerships
- Personalized medicine

Aprecia Pharmaceuticals
10901 Kenwood Rd | Blue Ash, OH 45242
513.984.5000 | **aprecia.com**

THE FUTURE OF 3DP PHARMACEUTICALS IS NOW

Aprecia is the biopharmaceutical leader in advanced additive manufacturing technologies. As a specialty CDMO, we help you overcome formulation challenges. Through novel oral dosage forms, we are redefining medicine so patients and caregivers can live their best lives.

APRECIA™
THE 3DP PHARMACEUTICAL COMPANY

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.

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 de risk 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 300 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.

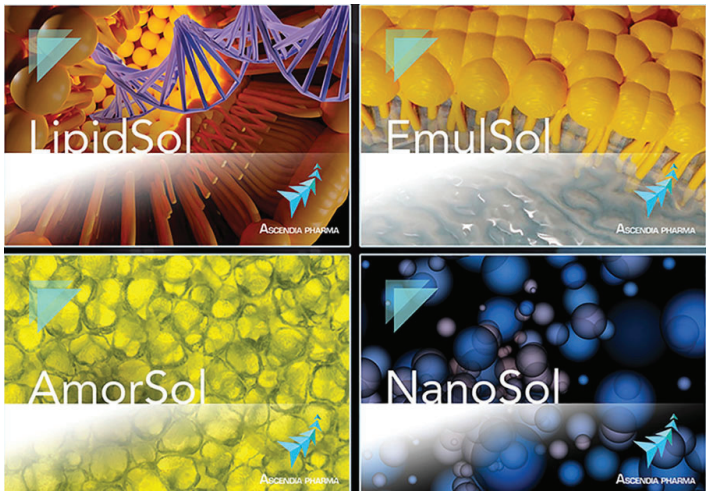
With our increased capacity and agility, together we can meet the world's biggest health challenges, today and tomorrow. Join us.

visit www.aptar.com/pharmaceutical

Shaping the future of injectables, together

Aptar pharma

ASCENDIA PHARMA



Ascendia Pharmaceuticals® is a specialty formulation CDMO for biologicals and gene deliveries, as well as small molecules. 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 and nutraceuticals.

Ascendia continues to expand its people, capabilities, and facilities to exceed customer expectations from pre-formulation through to commercialization. This investment allows Ascendia to continue be expert in sophisticated formulations, and well as cGMP sterile and non-sterile clinical trial and commercial manufacturing. Many clients have anointed Ascendia a "Partner of Choice" because of the successes it has achieved for them.

Ascendia's formulation experts make the *Impossible Possible* by developing formulations for projects when others have failed. These successful formulations use all GRAS materials to eliminate regulatory burden.

Company Background

Founded in 2012, Ascendia offers a comprehensive suite of pre-formulation, formulation development, cGMP manufacturing, and ICH stability services for all dosage forms using proprietary nanotechnologies in nanoemulsion, nanoparticles, and amorphous technology platforms. The company built its foundation of success on its customer-centric culture that exudes its ***BEST*** philosophy (Brilliant technology, Excellent service, Superior quality, and Trust).

Markets Served/Facilities

Headquartered in North Brunswick, NJ, Ascendia's 60,000 square-foot facility has Class 10,000 (ISO 7) and Class 100 (ISO 5) cleanrooms, as well as Class 10,000 (ISO 7) manufacturing suites.

Ascendia's expertise in discovering the most effective formulation development for poorly soluble molecules and biologics aligns the CDMO with pharmaceutical and biopharmaceutical companies developing new drugs, as well as new formulations for existing drugs for new uses.

Products, Services & Capabilities

Ascendia delivers sophisticated formulations to enhance bioavailability and solubility using four proprietary nanotechnologies – AmorSol®, EmulSol®, LipidSol®, and NanoSol®. It develops solutions for all dosage forms for small molecules and biologics, including lipid nanoparticles that enable gene therapy. Its facility maintains stability chambers for conducting non-GMP and cGMP stability studies in accordance with ICH guidelines. Ascendia stability studies:

- determine robustness of formulation prototypes during early development
- ascertain chemical and physical integrity of lead formulations before advancement into animal/toxicology studies
- ensure final formulations meet stability for clinical trials

Ascendia offers fast, flexible, and small-batch size services for conducting first-in-man study efficiently to stay on schedule and within budget.

ASCENDIA PHARMACEUTICALS®
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ASCENDIA PHARMA

Start your project within weeks; not months.

From pre-formulation to Phase III and commercial supply, Ascendia is the CDMO Partner of Choice for your most challenging projects.

Ascendia Pharma's combination of proprietary nanotechnologies and their BEST culture philosophy makes us a Partner of Choice for people with projects from complex formulations to commercial supply needs.

Technical Services from Ascendia:

- Rapid Early-stage Development Services
- Poorly Soluble & Low Bioavailability Drug Formulations
- LNP's for Vaccines, mRNA & Gene Therapy.
- cGMP Sterile & Non-sterile Clinical Trial Materials
- Sophisticated Formulations (Biologics & Small Molecules)
- 505(b)(2) Product Development

Contact Ascendia to find out how we can ***Make the Impossible Possible*** for you!

ASCENDIA PHARMA

732-658-4267

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France
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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.

Committed to Drug Delivery Excellence

At BD, we're committed to providing our pharmaceutical and biotechnology partners with drug delivery systems and solutions that help to derisk development and to shorten timelines. We mobilize our global resources to simplify the technical, medical, regulatory, and manufacturing complexities you face as you bring your combination product to market. Our innovative prefillable syringes, self-injection systems, and safety and shielding devices are designed to improve the lives of patients and care providers—while adapting to the complex requirements for today's combination products. Trust BD experience and expertise to support your success from development to market, and beyond. Learn more at **drugdeliverysystems.bd.com**

BD. Delivering expertise and innovation from development to market

BD

Bora Pharmaceuticals

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LinkedIn: https://www.linkedin.com/company/borapharmaceuticals
Twitter: https://twitter.com/borapharma

Bora Pharmaceuticals is a premier international cGMP CDMO specializing in complex oral solid dosage, non-sterile liquids, sterile and non-sterile ophthalmics, nasal sprays, and semi-solids pharmaceutical products for Clinical through Commercial manufacturing and packaging and clinical manufacturing of biologics drug substance.

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

Bora's teams, technologies, and facilities work seamlessly together to enable our clients to deliver much-needed therapeutics to patients worldwide.

We're proud to make success more certain.

Bora Pharmaceuticals

A partnership that lasts

Customized operations to meet your needs. Our next-level delivery excellence prioritizes responsive treatment, making our reliability your certainty.

Making Success More Certain

- Biologics
- OSD
- Semi-Solids
- Liquids
- Nasal Sprays
- Ophthalmics

Find out more:

www.boracdmo.com

CAPTISOL®

CAPTISOL, A LIGAND TECHNOLOGY
2033 Becker Drive, Suite 310
Lawrence, KS 66047
858-550-5632
www.captisol.com

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!

"With 80 years of combined experience working with Captisol and other cyclodextrins, our team is ready for any formulation challenge and look forward to helping you bring your product to market." — Lian Rajewski, PhD, Sr. Research Investigator

Your Partner in Solubility.

The scientists at Ligand Pharmaceuticals are experts at working with Captisol, have developed products in-house and aided clients in developing many successful formulations. Our expertise in navigating CMC, regulatory, and clinical issues is unparalleled in the industry. Captisol is a solubility enhancing excipient (derivatized cyclodextrin) that has been on the market for over 20 years and is in more than a dozen approved products.

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

858.550.5632 | cdinfo@captisol.com | Captisol.com

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LinkedIn: https://www.linkedin.com/company/cayman-chemical

Cayman Helps Make Research Possible

Cayman Chemical has been supplying high-purity lipids to the scientific community for more than 40 years. Our industry-leading expertise in lipid chemistry, synthesis, and purification is supported by state-of-the-art analytical equipment. We are committed to offering an unprecedented portfolio of lipid nanoparticle research tools to support research and development.

Our portfolio includes an impressive collection of ready-to-use and custom lipids for LNPs including ionizable cationic lipids, helper lipids, sterol lipids, and PEGylated lipids. We also offer research-ready LNPs to screen different LNP compositions and provide in-house lipid synthesis, screening, and LNP development services.

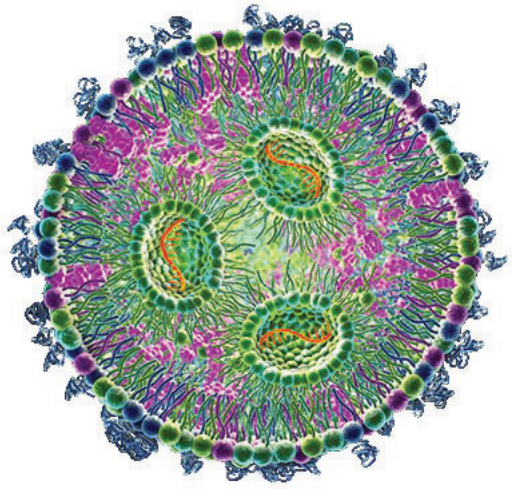
From R&D to GMP, Cayman Supports LNP Development

Cayman supports our clients by providing tailored solutions for LNPs, whether you require single-point or end-to-end support. 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.

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, GMP-compatible components for production in GMP suites at our Ann Arbor, Michigan headquarters. Cayman will work closely with your preferred formulation partner to ensure a smooth transition of identified formulations and any custom components to advance your program toward clinical trials.

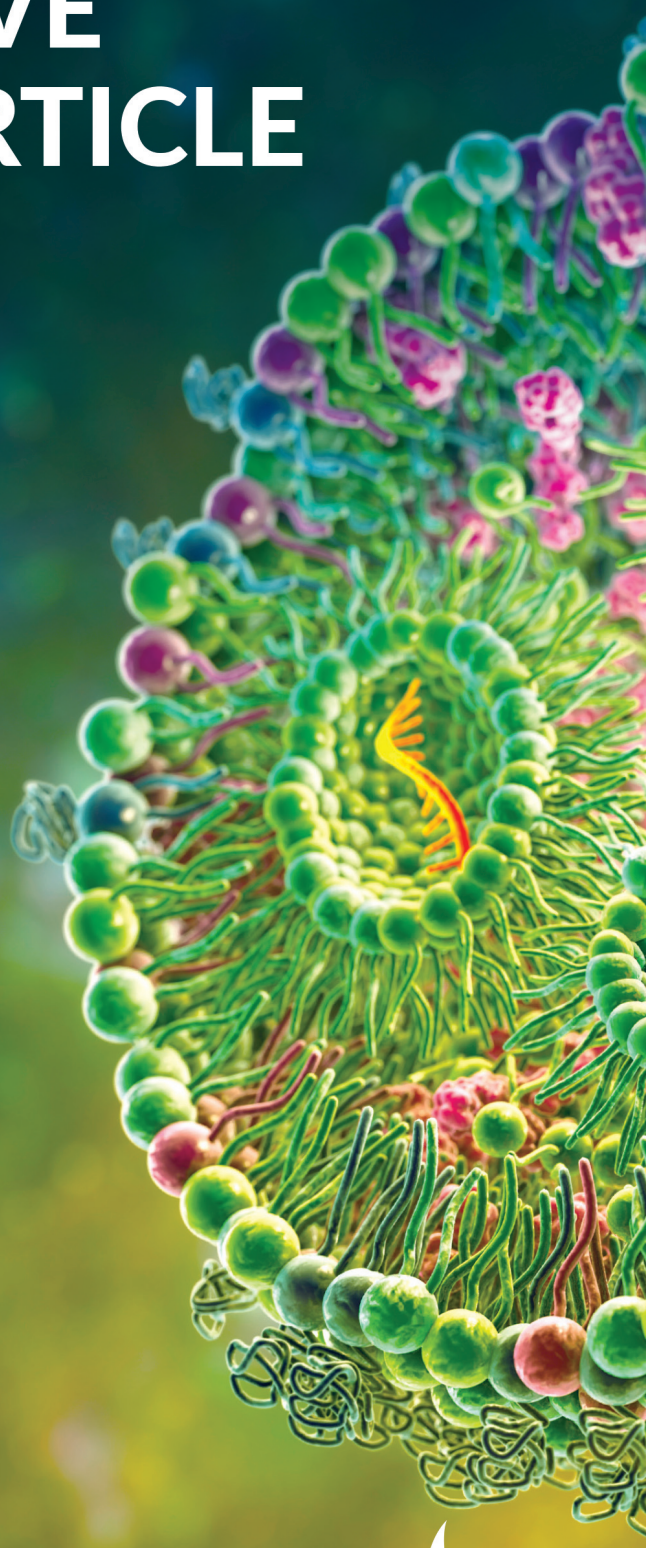
Cayman's LNP Development Services

- **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 Procurement**
  - **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 200 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, pK_a, stability, aggregation, and encapsulation efficiency.
- ***In Vitro* Screening** - Bioanalytical services for *in vitro* 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.
- **GMP Lipid Synthesis** - 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 for human trial LNP production.



DELIVERING A COMPREHENSIVE LIPID NANOPARTICLE TOOLKIT

With industry-leading expertise and state-of-the-art facilities, Cayman provides an impressive collection of lipid nanoparticle (LNP) research tools and integrated services spanning LNP formulation, characterization, and screening to GMP lipid production. We are a trusted US-based service provider backed by 40 years of experience in lipid chemistry, synthesis, and analysis.



- **Lipids for LNP Formulation**
- **Custom Lipid Synthesis**
- **GMP Lipid Production**
- **Research-Ready LNPs & Reagent Kits**
- **LNP Formulation, Characterization, & Screening Services**

Find Your Solution at Our New Lipid Nanoparticle Resource Center

WWW.CAYMANCHEM.COM/LNPs

Cayman CHEMICAL

Celanese

The chemistry inside innovation™

CELANESE
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

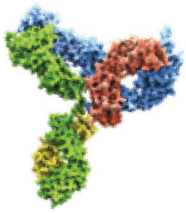
ABOUT CELANESE

Celanese Corporation is a global technology leader in the production of differentiated chemistry solutions and specialty materials used in most major industries and consumer applications. We partner with our customers to solve their most critical business needs and strive to make a positive impact on our communities and the world through our commitment to sustainability and The Celanese Foundation. Based in Dallas, Celanese employs approximately 13,300 employees worldwide and had 2022 net sales of $9.7 billion.

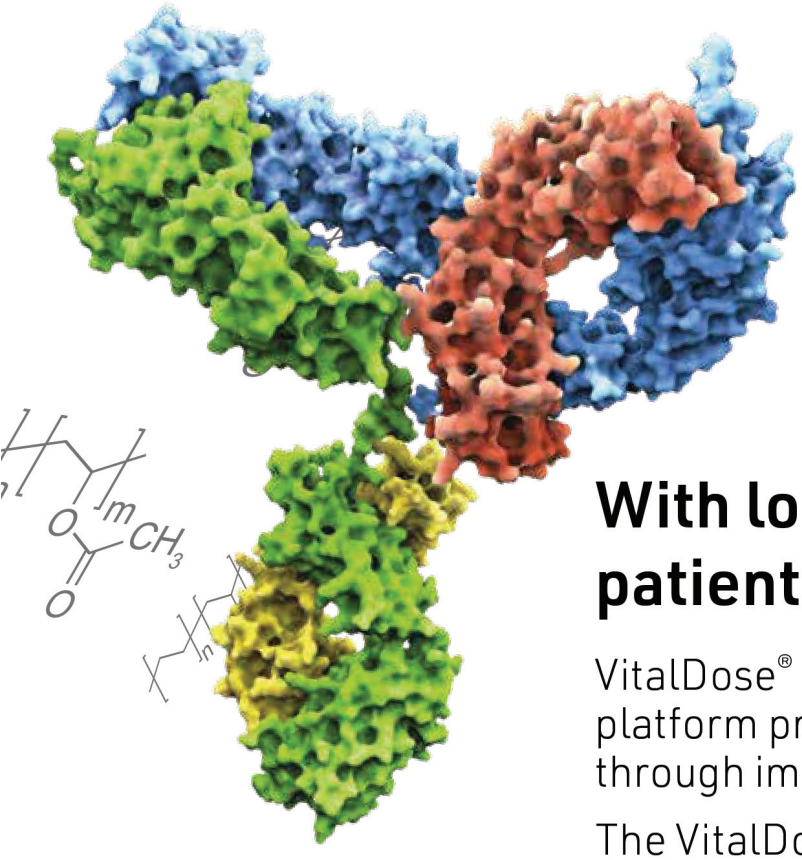
Celanese has supported the demanding requirements of the medical and pharmaceutical markets for over 40 years, expanding possibilities alongside our customers. We're focused on developing new cutting-edge approaches to improve patient care. Our portfolio includes solutions and technologies across applications including drug delivery, medical devices, implantable devices, advanced surgical instruments and connected devices.

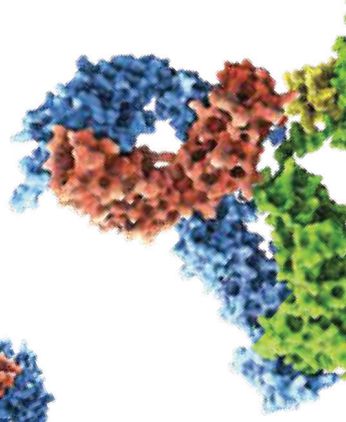
Celanese

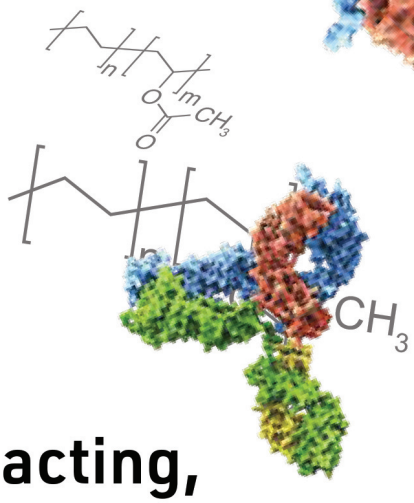
VITAL Dose®



Sustained Drug Delivery







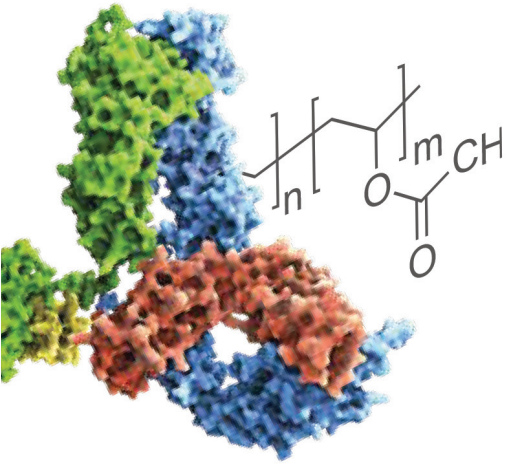
With long-acting, patient-centric therapeutics

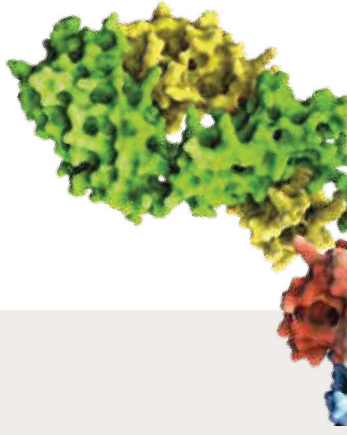
VitalDose® EVA is a copolymer drug-delivery platform providing controlled release through implant and insert dosage forms.

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.

Credence MedSystems is setting a new standard in drug delivery, helping you differentiate your products through innovative delivery systems while preserving your trusted processes.

Credence MedSystems is an innovator of drug delivery systems that solve unmet market needs for the pharmaceutical industry. Credence's philosophy of *Innovation Without Change*® allows pharma manufacturers to impress and protect their end users while preserving their existing processes, sourcing strategies and preferred primary package components.

Companion® Product Family

Add end-of-dose cues, automatic needle retraction, and intuitive safeguards to your products while improving the efficiency of your manufacturing processes, maintaining your sourcing strategy and enhancing your sustainability efforts.

Dual Chamber Reconstitution or Sequential Liquid Delivery

Simplify the delivery of your most complex drug products. Maintain separation of components during storage while offering users a safe and friendly experience like that of a liquid-stable drug. Simplified mixing or sequential delivery of two liquids combined with passive needlestick protection minimizes time, complexity and risk of dosing errors and contamination, all while improving safety and usability.

Credence Connect™

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.

Contact us to see *Innovation Without Change* in action and explore our portfolio of award-winning, industry-unique drug delivery systems.

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CREDENCE MEDSYSTEMS

INNOVATION WITHOUT CHANGE HAS ARRIVED

THE CREDENCE COMPANION

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Facebook: https://www.facebook.com/CuriaCDMO
Twitter: https://twitter.com/CuriaCDMO

Curia is a Contract Development and Manufacturing Organization with over 30 years of experience, an integrated network of 29 global sites and over 3,500 employees partnering with customers to make treatments broadly accessible to patients. Our biologics and small molecule offering spans discovery through commercialization, with integrated regulatory and analytical capabilities. Our scientific and process experts and state-of-the-art facilities deliver best-in-class experience across drug substance and drug product manufacturing. From curiosity to cure, we deliver every step to accelerate and sustain life-changing therapeutics. To learn more visit us at curiaglobal.com.

Services & Capabilities

BIOLOGICS

Our biologics offering spans discovery to clinic and fill-finish services across monoclonal antibodies, recombinant proteins and mRNA therapeutics. Our scientific and process experts and state-of-the-art facilities deliver best-in-class experience across drug substance and drug product manufacturing.

SMALL MOLECULE

Our small molecule offering spans discovery to commercial manufacturing and fill-finish services, integrating scientific, process, regulatory and analytical capabilities for API life cycle. Our combined state-of-the-art facilities, scalable technologies, and commitment to growth advance your program through drug substance and drug product manufacturing.

From curiosity to cure®

Curia is a Contract Development and Manufacturing Organization with over 30 years of experience, an integrated network of 29 global sites and over 3,500 employees partnering with customers to make treatments broadly accessible to patients.

Our **biologics** and **small molecule** offering spans discovery through commercialization, with integrated regulatory and analytical capabilities.

Our scientific and process experts and state-of-the-art facilities deliver best-in-class experience across drug substance and drug product manufacturing. From curiosity to cure, we deliver every step to accelerate and sustain life-changing therapeutics.

To learn more visit us at curiaglobal.com

curia

GETTING THE BEST OUT OF CYCLODEXTRINS

Pharma grade cyclodextrins • Early phase drug development
Fine chemical production • On-demand custom synthesis
Analytical services

CYCLO LAB

For more than 30 years, Cyclolab Ltd. has been involved in the development, production and distribution of research- and pharma grade cyclodextrin products for pharmaceutical product development purposes.

MAIN PRODUCTS

DEXOLVE™

Cyclolab' key product is Dexolve™: a Sulfobutyl-Betadex Sodium Salt manufactured in multiple tons scale quantity under GMP with a patented technology, complying both to USP NP and EP, with valid USFDA, MFDS, NMPA licenses.

SBECD is a versatile and potent excipient that can significantly improve the solubility, bioavailability, and stability of active pharmaceutical ingredients (APIs) in your products.

DIMEB

Cyclolab produces in kilogram-scale a methylated derivative of the beta cyclodextrin: Heptakis(2,6-di-O-methyl)-beta-cyclodextrin, (aka DIMEB), a single isomer with exactly 14 methoxy groups at positions C2 and C6, for extraction and solubilization of cholesterol from lipid bilayers with a unique potential applications in various fields of biotechnology.

SUGAMMADEX IMPURITY STANDARDS AND CONTRACT SERVICES

CycloLab has vast experience in the production of Per-6-halogeno-gamma-CD intermediates and has developed Sugammadex via various process routes and related compounds, supported by sensitive analytical tools to characterize the products.

Contract services

- synthesis
- process and formulation development
- contract analysis
- IP/FTO search and evaluation

Standards

- process intermediates
- process impurities

OUR SERVICES

ANALYTICAL SERVICES

- New CD-derivatives (on demand)
- Target synthesis
- Stability and release testing
- HPLC / HPLC-MS / GC / CE / UV- / IR- / NMR spectroscopy
- Ion mobility - high-resolution mass spectrometry
- Analytical method development
- Impurity isolation and characterization
- Custom method development
- Isomer / enantiomer separation
- Analysis of CD-API complexes
- Instrumental host-guest affinity determination
- Reaction kinetic studies

AS A CDMO, WE OFFER INTERGRATED SERVICES FOR THE POTENTIAL CUSTOMERS:

- Alkylation and acylation reactions
- Solution preparation (including emulsions, suspensions) under cGMP upto 500 liter
- Spray drying up to 20MT/Y in class 'D' clean area
- Pressure filtration up to 5 bar
- Tempered storage, with delayed stirring (in qualified cooling chambers)
- Purification steps (charcoal, resin treatment)
- In-house in-process controls in-house (HPLC, MS, GC, UV, DLS, IR, CE, etc.)
- Full release tests according to EP,USP, etc.
- Qualified, modularly applicable clean area 'D'
- Syringe-filling
- Autoclave sterilisation
- Evaporation under vacuum
- Filling of porous materials

For further information please visit cyclolab.hu

National Research, Development and Innovation Office Hungary

PROJECT FINANCED FROM THE NRDI FUND

CycloLab offers the widest variety of cyclodextrins in our webshop (**https://cyclolab.hu/products/**) for various purposes (research, analytics, cell cultures, formulation studies, etc).

DDL

Testing Experts. Service Specialists.

For over 30 years, **DDL** has provided extraordinary service and specialized testing expertise to the medical device and pharmaceutical industries. Our reliable quality, responsive attention, and on-schedule completion for packaging, medical device, and combination products testing secures confidence in performance and safety while achieving regulatory compliance.

Package Testing

DDL's package testing services evaluate the strength and integrity of packaging systems before and after simulating the anticipated distribution and storage conditions that the systems may undergo. Packaging professionals use this combination of simulation and evaluation to validate package compliance with ASTM, ISO, ISTA and other accepted industry standards. DDL offers full service package testing in Eden Prairie, MN and Irvine, CA, and select package testing capabilities in Edison, NJ.

Drug Delivery Device Testing

DDL specializes in mechanical and performance testing for pre-filled syringes (ISO 11040), needle-based injection systems (ISO 11608) and small-bore connectors (ISO 80369). In preparing for regulatory submission or verifying your products conform to the required industry standards, DDL provides reliable test data to document the performance and safety of your drug delivery product.

Container Closure Integrity Testing

Package integrity verification requires careful examination of package leakage given the specific product and its life cycle. DDL's CCI services include both the most recent deterministic capabilities, as well as probabilistic methods, as outlined in USP <1207>. We can provide tailored expertise to design and execute a CCI study based on your system, providing the support you need.

Medical Device Testing

DDL specializes in testing medical devices such as luer fittings, syringes, needles, catheters, guidewires, surgical sutures, cannulae and tracheal tubes. DDL tests to ANSI, ASTM, IEC, ISO, JIS, EN and other industry standards. Vibration, physical shock, thermal shock, friction, flow rate, force to operate, leakage and compression testing are among the many tests provided. Custom test development and protocol creation are also available.

Stability Storage

DDL's testing laboratories contain over 40,000 cubic feet of storage space that have been mapped and calibrated for long- and short-term shelf life studies under various temperature and humidity requirements. DDL has the conditions you need and the capacity to support your tight timelines. Custom storage conditions and reports are available to support your specific procedures.

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F: 714-979-1721

DDL – New Jersey
551 Raritan Center Parkway
Edison, NJ 08837
T: (732) 346-9200
F: (732) 346-0295

EMERGENT BIO SERVICES™

A Strategic & Collaborative Manufacturing Partner

Emergent Bioservices offers biotech and pharma companies a strategic and reliable manufacturing solution for their clinical and commercial products. With 25 years of experience developing, manufacturing, and delivering our own portfolio of therapeutics and vaccines, we have the scientific and regulatory compliance experience, development and manufacturing resources, and efficient technology transfer capabilities that can harness the urgency, acuity, and scalability required to bring life-saving, life-enhancing products to market.

Our capabilities include:

- Plasma protein purification, filling, and packaging
- Clinical and commercial aseptic fill/finish manufacturing for small and large molecules
- Nanoparticles & liposomal formulations
- Process development, optimization, and scale up
- Analytical services

As partners in bold initiatives, Emergent Bioservices and our clients are truly "Makers of a Better World".

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W: emergentbio.com
LinkedIn: www.linkedin.com/showcase/emergent-bioservices

MAKERS OF
A BETTER WORLD

EXPERTISE AND TRUST IN EVERY VIAL

For biopharma innovators tackling the most serious health threats and rare diseases, Emergent has the scientific and technical expertise, development and manufacturing resources, and efficient tech transfer capabilities that can bring life-saving, life-enhancing products to market.

As partners in bold initiatives, Emergent and our clients are truly “Makers of a Better World.”

EMERGENT BIO SERVICES

emergentbio.com

HEALTH SOLUTIONS
6201 America Center Drive
San Jose, CA 95002
E: healthsolutions@flex.com
W: flex.com

Partnering with you to create the extraordinary in design and manufacturing of medical products

Vital Statistics

- Flex was founded in 1969
- Number of Employees: 160,000+
- Number of Facilities: 130 sites in 30 countries, 6 design & engineering sites, 6 tooling and molding sites, 21 FDA registered entities, 31 ISO13485 designated sites

Who We Are

- Global design, development and manufacturing provider with over 30 years of medical experience across FDA Class I, II, and III products from simple disposables to smart drug delivery systems and immunoassay diagnostic systems
- 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"
- Medical footprint includes multiple plastics tool-making and injection molding facilities
- 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)

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.

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.

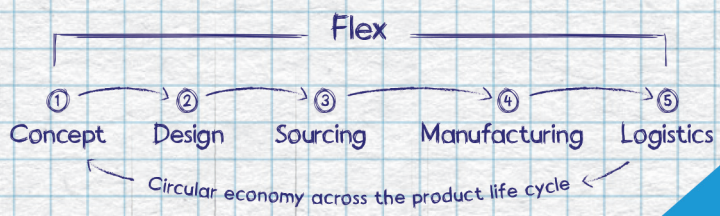
Drug Delivery

Autoinjectors, on-body injectors, smart injection pens, pumps and infusion systems, wearable pumps.

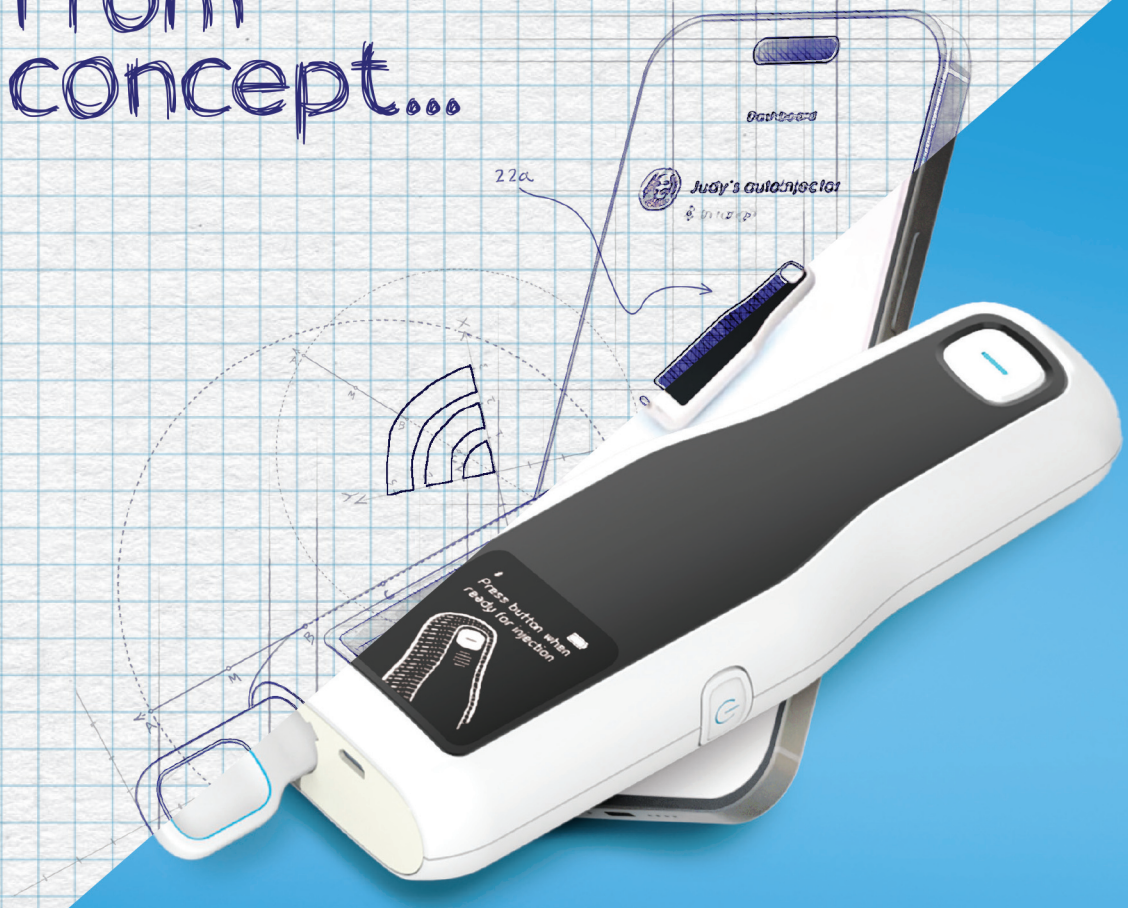
Precision Plastics

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

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

2023 Manufacturing Leadership Awards

Manufacturer of the Year
Large Enterprise

2023 WORLD'S MOST ETHICAL COMPANIES® ETHISPHERE™

flexintl

flex.com/health

FORTIS LIFE SCIENCES

nanoComposix

A FORTIS LIFE SCIENCES COMPANY

Fortis Life Sciences offers world-class reagents, tools, materials, and custom services with a best-in-class customer experience for our customers in the biopharma industry. Through our brand nanoComposix, we provide precisely engineered and highly characterized nanomaterials to a global customer base. nanoComposix is an ISO 13485 (2016)-Certified*, FDA-registered developer and contract manufacturer with a nanomaterial product portfolio containing hundreds of variants engineered to address the unique challenges presented by our customers. Our products and CDMO services are backed by technical teams with extensive expertise in nanotechnology, biology, chemistry, physics, and optics.

NANOMATERIALS FOR NANOMEDICINE

At Fortis Life Sciences, we provide solutions for the rapid development and commercialization of medical devices and therapeutic products. There are many nanomaterial companies and many GMP manufacturers but very few that specialize in both.

With our diverse expertise in nanoparticle fabrication to targeted delivery, controlled-release, photothermal therapy, and biofunctionalization, we help partners bring high- impact, nano-enabled products to market.

Find more details and case studies on our website: https://www.fortislife.com/nanomaterials-for-targeted-drug-delivery-and-photothermal-therapy

GMP NANOMATERIAL SYNTHESIS & MANUFACTURING

Fortis Life Sciences specializes in the development and manufacturing of devices and drugs with nanomaterial components. We are experts in the fabrication and scale-up of nanomaterials for use in products that require ISO13485:2016 and cGMP-compliant quality systems.

Tailored GMP Solutions

We work through a multi-stage process with each client to collaboratively develop a GMP Project Plan customized for the target application while maintaining cost efficiency and compliance.

Nanoparticle Manufacturing Expertise

We have been manufacturing nanoparticles for over 16 years. Our lead scientists have 80+ years of collective experience in nanomaterial fabrication, with an emphasis in metals and metal oxides like gold, silver, and silica as well as polymers like PLGA.

GMP Experience & Capabilities

Our facility offers production under the controls of our cGMP compliant / ISO13485 certified Quality Management System and provides scaled nanoparticle manufacturing for medical devices, topical therapeutics, and combination (drug/device) products for preclinical and Phase 1/2 clinical trials.

Find more details and case studies on our website:
https://www.fortislife.com/gmp-nanoparticle-manufacturing

***Specific to 4878 Ronson Ct. Suite J and 4888 Ronson Ct. Suite B**

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W: https://www.fortislife.com/
LinkedIn: https://www.linkedin.com/company/fortis-life-sci/

FORTIS
LIFE SCIENCES

Custom fabrication and functionalization of nanoparticles for therapeutics

Leverage our unique experience in nanoparticle development and GMP manufacturing to ensure rapid development and commercialization of your nano-enabled products.

We offer solutions from proof of concept to scaled manufacturing of therapeutic systems for:

- Targeted delivery
- Controlled release
- Photothermal therapeutics
- Theranostics
- Gene therapy

Learn more at: fortislife.com/drug-delivery-nanomaterials

nanoComposix

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 80 affiliates, Gattefossé prides itself in 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 to minimize attrition rates and shorten the drug development pathway. Through our Technical Centers of Excellence in the Americas, Europe, and Asia, we offer complimentary support for solubility screening, formulation design, and characterization for various routes of administration. Alongside, we provide guidance for regulatory, safety, and preclinical aspects of our excipients.

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GATTEFOSSÉ USA Regional Office
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www.gattefosse.com

People make our name

Paving the way for over 40 years of cutting-edge solutions in the USA

GATTEFOSSÉ

Timeless Dedication

Gattefossé USA will soon mark an incredible milestone of 40 years of unwavering dedication to the pharmaceutical and healthcare markets in the United States.

Throughout our company's history, Gattefossé has not only provided cutting-edge products and solutions to our customers, but we have also fostered deep and enduring partnerships with industry leaders and collaborated with some of the brightest minds and most prominent names in the pharmaceutical field.

Since Gattefossé's inception in 1880, our global network has demonstrated commitment to excellence, innovation, and well-being of patients worldwide. Our momentous anniversaries are a testament to our enduring legacy in the industries we serve. As we celebrate 145 years, we extend our heartfelt gratitude to all those who have been a part of our journey, and we look forward to continued collaboration and innovation in the years to come.

www.gattefosse.com

People make our name

HERMES PHARMA

Get the dose right®

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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, orally disintegrating granules and HERMES NutriCaps.

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.

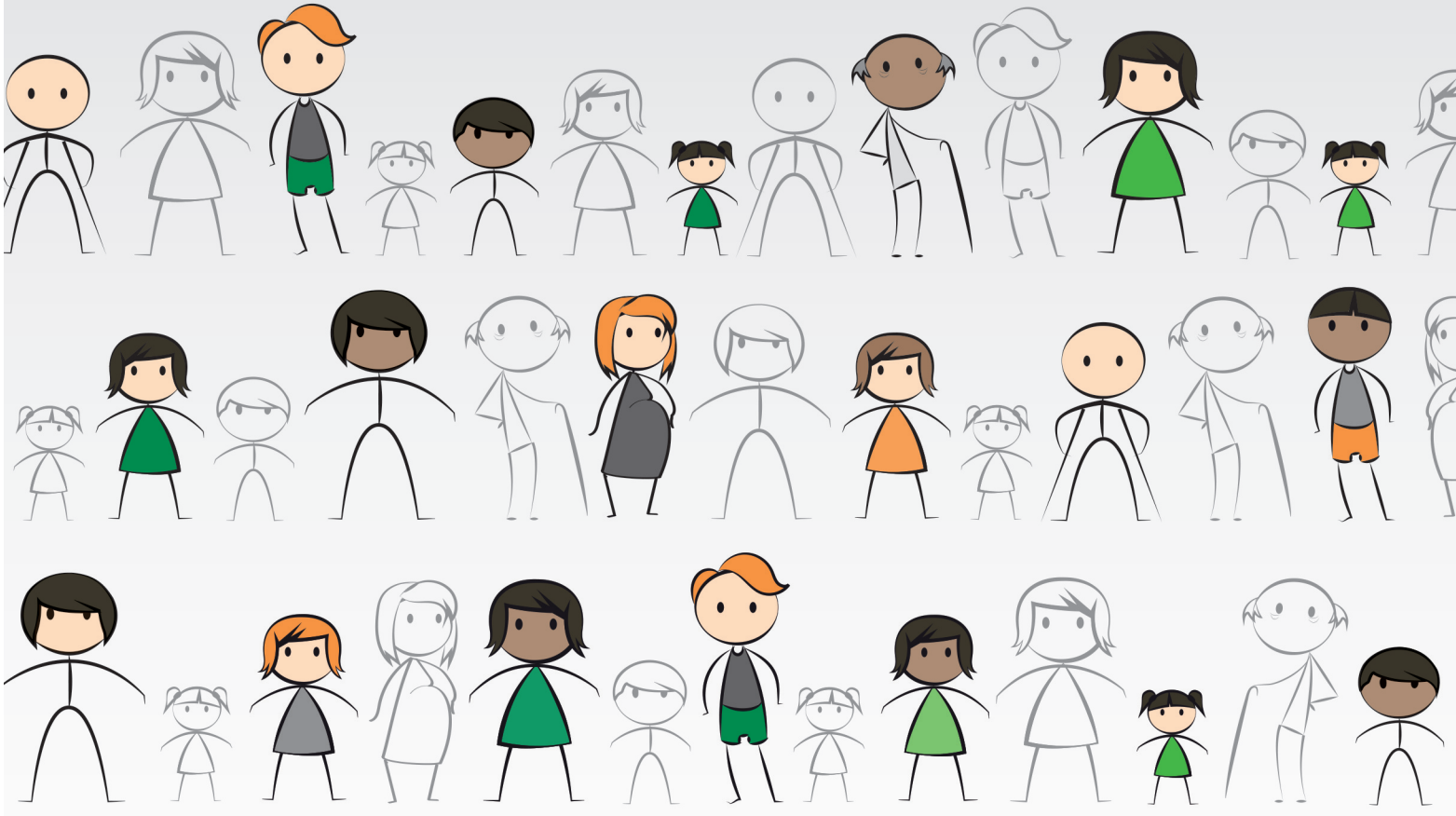
Our effervescent and chewable tablets, lozenges, instant drinks, orally disintegrating granules and HERMES NutriCaps are user-friendly alternatives to conventional tablets and capsules. They provide an added value to patients and consumers as they:

- 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®

Honeywell

Company Description

Honeywell delivers industry-specific solutions that include aerospace products and services; control technologies for buildings and industry; and performance materials globally. Our technologies help aircraft, buildings, manufacturing plants, supply chains, and workers become more connected to make our world smarter, safer, and more sustainable.

Honeywell Advanced Materials is an industry leading solutions provider, playing a crucial role in advancing industries worldwide through diverse applications, revolutionary inventions, and pioneering technologies focused on high growth mega-trends. Our science and technology experts create solutions that enable customers to overcome their challenges today and into the future.

Honeywell Aclar® Films is poly-chloro-trifluoro-ethylene (PCTFE) film that is the industry leading global packaging material and trusted choice in pharmaceutical packaging for more than 50 years. Aclar protects drug stability by providing the highest moisture barrier among all polymer materials. This thermoformable films facilitate the safe and secure delivery of healthcare and pharmaceutical products, even in the most extreme environments. Aclar® is crystal clear which allows patients to easily identify medication for enhanced safety and has a low push through force enhancing the user experience.

In addition to Aclar® thermoformable films, Honeywell offers many innovations that are applicable to the life science market including Solstice® Air which is a near-zero GWP propellant for metered dose inhalers and Spectra® Medical Grade Fiber designed to help make medical devices smaller, stronger, and more durable.

Whitepaper: https://advancedmaterials.honeywell.com/us/en/initiative/envision-your-impact-with-aclar-films

HONEYWELL
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Morris Plains, NJ 07950
W: www.honeywell.com
Contact: https://advancedmaterials.honeywell.com/us/en/contact-us

ENVISION YOUR IMPACT

Calculate your waste reduction benefits with the Aclar® Impact Estimator tool today

Aclar® film delivers a crystal-clear, high moisture barrier to protect medicines, while significantly reducing pack size, waste and carbon emissions, when compared to the same product packaged in Cold Form Foil (CFF).

Gain data-driven insight to see what you can achieve by using Aclar®, including:

- The number of shipping containers of packaging material that can be saved annually
- The reduction in transportation-related CO_2 emissions
- A unique view regarding waste reduction

Scan to learn more

THE FUTURE IS WHAT WE MAKE IT

Honeywell

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High Throughput Development

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W: www.htdcorp.com

HTD BIOSYSTEMS

HTD Biosystems is your expert in drug development, with a strong track record of success in bringing innovative therapies from discovery to the clinic. Our team includes seasoned professionals with a wealth of experience in drug discovery, preclinical development, clinical development, and manufacturing.

HTD Biosystems specializes in customized lyophilization and biotech drug development services, utilizing advanced techniques and extensive experience to deliver high-quality pharmaceutical products.

The benefits of working with HTD include flexibility, innovation, speed, and customer focus. We are able to respond quickly to changing project conditions and customer needs. We are open to taking calculated risks and trying new approaches to ensure that we are at the forefront of drug formulaton/delivery research and development.

OUR SERVICES

Protein Characterization & Formulation Development

Our protein characterization includes tertiary conformational, thermal stability, and colloidal stability (by DLS and FlowCam subvisible particle) analysis and biochemical protein analysis. We leverage our unique iFormulate™ platform. This platform utilizes an advanced algorithm for high-throughput analysis, integrating rational multivariate experiment design using DOE with four critical formulation parameters. Its focus is on developing stable drug products, including high-dose protein formulations. It effectively tackles challenges such as protein conformational and thermal stability, protein aggregation and solubility, The deliverables are developing both stable liquid and lyophilized products.

Lyophilization Process Development

Our lyophilization development focuses on freeze-drying proteins, liposomes, diagnostic kits, and small molecules. We emphasize the importance of successful scale-up to large production size dryers. The deliverable is a robust cost-effective cycle with detailed characterization data to rationalize lyophilization cycle and the drug product.

Manufacture of GLP Tox Lots Under Aseptic Fill/Finish Operations

We can aseptically manufacture and Fill/Finish Tox lots under GLP using BPRs that can be transferred to a cGMP facility for liquid and lyophilized products.

Liposomal & Lipid Nanoparticle Development

HTD has expertise in the development of liposomes and lipid nano particles for drug delivery applications of small molecules, proteins, and nucleic acids. We have developed a number of Drug Products such as vaccines, delivery systems of entrapped small molecules, and lipophilic drugs.

Consulting Services in Drug Development & Process Development

Our consulting services in biopharmaceutical drug and process development provide expertise in developing biological drugs, addressing challenges like product stability and manufacturing optimization. We collaborate with pharmaceutical companies to expedite product development, ensuring compliance and efficiency in bringing safe, effective biopharmaceuticals to market by bringing clarity to your Target Product Profile.

HTD

BIOSYSTEMS INC.

High Throughput Development

We Develop Biotech Drugs

Accelerating Biologics Drug Development

- Formulation Development
- Lyophilization Development
- Drug Delivery & Vaccines
- Biophysical characterization

LYOPHILIZATION

Discover HTD Biosystems– the industry's leading choice for lyophilization. From biologics and vaccines to liposomes and LNPs, we've got you covered. Benefit from our advanced lyo cycle development, optimization, and state-of-the-art pilot plant lyophilization. Plus, our fill-finish services are GLP-compliant, perfect for pre-IND tox studies.

FORMULATION

Discover HTD Biosystems – revolutionizing formulation development. Slash your costs and time by 80% with our cutting-edge DOE and iFormulate platform. From proteins, antibodies, and ADCs to enzymes, liposomes, LNPs, and vaccines – whether liquid or freeze-dried – we're your go-to solution.

HTD Biosystems Inc. 3197 Independence Drive, Livermore, CA 94551
Tel: 510.367.0528 Email: htd@htdcorp.com www.htdcorp.com

JUBILANT HOLLISTERSTIER
3525 N Regal Street
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E: info@jublhs.com
W: www.jublhs.com
LinkedIn: https://www.linkedin.com/company/jhs-cmo

Jubilant HollisterStier is an integrated contract manufacturer of sterile injectables, lyophilized products, ophthalmics, and sterile ointments. Our focus on expertise and customer service makes us the perfect choice as your next manufacturing partner.

By investing in long-tenured employees with cross-functional training and innovative equipment, we are able to seize your project's potential for next level performance at every opportunity. We provide a full-range of support and service to streamline the manufacturing process such as on-site assistance from process qualifications through product release.

JHS is a full-service CMO

- Sterile Fill Finish
- Lyophilization
- Ophthalmics
- Sterile Ointments
- Secondary Packaging
- Support Services
- Regulatory
- Scale-up and Tech Transfer
- Clinical Trial Manufacturing
- Analytical Support

Invested in Expertise

At Jubilant HollisterStier, we understand the value of investing in people and technology. Our $285 million expansion of our Spokane, Washington facility reflects this. We are currently scheduling line time of the first of our brand new lines and have begun construction on the second. These new lines are equipped with full isolator technology, 100% weight-checking capabilities at production speeds, three additional compounding suites, and disposable, single-use compounding and filling technologies. Schedule time with us now to complete your next project on our high-speed commercial fill finish line.

We handle it all, from fill to finish

With large-scale expansions on the way at both facilities, we're paving the way to double our manufacturing capacity. JHS currently has four vial filling lines, two three-piece bottle lines, a sterile ointment filler, and several lyophilizers ready to meet the needs of your next project.

Learn more at jublhs.com

jublhs.com | info@jublhs.com

JUBILANT HOLLISTERSTIER

KAHLE AUTOMATION
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KAHLE®
Manufacturer of Automation Equipment

We are DÜRR

KAHLE AUTOMATION S.R.L.
Viale Europa Unita, 57
Caravaggio (BG) 24043 ITALY
T: +39 0363 355511
W: www.KahleAutomation.com

If you're looking for an automation partner who understands the precision and care required to manufacture the world's finest drug delivery devices, consider Kahle Automation, Engineering Excellence since 1920 and now a part of the Durr Production Automation Systems Group.

Federico Ceresetti, CEO Kahle Automation: "Partnering with Durr and BBS Automation was the logical next step in Kahle's development." With access to the Durr's global reach and support Kahle is better situated to work on larger projects and continue its successful growth trajectory by leveraging manufacturing and service capabilities around the world.

CELEBRATING OVER 100 YEARS. Kahle is the only large-scale automation company in the world that focuses exclusively on custom automated assembly equipment for medical and pharmaceutical devices. For over a century, Kahle has shaped the industry through the use of innovative technologies. Today, we create systems that handle, assemble, inspect, test, and package every medical device imaginable – from syringes, tubing sets and catheters and needle products to diagnostic, pre-filled and combination pharmaceutical devices.

Safety and quality go hand-in-hand with a successful automation project. All of our work is guided by GAMP 5 and ISO 9001 quality standards, and we work with our customers to help them meet FDA 21 CFR Part 820 and Part 11 regulations.

Engineering Excellence requires an automation partner who brings the best technology to your project.

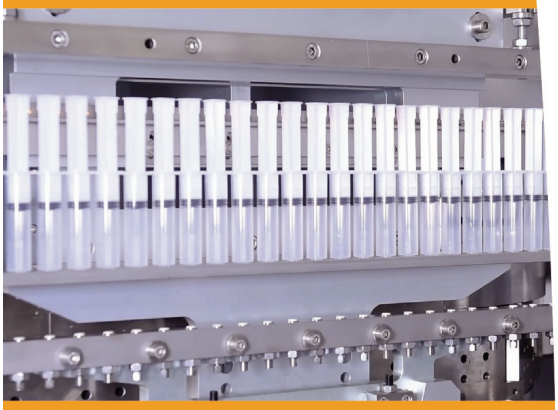
Regardless of whether you're looking for a system that assembles thousands of devices per minute, improves the quality and consistency of your manufacturing process, or whether you're simply trying to maximize the space in your clean room, Kahle has the technical solutions to meet your goals.

Every year, Kahle dedicates over 182,500 man-hours to designing automation systems that manufacture medical devices. This effort has resulted in the largest portfolio of proprietary automation technology in the entire industry. From this portfolio, you can choose from continuous, indexing, and asynchronous motion assembly platforms that feature the latest innovations in mechanical, pneumatic, and robotic assembly with premium inspection and process control operations. This flexibility allows us to create cost efficient, effective systems for projects of every size.

Engineering Excellence requires an automation partner that guarantees performance.

Beyond creating the ideal assembly system for your project, your Kahle team is also focused on getting your machine validated promptly and transitioned efficiently into production. Further, we want to make it easy for your employees to be trained to operate and maintain the equipment. To these ends, your Kahle machine arrives with the best quality and validation documentation in the industry.

Kahle® is dedicated to providing custom automation machinery solutions for the Medical Device, Pharmaceutical, and Healthcare Industries around the world.



Our ideas just got a whole lot brighter

We've merged with BBS Automation

Announcing a partnership in automation equipment that brings a whole new light to medical and pharmaceutical device manufacturing.

KAHLE®
Manufacturer of Automation Equipment
A BBS AUTOMATION COMPANY

Visit www.KahleAutomation.com
or contact Kahle@KahleAutomation.com

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PDA
Parenteral Drug Association

pda.org/2024annual

2024 PDA ANNUAL MEETING

REGISTRATION NOW OPEN!

REGISTER BY 28 JANUARY TO SAVE UP TO $500!

Get ready for the event of the year!

The *2024 PDA Annual Meeting* is just around the corner, and trust us, you won't want to miss out on this extraordinary experience. Join us for an epic week of innovation, collaboration, and inspiration.

What's in store:

- Top-notch plenary speakers who will ignite your imagination
- Informative tech talks and poster presentations to keep you at the forefront of the industry
- Cutting-edge insights that will elevate your expertise
- Vibrant networking events to connect and collaborate with the best and brightest in pharma

This isn't just one event – it's a week-long journey that includes the conference, filled with high-energy roundtable talks, and industry site visits, and continues with specialized trainings, and interactive workshops.

Visit pda.org/2024annual for more information, to view the agenda, and to register.

Don't miss out on the opportunity to be part of an event that will shape the future of pharma. Secure your spot today and join us where innovation meets inspiration!

25-27 MARCH | LONG BEACH, CA

EXHIBITION: 25-27 MARCH
#PDAannual

CONNECTING PEOPLE SCIENCE AND REGULATION®

LATITUDE Pharmaceuticals Inc.

CLEARSOL
A Broad-Spectrum Drug Solubilizer

LATITUDE: Your Formulation Specialist

LATITUDE Pharmaceuticals is a nimble, customer-focused CDMO with 20 years of providing innovative drug formulation development services and GMP manufacturing for early-phase clinical trials to the human and animal health industries. Founded in 2003, we have completed more than 1,100 client projects and have established a reputation for successfully formulating highly insoluble compounds – the most significant cause of drug development failure.

Formulation Development

LATITUDE's formulation scientists are the foundation of LATITUDE's reputation for creative approaches, reliability, transparency, rapid turnaround, and client satisfaction. LATITUDE's extensive experience and technical strengths in a wide range of dosage forms successfully address even 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.

LATITUDE has developed the following specialized drug delivery platforms:

ClearSol (Solubilization)

- A highly effective yet safe way to solubilize a wide range of active pharmaceutical ingredients
- Successful with a broader range of API than cyclodextrins, and solubilizes to higher concentrations
- All components are GRAS and FDA-approved for injection

PG Depot (Phospholipid Gel Depot)

- Allows a customizable sustained-release profile of a subcutaneously administered drug over 1-7 days
- Injectable through fine (up to 28 G) needles for easy administration
- Up to 20% drug loading

Nano-E (Nanoemulsion)

- A versatile solubility-enhancing platform for oral/injectable liquid formulations, also effective to alleviate vein-irritation for injectables

ARTSS (Aqueous Room Temperature-Stable Solutions)

- Allows the transformation of lyophilized powders or 2-8°C solutions into RT-stable aqueous solutions

GMP Manufacturing

LATITUDE Pharmaceuticals provides GLP- and GMP-compliant manufacturing and analytical testing services – we specialize in rapid customer response and delivery of Phase 1 and Phase 2 clinical trial materials. With a Quality Assurance System managed by experienced and dedicated staff, LATITUDE can GLP or GMP 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.

Contact us for more information and to discuss how LATITUDE can address your formulation or manufacturing needs.

LATITUDE PHARMACEUTICALS INC.
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LinkedIn: https://www.linkedin.com/company/latitude-pharmaceuticals

YOU define the starting line.
We'll help you cross the (fill) finish line, and beyond.

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 has also been a leading producer of pharmaceutical-grade, non-animal-sourced sodium hyaluronate since 1981 when we developed our fermentation-based process. Since then, we have become the preferred viscoelastic supplier to ophthalmic market leaders and our products have been used in the treatment of more than 150 million patients worldwide.

CDMO Services

- Multiple vial, syringe, and cartridge configurations.
- Expertise in complex formulations and highly viscous products (in excess of 100,000 cP).
- Capability to support pre-clinical process development, clinical trial batches, and commercial scale-up.
- End-to-end services for development, sterile filtration, aseptic fill/finish, packaging, and stability studies as well as in-process and release testing.

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
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LinkedIn: https://www.linkedin.com/company/27563/admin/

YOU DEFINE THE STARTING LINE

We'll help you cross the (fill) finish line, and beyond.

End-to-end injectables CDMO | Proven clinical and commercial manufacturer | Premium sodium hyaluronate producer

Registered FDA Device & Drug Establishment
Certified ISO 13485 Quality System
European GMP Certified

Lifecore® BIOMEDICAL

lifecore.com

Lonza

Lonza
Muenchensteinerstrasse 38
4002 Basel, Switzerland
T: +41 61 316 81 11 - F: +41 61 316 91 11
W: www.lonza.com

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.

We provide a wide range of services and products from early phase discovery to custom development and manufacturing of active pharmaceutical ingredients to innovative dosage forms for the pharma and consumer health and nutrition industries. Our scale and resources mean we can provide a one-stop solution for our customers to help people get well, feel well, and stay well. In 2022, we supported more than 825 preclinical and clinical small and large molecules, more than 195 commercial small and large molecules and produced around 250 billion capsules.

Founded in 1897 in the Swiss Alps, today, Lonza operates across five continents. With approximately 17,500 full-time employees, we comprise 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 business benefits from global supply chains, but we have worked to maintain the agility to address marketplace needs on a local level.

A firm commitment to responsible business and sustainability underpins everything we do. Minimizing our impact on the environment, conserving energy and natural resources, and helping to improve life quality are all central to our culture. Lonza's Vision Zero initiative is a prime example, as we strive to achieve zero workplace accidents and injuries, zero environmental incidents, zero product transportation incidents and zero manufacturing process incidents. We work to attract and retain the best talent, to make a meaningful difference to our own business, as well as the communities in which we operate.

Enabling a Healthier World

De-risk Early Stage Drug Development With Lonza Small Molecules

Our team of experts have a wide range of skills to support you with your early phase challenges.

Solid Form Screening Services

We will help you determine the most suitable chemical and physical form for your API. Our SFS services are built on a foundation of API characterization, materials science, and problem statement analyses.

Physiologically Based Pharmacokinetic Modeling Services

Using established ADMET Predictor® and GastroPlus® modeling software, linked with an expansive set of in vitro tests, we can identify absorption risks, and select technologies that will enable bioperformance targets to be met.

Route Scouting Services

Our experts use a range of retrosynthetic technologies, powered by real-world chemical and commercial data, to help you implement shorter, more efficient synthetic routes for making your NMEs.

Scan the QR code to learn more:

LUBRIZOL LIFE SCIENCE

LUBRIZOL LIFE SCIENCE HEALTH

Company Description

The Health business of Lubrizol Life Science (LLS Health), in partnership with customers, advances solutions inspiring a healthier life. We specialize in helping clients from idea to execution by offering innovative polymers and excipients, as well as best-in-class contract development and manufacturing services. Our long history of polymer expertise and continued investment in research and manufacturing means we offer you and your customers a smooth and streamlined approach to innovative healthcare solutions.

Excipients

Our pharmaceutical grade Carbopol® polymers, Noveon® polycarbophil, and Pemulen™ polymers are used in a wide range of applications, including:

- Sustained release oral solids
- Topical semisolids and liquids
- Transdermal patches
- Oral liquids
- Drug-eluting devices (Pathway™ thermoplastic polyurethane)

These excipients have been used in both Rx and OTC products for decades to impart critical functionalities, such as mucoadhesion, rheology modification, and controlled drug release.

Additionally, our Apinovex™ and Apisolex™ polymers function as solubility and bioavailability enhancers in oral solid and injectable applications, respectively.

CDMO

We offer end-to-end contract development and manufacturing (CDMO) services. For over 20 years, we've partnered with clients to overcome formulation challenges and help get their products to market. Our FDA-inspected facility in Bethlehem, PA features clinical and commercial manufacturing suites to accommodate vials, bottles, syringes, and non-traditional dosage forms. Our focus areas include:

- Solubility and Bioavailability Enhancement
- Long-Acting Injectables and Implantables
- Aseptic Manufacturing/Sterile Fill-Finish
- Biologics
- Highly Potent APIs and Controlled Substances

HEALTH

Contact Us page: Contact Us about Pharmaceutical Excipient Products and Solutions – Lubrizol
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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.

LUBRIZOL | 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 for preparation of health care products.

Clients leverage on our abilities for bringing new products to the clinic and implementing improvements for current products. Capitalize on over 25 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 support in successful collaborations for a variety of projects. These projects span initial product and process development for new entities right out of drug discovery through Phase I/II clinical material, 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 North America.

SERVICES OFFERED

Capabilities

- Pre-clinical through Phase II Clinical Materials
- 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 formulation 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
- Cycle Design/Refinement
- Product Characterization
- Pilot Plant Scale-up
- Isolation/Containment
- Cartridges

Clinical Manufacturing

US/EU compliant Clinical Manufacturing Area (CMA) for preparation of clinical material enables 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 and pre-filled syringes.

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

Technical Services

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

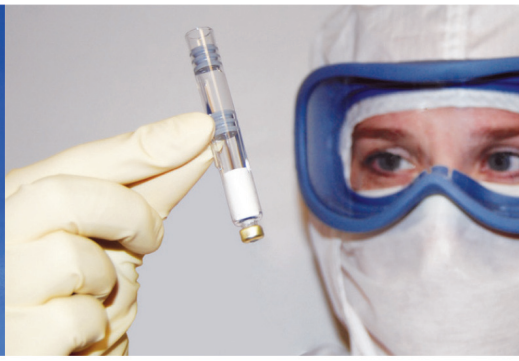
- Customized Training
- Consulting on equipment specifications
- Process requirements
- Guidance on CMC submission
- Support on IQ/OQ and process validation
- Technology transfer
- Process excursions
- Product and process troubleshooting
- Batch record review
- Compliance auditing

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

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 a large and diverse portfolio of reliable, plant-based excipients, nutraceutical active ingredients, active pharmaceutical ingredients, high-quality and multi-compendial specialty ingredients, and pyrogen-free carbohydrates. Our products are designed for a range of applications encompassing prescription and OTC drugs, generics, nutraceuticals, biopharmaceuticals, and injectables and dialysis. US Innovation Center Near Philadelphia - Dedicated to advancing the research of drug delivery systems while improving speed to market, our US innovation lab also serves as an Applied Science and Customer Technical Support (CTS) center for advanced research in drug delivery systems for oral prescription (small molecule) drugs as well as nutraceuticals. This proximity with our US customers helps expedite drug development and market release. For more information, visit Roquette Pharma Solutions at www.roquette.com/pharma.

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

SOLID FOUNDATION

FLEXIBLE SOLUTIONS

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

MilliporeSigma

Company Description

MilliporeSigma is a leader in Life Science. Researchers around the world rely on our tools, services and expertise to do their best science — from familiar experiments to novel approaches. Our presence extends well beyond the labs as our innovations touch individuals around the world. Together, we impact life and health with science.

Company Background

MilliporeSigma is a business of Merck KGaA, Darmstadt, Germany. Our ideals have been shaped by our history of more than 350 years – right from the very start. Each of the 13 generations of the Merck family has contributed in its own way, making us what we are today: a leading science and technology company.

Our passion for science and technology is what drives our more than 64,000 employees in 66 countries to find solutions to some of today's toughest challenges and create more sustainable ways to live. Thanks to the constant curiosity of our employees, we are making discoveries that can change the landscape of entire industries. For more than 350 years, we have been pushing the boundaries of what is possible, and we will continue to do so in the years to come.

Services & Capabilities

Our tools, services and digital platforms empower researchers from a wide range of fields — from small labs to massive operations — to work more effectively. Through our offer of state-of-the-art tools and techniques we set the stage for future scientific discoveries, empowering scientists and engineers at every stage of discovery.

Our integrated offering supports all stages of pharma and biopharmaceutical manufacturing from process and formulation materials, single-use manufacturing, filtration, process development, process analytical technologies, formulation support and application services to contract manufacturing services - all with extensive regulatory documentation.

Our CTDMO services provide a streamlined experience in a single partner for mAbs, HPAPIs, ADCs, mRNA, and LNP formulation. Our standalone contract testing and analytical development services ensure the safety of the world's therapeutics.

MilliporeSigma
400 Summit Drive
Burlington, MA 01803

W: https://www.sigmaaldrich.com/campaigns/api-formulation-request-information or https://www.sigmaaldrich.com/products/pharma-and-biopharma-manufacturing/formulation

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Facebook: https://www.facebook.com/MilliporeSigma

Instagram: https://www.instagram.com/milliporesigma/

YouTube: https://www.youtube.com/@milliporesigma2407/featured

Facilities: Headquarters Darmstadt, Germany, and facilities around the world

Solve the Solubility Challenge

Strategies to Solubility Enhancement from Drug Discovery to Formulation

With continuously increasing numbers of poorly soluble APIs in the drug development pipeline, targeted approaches to enhance API solubility are important – now more than ever.

Choose from a variety of available approaches to enhance solubility through physical or chemical modification, dissolution promoting or solubility enabling formulation:

- In early stages of drug development, API properties can be enhanced using API processing.
- In later stages of development, formulation approaches such as dissolution enhancers or solid dispersions can be used.

As there is no one-size-fits-all solution available, it is key to have a toolbox of methods established to choose from.

Learn more about solubility enhancing strategies and suitable products:
SigmaAldrich.com/api-solubility-enhancement

MS_AD12753EN Ver. 1.0 50807 08/2023

SAFC®
Pharma & Biopharma Raw Material Solutions

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 excellent oxygen and 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.

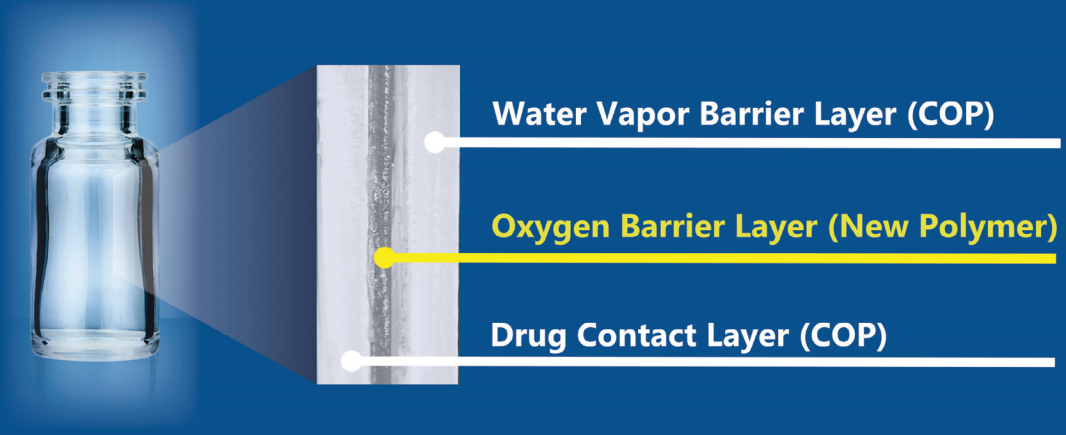
The oxygen barrier of OXYCAPT-P vial is about 20 times better than that of COP monolayer vial. OXYCAPT™ also provides an excellent UV barrier. While about 70% of 300-nm UV light transmits through glass and COP, only 1.7% transmits through OXYCAPT™. The OXYCAPT™ vial is produced by co-injection blow-molding 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 bulk and ready-to-use (RTU) vials. The RTU vials are provided in ISO-based nest and tub formats. The nest and tub are mainly sterilized using gamma rays. There are 2-, 6-, 10-, and 20-mL variants for vials. MGC is pleased to consider customizing the shape and size if there is a request from customers.

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 strong oxygen and UV light barrier. MGC believes OXYCAPT™ offers a lot of benefits to the rapidly growing field of biologics and gene/cell therapies.

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

Multilayer Structure



- Excellent Oxygen Barrier
- High Water Vapor Barrier
- Very Low Extractables
- Low Protein Adsorption
- Excellent Ultraviolet Barrier
- High Break Resistance
- High pH Stability
- Gamma-sterilized Vial
- For Biologics & Gene/Cell Therapy
- Customizable

2, 6, 10, 20mL Vial

Nest & Tub for Vial

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

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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

Owen Mumford
Pharmaceutical Services

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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.

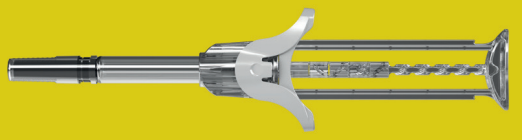
UniSafe® Platform

Delivering the future with safety and simplicity

Developed around UniSafe®, our platform meets the needs of you, our partner, and your varying patients' needs both now and in the future.

UniSafe® 1mL

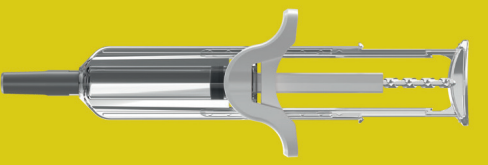
A spring-free, passive safety device for 1mL pre-filled syringes, designed for simple assembly and use.



Proven, on market, in patient use

UniSafe® 2.25mL

A spring-free, passive safety device for 2.25mL pre-filled syringes, designed for simple assembly and use.



Fully industrialised and ready to supply

UniSafe® 1mL
Auto-injector

A reusable companion auto-injector for UniSafe® 1mL.

Coming soon

UniSafe® 1mL
Connected Auto-injector

A reusable connected companion auto-injector for UniSafe® 1mL.

Coming soon

Want to know more?

Visit **ompharmaservices.com/ddd-oct2023** or email **pharmaservices@owenmumford.com**

Owen Mumford
Pharmaceutical Services

OMPS/dd&d/ad/ob/1023/7

PACE® LIFE SCIENCES –
PEOPLE ADVANCING SCIENCE
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Oakdale, MN 55128
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W: www.pacelifesciences.com

ADDITIONAL CDMO/CRO NETWORK SITE LOCATIONS:
Boston, MA
Salem, NH
San Diego, CA
Norristown, PA
Ann Arbor, MI
South New Berlin, NY
San German, PR

PHARMACEUTICAL CMC DEVELOPMENT (CDMO)

PEOPLE ADVANCING SCIENCE

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 emphasizes 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.

Our Pharmaceutical Development laboratories in Boston, MA, Salem, NH, San Diego, CA, Philadelphia, PA, and Ann Arbor, MI, 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. Strategic partnering with Pace® 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

- Characterization of Novel Molecules & Biologics
- Solid State and API Characterization
- Formulation Development
  - Long-Acting Injectables
  - Lyophilization
  - Hot-Melt Extrusion
  - Spray Drying
- Clinical Supplies Manufacture (Sterile & Non-Sterile Capabilities)
  - Sterile Aqueous Products
  - Ophthalmic
  - Tablets/Capsules
  - Solutions, Suspensions, Ointments, Creams Clinical Packaging

ANALYTICAL METHOD DEVELOPMENT

GMP Laboratory Testing

- 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 CDMO for your project
www.pacelifesciences.com

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

pci PHARMA SERVICES

PCI Pharma Services

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 five decades in the delivery of supply chain healthcare services. With 30 sites across Australia, Canada, North America, the UK and Europe and over 5,500 dedicated employees, our mission is to bring life-changing therapies to patients. Leading technology and continued investment enable us to deliver development to commercialization solutions throughout the product lifecycle, collaborating with our clients to improve the lives of patients globally.

Drug Development & Manufacturing Solutions

PCI are experts and innovators offering full service formulation development including in-house analytical development services for both sterile and non-sterile dosage forms. Our scalable development and manufacturing capabilities for tablets, capsules, gels, ointments, liquids, sterile dosage forms and lyophilized drug products aid delivery of life-changing therapies to patients from early phase clinical trials through to commercialization.

Clinical Trial Services

PCI provides a global service with localized focus, delivering over 200 protocols a year in over 100 countries, utilizing best-in-class technologies combined with our experienced and dedicated teams. Providing a seamless service, PCI supports the global supply of investigational medicines with pharmaceutical development, clinical drug product manufacturing, packaging, labeling, storage and distribution and full returns service.

Advanced Drug Delivery

Driven by innovation and patient-centricity, PCI's design and development expertise combined with our sterile manufacturing, device assembly and advanced drug delivery packaging capabilities offer flexible solutions for a diverse portfolio of conventional and specialty injectable drug-device combination products. We have the scalability to handle the dynamic volumes of biopharmaceutical therapies, whether large or small, from niche personalized medicines to large-volume treatments.

Commercial Packaging Technology

With true customer focus and flexibility at the core of our commercial packaging services, we are able to support the unique requirements of each product type and global market supplied. Utilizing state-of-the-art packaging technologies, we provide advanced primary, secondary and tertiary packaging solutions for a diverse portfolio of conventional dosage forms including oral solids, powders, liquids, creams and gels, as well as specialist injectable and parenteral delivery forms including vials, cartridges, prefilled syringes and auto-injectors.

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W: www.pci.com

pci
PHARMA SERVICES

Your world, our world.

WE ARE A GLOBAL, LEADING CDMO

Development and Manufacturing | Clinical Trial Services

Advanced Drug Delivery | Commercial Technology Services

Let's talk future™

talkfuture@pci.com | pci.com

Your bridge between life-changing therapies and patients

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.

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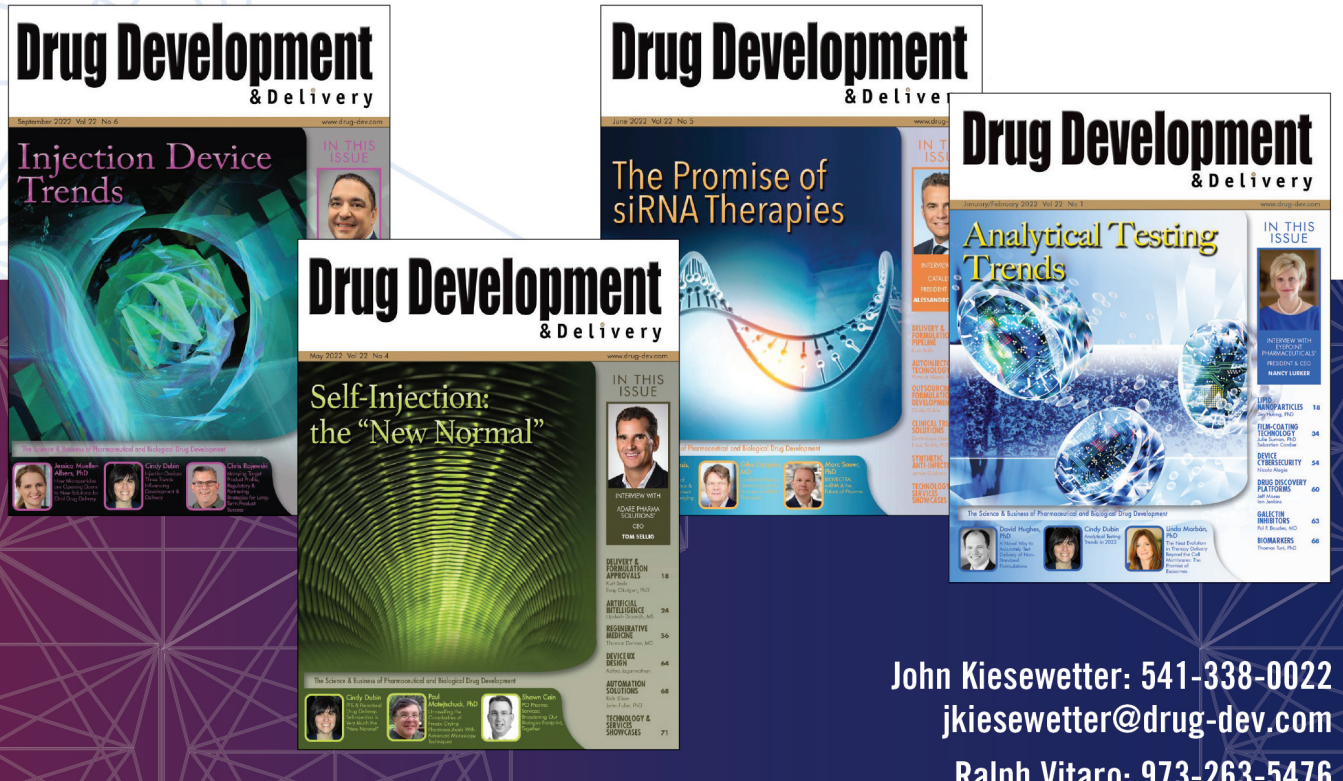
- eBooks
- eNewsletters



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Pfanstiehl is a global leader in the manufacture of cGMP high purity, low endotoxin, low metal injectable-grade excipients and biopharmaceutical components for upstream bioprocessing, downstream formulation, and specialty applications. In addition, Pfanstiehl is a leading contract development and manufacturing organization (CDMO) specializing in the isolation, purification, custom synthesis, and scale-up development of small molecule Active Pharmaceutical Ingredients (APIs), in gram to multi-ton commercial quantities. While most ingredient manufacturers or resellers focus on many other industries, such as food, cosmetics, agriculture, and/or nutritional supplements, offering only a subset of "pharma- grade" ingredients, Pfanstiehl and its entire product portfolio are focused on Biopharma applications. It's all we do. Pfanstiehl's ICH Q7-compliant and US FDA inspected and approved manufacturing facility is centrally located just North of Chicago, and only 35 minutes by car from O'Hare International Airport.

Pfanstiehl's tried and true, platform-enabling protein and cell membrane stabilizers include Trehalose, Sucrose, Arginine, and Maltose. Parenteral-grade, multi-compendial Mannitol and Sodium Succinate Hexahydrate are also offered as key tools for formulation optimization. Recent launches include amino acids Histidine, Methionine, Glutamine and TRIS base. We are continuing to expand this portfolio to include other key excipients based on feedback from our clients who want real cGMP manufacturing from a company that understands and supports their requirements. Many clients are not simply looking for a high quality source of consistent ingredients, but seek a partner who can adapt to the ever-evolving regulatory landscape and quality requirements to address emerging formulation challenges collaboratively. For upstream applications, Pfanstiehl manufactures high purity, low endotoxin, low metal galactose for reduction of lactate and ammonia production. Overall cell culture performance improvements can be achieved with optimized titration of galactose in lieu of other carbon sources. Pfanstiehl offers multiple types of galactose, including a non-animal- derived product. Mannose is also offered as a high purity cell culture supplement to improve native glycosylation and improve consistency in product quality attributes, particularly in high titer processes. Trehalose can be utilized in upstream bioprocessing and cell therapy applications to reduce protein aggregation and improve cell robustness.

Pfanstiehl was founded in 1919 and is celebrating its 104-year anniversary as a leader in carbohydrate and process chemistry. Pfanstiehl's customers include most of the world's leading biopharmaceutical, vaccine and pharmaceutical companies. Our products are utilized in market-leading drugs that treat life-threatening and debilitating diseases, including cancer, rheumatoid arthritis, STDs, and diabetes as well as in leading vaccine platforms including mRNA, viral vector based or traditional protein based ones.

Increasing regulatory and quality requirements are benefiting high integrity biopharmaceutical and pharmaceutical manufacturers like Pfanstiehl with high purity, strong cGMP controls and a strong reputation with FDA and other regulatory agencies. In everything we do, Pfanstiehl is motivated by a concern for both product quality and environmental/worker safety. We design and equip our plant, write our procedures and train our people to meet or exceed US FDA, cGMP, OSHA and international regulatory and multi-compendial standards. Quality, Purity and Safety of the patients as well as Security of supply of critical Biopharma Excipients are what Pfanstiehl is all about and we deeply care of.

Delivering on the Promise of Purity

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.

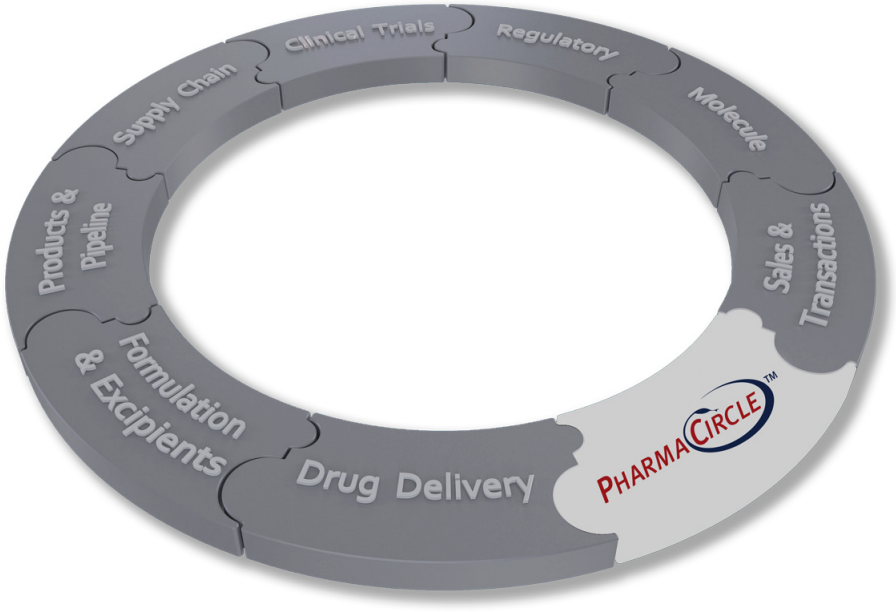
PharmaCircle's premier database tracks drugs, biologics and combination products in all stages of development, connecting pipeline and product information with formulation and component details. The database delivers seamless integration of scientific, clinical, safety, regulatory, manufacturing and commercial information, and detailed analyses on over 8,500 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
- Epidemiology Data
- Medical Diagnostics Explorer

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



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phosphorex

Advancing Nanomedicines Together

Phosphorex, a leading CDMO located just 26.2 miles from Boston in Hopkinton, MA. Our state-of-the-art facility spans at 30,000 Sq. Ft., with an additional 12,000 Sq. Ft. of cGMP space set to come online in 2024.

With our expertise and innovative technologies, we excel in encapsulating drugs into microspheres or nanoparticles, enabling targeted delivery, protection of therapeutic agents, controlled release, and improved bioavailability. From proof-of-concept to clinical studies, our integrated solution supports all phases of formulation development.

Our team of technical experts brings extensive experience in various areas, including:

- Lipid Nanoparticles (LNPs) for Nucleic Acid Delivery
- Polymeric Nanoparticles (PNPs) for Targeted Delivery
- Polymeric Microspheres for Sustained-release Delivery

Phosphorex is at the forefront of harnessing the immense potential of microspheres and nanoparticles to revolutionize drug delivery. We provide a comprehensive range of customizable drug delivery solutions, catering to diverse applications. From formulation development to clinical trials, we work closely with clients and collaborators to bring innovative therapies to life.

When working with us, our team of experts offer:

- **Customizable Solutions:** We understand the unique requirements of each application and tailor our drug delivery systems, accordingly, ensuring precision and effectiveness
- **Collaborative Approach:** We foster close partnerships with our clients and collaborators, working hand-in-hand throughout the entire drug formulation & development journey
- **Seamless Transitions:** From formulation development to clinical trials, our integrated approach ensures a smooth and efficient progression, saving valuable time and resources
- **Innovative Technologies:** With the use of advanced systems & technologies and our expertise in microspheres and nanoparticles allows us to develop advanced drug delivery solutions that optimize therapeutic outcomes

Phosphorex offers the following services:

- Formulation Feasibility & Optimization
- Process Development & Scale Up
- Pre-clinical Batch
- cGMP Manufacturing (Coming in late 2024)
- Supporting Analytical Services

Our Payload Expertise Includes:

- **Nucleic Acid Payloads:** DNA, mRNA, siRNA, and antisense oligonucleotides (ASO) find their ideal carriers in lipid nanoparticles (LNPs), maximizing their therapeutic potential.
- **Small Molecules, Peptides, and Proteins:** Biodegradable polymers form the foundation for our microspheres and nanoparticles, effectively encapsulating these payloads to enhance their performance.
- **Other Formulations:** Explore our wide array of formulations, including liposomes, micelles, nanocrystals, hydrogels, and their combinations, boosting the efficacy of active ingredients.

Our Drug Carrier Expertise Includes:

- Lipid Nanoparticles
- Liposomes
- Polymeric Nanoparticles
- Polymeric Microspheres
- Micelles
- Lipid-polymer Hybrid
- Polyplexes

At Phosphorex, we are committed to pushing the boundaries of drug delivery, delivering superior solutions, and driving the success of our clients. Partner with us to unlock the full potential of your pharmaceutical innovations.

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LinkedIn: https://www.linkedin.com/company/phosphorexllc/?viewAsMember=true
Facebook: https://www.facebook.com/people/Phosphorex-LLC/100088978729406/
X (Twitter): https://twitter.com/i/flow/login?redirect_after_login=%2FPhosphorexLLC

Pii
Pharmaceutics International, Inc
Challenges Frame Opportunities

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10819 Gilroy Road
Hunt Valley, MD 21031
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E: bd@pharm-int.com or pdupont@pharm-int.com
W: www.pharm-int.com

Year Founded: 1994
Number of Employees: 250
Key Personnel: John Fowler, President & CEO
Business Development Team: Christian Ahlmark, Vice President of Business Development; Gerri Mirkin, Director of Business Development, East Coast; Cindy Koonce, Director of Business Development, Mid Atlantic; and Brad Arnold, Director of Business Development, West Coast
Human Resources: George Sanders, Vice President of Human Resources
R&D: Sundeep Sethia, Head of R&D
Quality: Thomas Pamukcoglu, Vice President of Quality
Quality Control: Cathy Sioma, Director of QC Analytical Services
Supply Chain: David Fidler, Senior Director of Supply Chain
Operations: Alan Saidel, Head of Operations
Project Management: Devan Patel, Senior Director of Business Development; Stephanie Taylor, Senior Project, Project Development; and Tobie McQueen, Project Coordinator
Marketing: Devan Patel, Senior Director of Business Development, and Paul Dupont, Head of Digital Marketing

Concept to Clinic to Commercialization

At Pharmaceutics International, Inc. (Pii), our motto is "challenges frame opportunities." We are a US-based contract development and manufacturing organization (CDMO) that has a passion for solving problems efficiently with the highest quality standards. Emphasizing a collaborative relationship with our clients, Pii's experts embrace the art and science of drug development and manufacturing. Our outcome is to deliver better results faster for our clients and their patients.

Pii's Hunt Valley, Maryland campus includes four cGMP and FDA certified facilities, 70 manufacturing suites with all the necessary analytical testing capabilities on site, and four integrated aseptic filling suites delivering quality, safety, and efficiency.

Experienced with small and large molecule compounds, we have special expertise in developing and manufacturing complex parenteral drugs, vaccines, extended-release formulations, and non-aqueous injectable drug products. We can also overcome stability challenges with precision lyophilization cycle development and production.

Services

- Formulation & Process Development
- Oral Drug Development
- Parenteral Drug Development
- Bioavailability Enhancements
- Method Development & Validation
- Stability Testing
- Clinical Trial Manufacturing
- Commercial Manufacturing
- Highly Potent Drug Manufacturing
- Analytical Services
- Quality Systems Development

Capabilities

- Development & Commercial Technology Transfer
- Vaccine Fill/Finish
- Sterile — vials, syringes, cartridges
- Lyophilization
- Highly Potent Compounds — hormones, cytotoxins
- Parenterals — aqueous, non-aqueous
- Oral Solids — soft gels, tablets, capsules
- Oral Liquids — suspensions, syrups, solutions
- Solid dispersions
- Topicals
- Controlled release formulations
- Fluid-bed processing
- Micro & nanotechnologies
- Coating
- Packaging Serialization
- Enhanced Project Management

POREX CORPORATION
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Fairburn, GA 30213
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W: https://www.porex.com
LinkedIn: https://www.linkedin.com/company/porex/

COMPANY DESCRIPTION

As a partner for 17 out of 20 of the world's leading medical device companies and brands, Porex engineers solve technical challenges for drug delivery products with custom-engineered high-quality components and resources designed specifically for the end device. Whether the drug delivery device is an inhaler, an injectable or a topical applicator, porous polymer technologies can be used for particle filtration, applicators, flow metering, fluid management, and sound diffusion. By combining our extensive material science expertise with our global manufacturing capability, we help our drug delivery customers find the perfect component to make their unique product design come to life.

COMPANY BACKGROUND

In 1961, Mr. Bob Dickey, a research scientist, started a small business making sheet material out of various polymers to be used in a caustic fluid separation process. At this time, the porous plastics industry was still in its infancy, and the small company applied their new technology to making the first porous plastic nibs for coloring markers, which is still a core part of its business. In the decades to follow, Porex garnered a leading presence in diverse markets including biomedical and life sciences, electronics, cosmetics and more. The unique properties of porous plastics materials combined with its innovative design and engineering expertise fostered continued growth that spurred entrance into critical markets and led to key acquisitions, including the Porous Technologies business of Essentra. Today, Porex has eight ISO-certified manufacturing sites across the United States, Europe, and Asia Pacific to support our customers' supply chain needs.

In 2013, Porex became a member company of the Filtration Group. Filtration Group is on a mission to make the world safer, healthier and more productive. With a passionate workforce, global footprint and world class engineering and manufacturing capabilities, Filtration Group is driving innovation and developing solutions across a broad spectrum of applications in the fast-growing global filtration industry.

SERVICES

Porex has been serving our customers for more than 60 years. Our material design and manufacturing capabilities span across 8 production facilities in North America, Europe and Asia Pacific to support our global customers' supply chain needs.

Our custom porous media enables engineers to unleash their creativity to design innovative drug delivery devices that increase effectiveness of their therapeutics and reduce usage of more expensive components.

Inhalation Devices

Filtration, diffusion & wicking media in:

- Metered dose inhalers (MDI)
- Dry powder inhalers (DPI)
- Nasal sprays & pumps
- Nebulizers

Injectable Devices

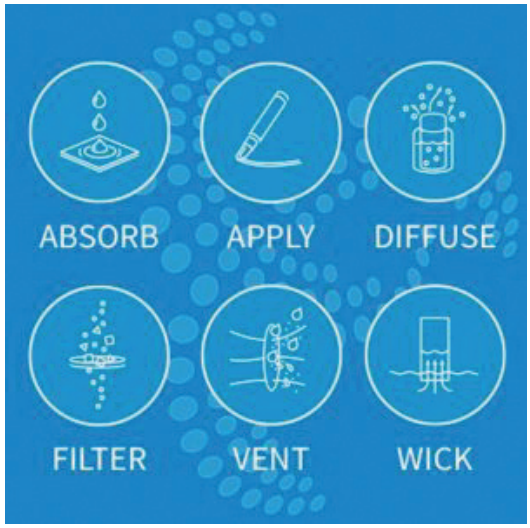
Filtration & venting media in:

- Autoinjectors
- Infusion therapy devices
- Electronic injection
- Glass ampoule syringes

Topical Applicators

Absorbing, wicking, filtration & venting media in:

- Surgical wands/applicators
- At-home OTC applicators
- Dental applicators



POROUS MEDIA: REVOLUTIONIZING DRUG DELIVERY DEVICES

Porex is your trusted partner in drug delivery innovation, whether it's integrating porous media components into cutting-edge designs or optimizing your current product lines.

Enhance the safety and performance of your drug delivery device with **ultra-pure porous polymer components**, available in both customizable and standard options.

CERTIFIED PURE POREX

Inhalation Devices:
Improved dosing and filtration with simplified assembly

Topical Applicators:
Filtration and softness within the same applicator

Injectable Devices:
Venting & filtration media for safer injections

Infusion Therapy:
Venting & filtration media for safer & more efficient fluid delivery

Discover how our **advanced porous media solutions** empower you to excel in meeting patient needs and surpassing industry standards with your drug delivery device.

Request a sample today

POREX Filtration Group
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PROVERIS SCIENTIFIC CORPORATION
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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:

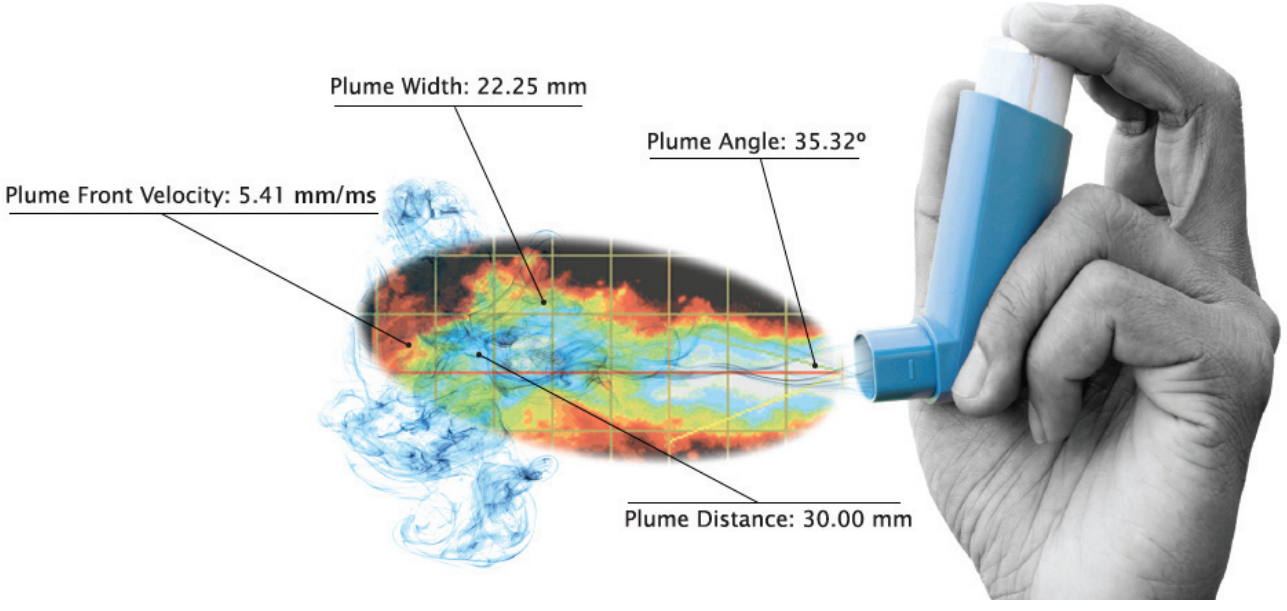
- accelerate successful product development and prevent late-stage development failures
- realize significant savings in time and resources by streamlining testing workflows
- evaluate the suitability of various OINDP delivery devices and optimize device parameters for maximum efficacy
- optimize testing 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.



YOUR DRUG PRODUCT PARTNER...

FROM DEVELOPMENT TO APPROVAL

Scientific Expertise and Laboratory Test Services for Generic and Innovator OINDPs

DEVELOPMENT

Human Usage Studies

Device and Formulation Screening

Methods Development

Alternative BE Studies

Spray Velocity
(Plume Front Velocity)

Regional Drug Deposition
(Human Realistic)

Evaporation Fraction

CMC SERVICES

In Vitro Testing

Drug Product Characterization

Priming/Repriming

Device Robustness

COMMERCIAL SUPPORT

Methods Transfer/Validation

Batch Release Testing

Long-term Stability Testing

Root Cause Analysis

OOS/OOT Investigation

LEARN MORE:

www.proveris.com/why-proveris

contactus@proveris.com • +1 508 460-8822

proveris®
LABORATORIES

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. By integrating drug substance, drug product, and clinical testing activities under a single provider, Translational Pharmaceutics® has been proven to shorten development times by an average of 12 months or more, minimizing risk while reducing R&D costs.

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

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Instagram: https://www.instagram.com/quotient_sci
Youtube: https://www.youtube.com/@quotientsciences

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

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www.resilience.com

Resilience recently invested in two Cytiva SA25 aseptic filling workcells for its manufacturing site in Florida.

COMPANY DESCRIPTION

Resilience is a technology-focused biomanufacturing company dedicated to broadening access to complex medicines across a variety of therapeutic areas. 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 all large molecule drugs by revolutionizing how they are developed and manufactured.

The technology of manufacturing complex medicines hasn't kept pace with the wave of scientific discoveries fueling them over the past three decades.

Additionally, Resilience has collaborated with numerous institutions, including Mayo Clinic, MD Anderson Cancer Center and Harvard University, to seek to accelerate innovation in the creation of impactful therapies and technologies to benefit patients.

MARKETS SERVED/FACILITIES

Resilience serves global customers through its sites located in six states across the U.S., as well as in Canada.

PRODUCTS, SERVICES & CAPABILITIES

With more than 50 active customers 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 more than 70 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.

By integrating expertise across five core modalities, we help you advance your novel science by applying both proven and emerging technologies and processes in novel ways.

RESILIENCE

ON YOUR MARK. GET SET. WAIT.

Nothing's more frustrating than knowing there must be a better way – and being powerless to do anything about it. That's why there's Resilience.

We recognized that the technology of manufacturing complex medicines, like cell and gene therapies, hasn't kept pace with the wave of scientific discoveries fueling them. And we knew that we could revolutionize how those novel medicines could be made, funded, and scaled. So we're doing exactly that. Because your innovation deserves nothing less than a fully engaged and committed Biomanufacturing Innovation Partner.

REMAKING THE WAY MEDICINES ARE MADE

resilience.com
contact@resilience.com

ROQUETTE PHARMA SOLUTIONS
SPRING HOUSE INNOVATION PARK
727 NORRISTOWN ROAD, BUILDING 9, FLOOR 2
LOWER GWYNEDD TOWNSHIP, PA 19002
W: ROQUETTE.COM/PHARMA

Roquette Pharma Solutions offers a large and diverse portfolio of reliable, plant-based excipients, nutraceutical active ingredients, active pharmaceutical ingredients, high-quality and multi-compendial specialty ingredients, and pyrogen-free carbohydrates. Suitable for a range of applications encompassing prescription and over-the-counter drugs, generics, nutraceuticals, biopharmaceuticals, injectables and dialysis, our solutions include:

- Cellulose
- Dextrose and glucose
- Maltodextrins
- Cyclodextrins
- Organic acids and their salts
- Polyols
- Proteins
- Starches
- Salts of fatty acids
- Co-processed excipients
- Specialty blends

US Innovation Center Near Philadelphia

Our Pharmaceutical Innovation Center in the US is dedicated to advancing the research of drug delivery systems for oral prescription drugs while improving speed to market. It complements the advanced biopharmaceutical research conducted at our Singapore Innovation Center, as well as our central R&D facility in France.

The site also serves as an Applied Science and Customer Technical Support (CTS) center for advanced research in drug delivery systems for oral prescription (small molecule) drugs, as well as nutraceuticals. One of the main goals for this laboratory is developing drug delivery technologies that increase patient compliance. This facility allows us to work in close partnership with our US customers and partners to develop essential drug solutions and get them to market faster.

OUR MARKET SEGMENTS

Pharmaceuticals

- Extensive portfolio of pharma excipients for prescription and over-the-counter (OTC) oral dosage solutions.
- Scientific expertise helps us deliver superior formulation performance to our partners.
- From patient appeal to regulatory compliance, manufacturers can rely on us to provide the ingredients and support they need to develop solutions that put patients first.

Nutraceuticals

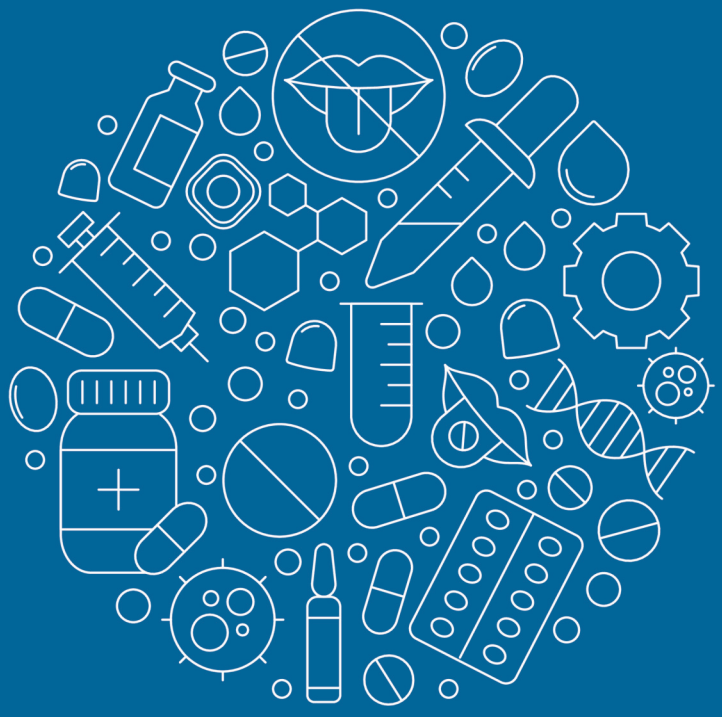
- Broad range of plant-based excipients and nutraceutical active ingredients, enabling formulators and marketers to create customized dosage forms, enhance manufacturing productivity and improve consumer appeal.
- Extensive portfolio supports development of safe, stable, and convenient medicated gummies, tablets, capsules or powder sachets.
- Widest range of forms and functions on the market, alongside formulation support and customized solutions designed to maximize consumer experience.

Biopharma

- High-quality and multi-compendial specialty ingredients to bring life-saving drugs to market quickly and safely.
- Technical and regulatory support to achieve the strictest quality, safety and compliance standards.
- Vertically integrated and transparent supply chain.

Injectables, Dialysis and Specialty APIs

- Pharmaceutical-grade, pyrogen-free excipients and APIs aimed at elevating the end product.
- Controlled processes to ensure every product is pharmacopeia-compliant and manufactured to the very highest quality standards.
- Technical expertise, customer-focused solutions and supply chain transparency.



ROQUETTE

Offering the best of nature™

Together we can solve the **toughest challenges** in drug delivery.

Roquette Pharma Solutions works with you to accelerate the earliest stages of drug development. Our large and diverse portfolio of reliable, sustainable excipients, nutraceutical active ingredients and APIs, combined with our rigorous regulatory and safety standards help push the boundaries of what's possible — from product development to finished formulation.

From our multidisciplinary expertise to our **state-of-the-art Innovation Center in Pennsylvania**, we are committed to help make your product development process more robust, cost-effective and efficient.

Request samples!

PHARMA & NUTRACEUTICALS
Prescription Drugs
Over-the-counter
Nutraceuticals
Injectables, Dialysis & Specialty APIs

BIOPHARMA
Protein Stability
Cell Culture Solutions
Precision Dispensing Technology

Sever Pharma Solutions, a CDMO that can provide our customers with unique capabilities and expertise. Sever Pharma Solutions brings your pharmaceutical ideas to life by offering expertise in Polymer based dosage forms including HPAPI and Controlled Substance Hot Melt Extrusion development, a drive to enhance performance, a passion for perfection, and a commitment to be your partner through the whole journey. We can enhance your reach by ensuring that your products can benefit patients all over the world. We can enhance your efficiency by providing you with a complete value chain to offer you an optimized end-to-end solution. We can enhance your product and outcome by adding value through all development and manufacturing processes. We are Extrusion. We are Polymer Based Dosage Forms. We are Formulation of HPAPI dosage forms. We are Long-Acting Implants. We are Intra-Vaginal Rings. We are Amorphous Solid Dispersions and Solid Dosage Forms. We are Injection Molding using Silicon and Polymers. We are Controlled Substance dosage forms. We are Aseptic Fill and Finish for Auto Injectors and Pre-Filled Syringes. We are Sever Pharma Solutions.

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SEVER
PHARMA SOLUTIONS

WE BRING YOUR PHARMACEUTICAL IDEAS TO LIFE

Sever Pharma Solutions is proud to announce the ground-breaking of our new, high potency manufacturing suite in Putnam, CT, USA. This is a welcome addition to continue providing our clients with world-class capabilities.

Sever Pharma Solutions is your committed CDMO specializing in HPAPI in a range of dosage forms including Polymer based dosage forms like rings and implants, Aseptic Fill & Finish syringes and Hot-melt extrusion OSD.

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 5,300 people in 16 sites in 9 countries and generated more than 980 million euros of revenues in 2022. 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, diabetes care, anesthetics, hormones, anticoagulants, and biologics. 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.

Your Specialist in Contract Manufacturing

Stevanato Group offers a broad range of manufacturing services and capabilities to produce high-quality devices, including pen-injectors, auto-injectors, and wearables. As a one-stop solution provider and manufacturer, it can cover all parts of the process, harmonizing them from product development to delivery of the final product, packaged and sterilized as needed.

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

MANAGING COMPLEXITY, DELIVERING VALUE

Creating a reliable ecosystem to empower our partners and their ability to produce safe, easy-to-use and cost-effective treatments to improve patients' lives.

Stevanato Group

stevanatogroup.com

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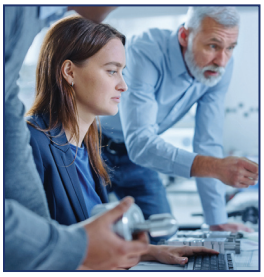



We place heightened focus on your success as your strategic partner.
Vetter produces aseptically prefilled syringes, cartridges, vials and dual-chamber systems as a globally operating CDMO partner. We are a family owned, independent company rooted in 70+ years of history. We do not manufacture our own 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, 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
- Commercial production sites in Ravensburg and Langenargen, Germany
- Dedicated clinical production facilities in Rankweil, Austria, and Chicago, USA
- Branch offices for Asia Pacific in Singapore, Japan, South Korea, and China
- More than 6,000 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

CONTACT US
Visit www.vetter-pharma.com or contact us at info@vetter-pharma.com (EU/APAC), infoUS@vetter-pharma.com (US), for more information.

Unlock the full potential of your injectable product

Meet our experts @ Pharmapack, January 24–25, 2024

CDMO LEADERSHIP AWARDS 2023

BEST MANAGED COMPANIES GERMANY

GOLD 2022 ecovadis Sustainability Rating

Partner with a leading global CDMO for aseptic fill & finish

For 40+ years, pharma and biotech companies around the world have relied on Vetter 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.

in vetter-pharma.com

VETTER

windgapmedical

Windgap Medical offers drug delivery devices that simplify, automate, and accelerate the administration of complex injectables. With our patient-centric design approach, our products are designed to manage the challenges of reconstitution, liquid/liquid mixing, and sequential delivery of multiple liquid drugs. By reducing the number of user steps, our products fit easily into a patients' daily life, enhancing usability and adherence.

Windgap's injection devices are ideal for:

- mAbs and other biologics
- Long acting Injectables
- Lyophilized drugs and suspensions
- High viscosity liquids (up to 5000+cP)
- Large volume injections (up to 10mL)

In partnership with pharmaceutical companies, we leverage our enhanced product features to improve outcomes for your life-changing molecules.

CORE CAPABILITIES

Mixing: Our automated approach to fluid management enables active, in device-controlled, mixing that eliminates shaking and swirling from the instructions for use. We provide a reliable end-point that ensures a lyophilized (or powdered) drug is mixed the same way, every single time.

Multi-Liquid Delivery: In two simple steps, we can administer two liquid drugs through the same delivery needle. The perfect platform for drugs that can't be co-formulated in the same container.

PRODUCT PLATFORMS

LVDC (Large Volume Dual Chamber) Platform: The novelty of Windgap's LVDC platform stems from its innovative arrangement of standard off-the-shelf primary drug containers (PDC). The PDC architecture features side-by-side nesting of two, readily available, single-chamber cartridges with Windgap's proprietary mixing and delivery needle hub. The side-by-side nesting permits use of ISO-compliant cartridges compatible with industry-standard filling methods, while maintaining a compact, easy-to-handle form factor.

The cartridges can be either plastic or glass; cartridge sizes from 1mL to 5mL. The design is compatible with standard aseptic filling methods or terminal sterilization strategies; and IM or SC needle lengths.

ANDI (Automatic recoNstitution Dual Chamber Injector) Platform: This offers a revolutionary twist on emergency autoinjectors. This compact device provides a thermally stable SC/IM drug delivery platform for automatic mixing and rapid dissolution of delivered doses up to 0.3 mL. ANDI is designed to meet the 99.999% reliability metrics for rescue applications. Windgap's first combination product, the ANDIpen®, is being commercialized in partnership with ALK-Abelló to deliver emergency IM epinephrine doses.

INJECT SIMPLICITY™ INTO YOUR NEXT COMBINATION PRODUCT

Reach out via email or LinkedIn to discuss your molecule's unique needs and opportunities to collaborate via partnership or feasibility studies.

You focus on the formulation. We'll deliver the solution.

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LINKEDIN: HTTPS://WWW.LINKEDIN.COM/COMPANY/WINDGAP-MEDICAL

A New Frontier for Pharmaceuticals

windgapmedical

Injecting Simplicity

Into Complex Drug Delivery

With its **patient-centric approach** and **innovative drug delivery technologies**, Windgap Medical is freeing patients and potential cures from the limitations of current delivery systems. Find out how our autoinjector products **simplify, automate, and accelerate** the path to market—and a better patient experience.

Large-Volume Dual-Chamber Autoinjector

A BETTER PATIENT EXPERIENCE AT THE PRESS OF A BUTTON

The customizable platform for automatic reconstitution, liquid/liquid mixing, and sequential delivery of two liquids—including high viscosities and injections up to 10 mL.

Compact Dual-Chamber Autoinjector

A REVOLUTIONARY TWIST ON EMERGENCY AUTOINJECTORS

The thermally stable drug delivery platform for automatic mixing and rapid dissolution of delivered doses up to 0.3 mL.

For information on partnerships and custom solutions contact us at bd@windgapmedical.com or visit windgapmedical.com

* Unless specifically stated, products are not approved for sale in the United States or the European Union.

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 Corporation is dedicated to the advancement of essential bioavailability enhancement and formulation development technology. 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. 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. For more information, visit ABITEC at **www.abiteccorp.com.**

CDMO+CRO Services

Abzena is the leading end-to-end bioconjugate and complex biologics CDMO + CRO. 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 and bioconjugates include discovery, design, lead candidate selection, analytics, bioassays, immunogenicity, protein engineering & developability, antibody design & development, mammalian cell line development, linker payload design & synthesis, analytical method and formulation development, process development & cGMP manufacturing, technology transfer & scale-up, and regulatory support. Discuss your drug program with our experts today and discover how Abzena can help you reach your next project milestone faster. For more information, visit Abzena at www.abzena.com/contact 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 **www.adarepharmasolutions.com.**

CDMO Services

Ajinomoto Bio-Pharma Services is a fully integrated contract development and manufacturing organization, with sites in Belgium, United States, Japan, and India, providing comprehensive process development services, cGMP manufacturing and drug product fill finish services of small molecule and large molecule APIs and intermediates. Ajinomoto Bio-Pharma Services offers a broad range of innovative platforms and capabilities to rapidly scale from clinical and pilot programs to commercial quantities, including: Corynex technologies, oligonucleotide synthesis, high potency APIs (HPAPI), biocatalysis, continuous flow manufacturing, and more. Ajinomoto Bio-Pharma Services is dedicated to providing a high level of quality and service to meet our clients' needs. For more information, contact Ajinomoto Bio-Pharma Services at **www.AjiBio-Pharma.com.**

CDMO Services

Alcami is a contract development, manufacturing, and testing organization headquartered in North Carolina with over 40 years of experience advancing products through every stage of the development lifecycle. Approximately 700 Alcami employees across four campuses in the United States serve biologics and pharmaceutical companies of all sizes, helping to deliver breakthrough therapies to patients faster. Alcami provides customizable and innovative solutions for formulation development, analytical development and testing services, clinical and commercial finished dosage form manufacturing (oral solid dose and parenteral), packaging, and stability services. For more information, visit Alcami at **www.alcaminow.com.**

Specialty CDMO

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

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/.**

Microcrystalline Cellulose

Asahi Kasei microcrystalline cellulose (MCC) Ceolus™ brings a key difference compared to standard MCC products: its high performance stemming from innovative particle morphology. It enables challenging formulations with poorly compactible APIs or high-dose APIs. It solves tableting issues, such as capping or sticking. It also enables unique and patient-friendly dosage forms, including MUPS and small tablets. In addition, less black particles, less impurities, including nitrite and nitrate, which may cause nitrosamine-associated risk, and the consistent high quality of Ceolus™ directly contributes to the quality improvement of customers' formulations. For more information, visit Asahi Kasei at **www.ceolus.com/en/.**

Formulation Development

Ascendia Pharmaceuticals is a speciality CDMO dedicated to developing enhanced formulations of existing drug products, and enabling formulations for pre-clinical and clinical-stage drug candidates. We specialize in developing formulation solutions for poorly water-soluble molecules and other challenging development projects. Combining our extensive knowledge and experience of formulation capabilities with our suite of nano-particle technologies, we can assess the feasibility of a broad array of robust formulation options to improve a drug's bioavailability. Thusly decreasing the amount of drug and the number of injections and greatly reducing in some cases the daily pill-burden from 20 to 4. Ascendia's expertise spans across (IV, SC, or IM), injection, ophthalmic, transdermal, nasal delivery, along with immediate- and controlled-release products for oral administration and complex generics. For more information, visit Ascendia at **www.ascendiapharma.com.**

Global Data & Analytics

PharmaCircle is a leading provider of global data and analysis on the pharmaceutical, biotechnology, and drug delivery industries. PharmaCircle's premier database delivers an integrated scientific, regulatory, and commercial landscape view with unprecedented access to hundreds of company, product, and technology attributes. PharmaCircle connects product and pipeline information for drugs and biologics with formulation and component details, and provides due diligence level data on nearly 6,000 drug delivery technologies and devices. Drug label comparison tools and full-text document search capabilities help to further streamline research. No other industry database matches PharmaCircle's breadth of content and multi-parameter search, filtering, and visualization capabilities. To learn more, email contact@pharmacircle.com, call (800) 439-5130, or visit **www.pharmacircle.com.**

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.**

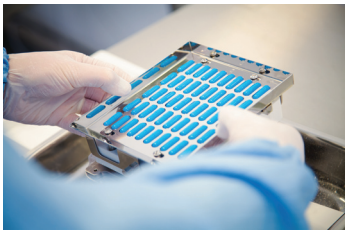
International CGMP CDMO

Bora Pharmaceuticals is dosage, non-sterile liquids, sterile and non-sterile ophthalmics, nasal sprays, and semi-solids pharmaceutical products for Clinical through Commercial manufacturing and packaging and clinical manufacturing of biologics drug substance. Bora owns and operates sophisticated cGMP manufacturing facilities (across North America and Asia), built to the highest international standards for development manufacturing, packaging, and analytical testing. Our sites deliver to more than 100 markets around the world. For more information, visit Bora Pharmaceuticals at **https://www.boracorpcdmo.com/.**

Formulation Technology

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! **www.captisol.com**

Analytical Formulation & Development Services



Catalent, a global leader in formulation and development, offers a broad array of analytical solutions for small and large molecules. With extensive laboratory and stability chamber capacity, industry-recognized experts, and a suite of services ranging from compendial to extractables and leachables testing, Catalent provides tailored analytical solutions for stand-alone projects, and can help its partners advance their molecules from development to commercialization. Catalent's US and European locations provide global solutions for a wide range of dosage forms, with specialized capabilities in handling challenging molecules, including controlled substances, highly potent compounds, as well as temperature, light, pH or oxygen-sensitive APIs. For more information, contact Catalent Pharma Solutions at (888) SOLUTION or visit **www.catalent.com.**

Lipid Nanoparticle R&D

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 ready-made lipids for LNP formulation. Cayman also offers custom synthesis of novel lipids, GMP lipid production, and LNP formulation, characterization, and screening services. For more information, visit Cayman Chemical at **www.caymanchem.com.**

Drug Delivery Platform

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.**

CDMO Experts

curia

Curia is a Contract Development and Manufacturing Organization with over 30 years of experience, an integrated network of 29 global sites and over 3,500 employees partnering with customers to make treatments broadly accessible to patients. Our biologics and small molecule offering spans discovery through commercialization, with integrated regulatory and analytical capabilities. Our scientific and process experts and state-of-the-art facilities deliver best-in-class experience across drug substance and drug product manufacturing. From curiosity to cure, we deliver every step to accelerate and sustain life-changing therapeutics. For more information, visit Curia at **curiaglobal.com.**

Testing Services

DDL

Testing Experts. Service Specialists.

DDL is an independent third-party ISO 17025 accredited testing laboratory that provides packaging, device, and materials testing. For over 30 years, DDL has provided extraordinary service and specialized testing expertise to the medical device and pharmaceutical industries. We employ a team of engineers, technical, and quality experts devoted to helping our customers bring medical device and drug delivery products to market. Our single source, totally integrated approach enables organizations of all sizes from start-ups to globally recognized corporations maximize product performance, reliability, and safety while seamlessly achieving regulatory compliance. We work hard to build strong partnerships with our clients and have an unwavering commitment to assist in getting products to market on time. For more information, visit DDL at **www.DDLTesting.com.**

Strategic & Collaborative Manufacturing

EMERGENT BIO SERVICES™

Emergent Bioservices offers biotech and pharma companies a strategic and reliable manufacturing solution for their clinical and commercial products. With 25 years of experience developing, manufacturing, and delivering our own portfolio of therapeutics and vaccines, we have the scientific and regulatory compliance experience, development and manufacturing resources, and efficient technology transfer capabilities that can harness the urgency, acuity, and scalability required to bring life-saving, life-enhancing products to market. For more information, visit Emergent Bioservices at **www.emergentbio.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.**

CDMO & Manufacturing Services

FORTIS LIFE SCIENCES

Fortis Life Sciences offers world-class reagents, tools, materials, and custom services with a best-in-class customer experience for our customers in the biopharma industry. Through our brand nanoComposix, we provide precisely engineered and highly characterized nanomaterials to a global customer base. nanoComposix is an ISO 13485 (2016)-Certified*, FDA-registered developer and contract manufacturer with a nanomaterial product portfolio containing hundreds of variants engineered to address the unique challenges presented by our customers. Our products and CDMO services are backed by technical teams with extensive expertise in nanotechnology, biology, chemistry, physics, and optics. *Specific to 4878 Ronson Ct. Suite J and 4888 Ronson Ct. Suite B. For more information, visit Fortis Life Sciences at **https://www.fortislife.com/gmp-nanoparticle-manufacturing.**

Hands-On Formulation Support

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**.

User-Friendly Oral Dosage Forms

HERMES PHARMA
Get the dose right®

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.**

Innovative Moisture Barrier

Aclar® film delivers a crystal-clear, high moisture barrier to protect medicines, while significantly reducing pack size, waste, and carbon emissions when compared to the same product packaged in Cold Form Foil (CFF). Calculate your waste reduction benefits with the Aclar Impact Estimator tool and see what you can achieve by using Aclar, including the number of shipping containers of packaging material that can be saved annually, the reduction in transportation-related CO_2 emissions, and a unique view regarding waste reduction. For more information, visit **Honeywell** at **https://hwll.co/8leoao.**

Biotech Drug Development

HTD BIOSYSTEMS INC.
High Throughput Development

HTD Biosystems team, comprising experienced professionals in various biotech drug development aspects, excels in protein and vaccine formulation, lyophilization, and biophysical protein characterization. Key strengths include flexibility, innovation, speed, and a customer-centric approach, with a readiness to adapt to changing conditions and client needs. Our services encompass protein developability, characterization and formulation development, utilizing the iFormulate™ platform for high-throughput analysis and tackling issues like protein aggregation and stability. We are experts on lyophilization process development for proteins, liposomes, diagnostic kits, and small molecules, ensuring successful scale-up and cost-effective production. HTD also manufactures GLP tox lots under aseptic conditions and offers expertise in liposomal and lipid nanoparticle development for various drug products. Our consulting services provide valuable insights into biopharmaceutical drug and process development. For more information, visit HTD Biosystems at **www.htdcorp.com.**

Integrated Contract Manufacturer

JUBILANT HOLLISTERSTIER

Jubilant HollisterStier is an integrated contract manufacturer of sterile injectables, ophthalmics, otics and sterile and non-sterile topicals and liquids. Our facilities in North America provide specialized manufacturing for the pharmaceutical and biopharmaceutical industries. We provide a full-range of support and services to streamline the manufacturing process such as on-site assistance from process qualifications through product release. With over 100 years of manufacturing expertise with a global reach, our team is committed to meeting your project's milestones efficiently. For more information, visit Jubilant HollisterStier at **www.jublhs.com.**

Medical Manufacturing

Kahle Automation designs and builds machines for the assembly and inspection of all types of medical devices and drug delivery products. Kahle's services include custom equipment design, system integration, parts feeding, material and package handling, and equipment validation, along with the documentation to meet the unique requirements of all types of manufacturing applications. Kahle' staff is dedicated to designing solutions for only one industry, allowing us the opportunity to develop the expertise required to build turnkey production systems with a complete understanding of the challenges that face the Medical Manufacturing community. For more information, visit Kahle Automation at **www.KahleAutomation.com.**

Formulation & Manufacture

LATITUDE Pharmaceuticals provides innovative drug formulation services and GMP manufacturing for early phase clinical trials. Having completed more than 1,100 projects since 2003, LATITUDE's extensive experience in a wide range of dosage forms addresses the most difficult formulation challenges, including solubility, instability, and bioavailability. LATITUDE scientists have expertise in complex injectables (nanoemulsions, liposomes, microspheres, and nanoparticles). LATITUDE Pharmaceuticals also provides GLP- and GMP-compliant manufacture and analytical testing, specializing in rapid customer response and delivery of Phase 1 and Phase 2 clinical trial materials. LATITUDE can manufacture sterile injectable, ophthalmic, non-sterile oral, and topical dosage forms to support GLP-tox studies or early stage clinical trials. LATITUDE is especially proficient in the manufacture of complex liquid formulations, including nanoemulsions, liposomes, and nanoparticles. For more information visit LATITUDE Pharmaceuticals at **www.latitudepharma.com**.

Highly Viscous & Complex Injectables

Lifecore Biomedical is a fully integrated CDMO with differentiated capabilities in the development, fill, and finish of complex sterile injectable pharmaceutical products. Success with difficult, highly viscous products (>100,000 cP) highlights our ability to undertake new challenges. With >25 commercial products, we are deeply knowledgeable on how to efficiently drive programs from clinical to commercial. 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 Polymers & Excipients

The Health business of **Lubrizol Life Science (LLS Health)**, in partnership with customers, advances solutions inspiring a healthier life. We specialize in helping clients from idea to execution by offering innovative polymers and excipients, as well as best-in-class contract development and manufacturing services. Our long history of polymer expertise and continued investment in research and manufacturing means we offer you and your customers a smooth and streamlined approach to innovative healthcare solutions. For more information, visit Lubrizol Life Science at **https://www.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.

Technology & Service Provider

From lab experiments through to aseptic/cGMP manufacturing, **Micropore's** award-winning membrane-based, formulation equipment offers the precision of microfluidics (CV of less than 10%) without the manufacturing burden of process parallelization or "scale-out." The low-shear processing prevents damage to protein-based therapies and other sensitive APIs in controlled-release, sterile injectable drug products and allows the replacement of undesirable emulsifying agents. Crossflow mixing also simplifies the solvent injection approach to nanoformulation, enabling efficient liposome, lipid nanoparticle, and polymer nanoparticle self-assembly. We offer early stage formulation development services, cGMP process consultation, tech transfer of production hardware, and global manufacturing support. For more information, visit Micropore Technologies at **www.micropore.co.uk/.**

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 **www.mikart.com.**

Life-Saving Therapies

MilliporeSigma is a leading science and technology company in healthcare, life science, and performance materials. MilliporeSigma offers more than 400 pharmaceutical formulation raw materials for solid, liquid, and semi-solid dosage forms, a wide range of active pharmaceutical ingredients and drug delivery compounds that include activated PEGs, lipids, and PEG lipids for bioavailability enhancement. In addition, MilliporeSigma provides extensive documentation and support to ensure regulatory compliance and to help advance the promise of life-saving therapies. For more information, visit MilliporeSigma at **www.embmillipore.com.**

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.**

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
Delivering on The Promise of Purity

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.**

Formulation & Development

phosphorex
Advancing Nanomedicines Together

Phosphorex is a leading CDMO with over 18 years of experience in sustained release formulation, nanomedicine, and nucleic acid delivery. With Phosphorex's expertise and innovative technologies, our team excel in encapsulating drugs into microspheres or nanoparticles, enabling targeted delivery, protection of therapeutic agents, controlled release, and improved bioavailability. From proof-of-concept to clinical studies, our integrated solution supports all phases of formulation development. Based in Hopkinton, MA, our cutting-edge CDMO facility encompasses an impressive 30,000 sq. ft. of lab space, with a cGMP facility coming online in late 2024. Phosphorex is owned by Ampersand Capital Partners, a private equity firm specializing in growth equity investments in the healthcare sector. For more information, visit Phosphorex at **www.phosphorex.com.**

Drug-Development Library

Pharmaceutics International Inc. (Pii) proudly offers a library of e-books for Bio/Pharma scientists. The series of e-books is ideal for Bio/Pharma companies seeking to partner with a Contract Development and Manufacturing Organization, such as Pii, and bring a molecule from clinic to commercialization. Using state-of-the-art specialized equipment, Pii offers phase-appropriate development in early stages to support your program and accelerate timelines. In these e-books, you will learn that partnering with a CDMO garners success when dealing with the following: Aseptic Manufacturing, Sterile Fill & Finish, Lyophilization Cycle Development, Scale-Up & Tech Transfer, HPAPI; Controlled Drugs/DEA Scheduled Drugs, BCS Class II to IV Drugs, Oxygen-Sensitive Drugs, and Regulatory Hurdles. Don't delay in connecting with Pii's R&D team! Download an e-book from the Pii library! For more information, visit Pii at **https://www.pharm-int.com/ebook-drug-development-library/.**

Material Design & Manufacturing

POREX
Filtration Group®

As a partner for 17 out of 20 of the world's leading medical device companies and brands, **Porex** engineers solve technical challenges for drug delivery products with custom-engineered high-quality components and resources designed specifically for the end device. Whether the drug delivery device is an inhaler, an injectable, or a topical applicator, porous polymer technologies can be used for particle filtration, applicators, flow metering, fluid management, and sound diffusion. By combining our extensive material science expertise with our global manufacturing capability, we help our drug delivery customers find the perfect component to make their unique product design come to life. For more information, visit Porex at **www.porex.com.**

OINDP Development Services

proveris®
LABORATORIES

Proveris® Laboratories offers Orally-Inhaled and Nasal Drug Product Development (OINDP) expertise to pharmaceutical developers, including contract services employing new innovative in vitro techniques. These include measuring plume front velocity, evaporate rate, and quantifying deposition of inhaled drug products using human-realistic models. Employing in vitro approaches that are human-realistic can enable companies to make data-driven decisions and expedite product development and approval while saving time and resources. For more information, visit Proveris Laboratories at **https://www.proveris.com/why-proveris/.**

Integrated Drug Substance & Drug Product Services

Quotient Sciences
Molecule to cure. Fast.™

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 substance, 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. 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. Resilience serves global customers through its sites located in six states across the US, as well as in Canada, by continuously advancing the science of biopharmaceutical manufacturing and development. Resilience works across all stages of five primary modalities: Biologics, Vaccines, Nucleic Acids, Cell Therapy, and Gene Therapy. 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. For more information, visit Resilience at **www.resilience.com**.

Excipients & Ingredients

Roquette Pharma Solutions offers a large and diverse portfolio of reliable, plant-based excipients, nutraceutical active ingredients, active pharmaceutical ingredients, high-quality and multi-compendial specialty ingredients, and pyrogen-free carbohydrates. Our products are designed for a range of applications encompassing prescription and OTC drugs, generics, nutraceuticals, biopharmaceuticals, and injectables and dialysis. US Innovation Center Near Philadelphia - Dedicated to advancing the research of drug delivery systems while improving speed to market, our US innovation lab also serves as an Applied Science and Customer Technical Support (CTS) center for advanced research in drug delivery systems for oral prescription (small molecule) drugs as well as nutraceuticals. This proximity with our US customers helps expedite drug development and market release. For more information, visit Roquette Pharma Solutions at **www.roquette.com/pharma**.

Specialized CDMO

Sever Pharma Solutions, a CDMO providing customers with unique capabilities and expertise, brings your pharmaceutical ideas to life by offering expertise in Polymer- based dosage forms, including highly potent drug dosage development. We enhance your reach by ensuring your products benefit patients all over the world. We increase your efficiency by providing you with a complete value chain to offer you an optimized end-to-end solution. We improve your product and outcome by adding value through all development and manufacturing processes. We are Extrusion. We are Polymer-Based Dosage Forms. We are Formulation of Highly Potent dosage forms. We are Long-Acting Implants. We are Solid Dosage Forms. We are Injection Molding. We are Aseptic Fill and Finish. For more information, visit Sever Pharma Solutions at **www.severpharmasolutions.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 Stevanator Group at **www.stevanatogroup.com.**

FULL-SERVICE CDMO

Vetter is a leading 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 3 to Vetter Commercial Manufacturing for large-scale production. For more information, visit Vetter at **www.vetter-pharma.com.**

Injecting Simplicity ™ Into Complex Drug Delivery

Windgap Medical offers drug delivery devices that simplify, automate, and accelerate the administration of complex injectables. With our patient-centric design approach, our products are designed to manage the challenges of reconstitution, liquid/liquid mixing, and sequential delivery of multiple liquid drugs. By reducing the number of user steps, our products fit easily into a patients' daily life, enhancing usability and adherence. Windgap's injection devices are ideal for: mAbs and other biologics, long acting injectables, lyophilized drugs and suspensions, high viscosity liquids (5000cP+), large volume injections (up to 10mL). In partnership with pharmaceutical companies, we leverage our enhanced product features to improve outcomes for your life-changing molecules. For more information, visit Windgap Medical at **www.windgapmedical.com**.

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ABITEC Corporation	54,55		www.abiteccorp.com
Abzena	56,57	info@abzena.com	www.abzena.com
Actylis	58,59	Marketing@actylis.com	www.actylis.com
Adare Pharmaceuticals	7,60,61	BusDev@adareps.com	www.AdarePharmaSolutions.com
Ajinomoto Bio-Pharma Services	62,63	info@US.AjiBio-Pharma.com	www.AjiBio-Pharma.com
Alcami Corporation	64,65,164		www.alcaminow.com
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Aptar Pharma	68,69	info.pharma@aptar.com	https://www.aptar.com/pharmaceutical/
Ascendia Pharma	9,70,71		www.ascendiapharma.com
BD Medical Pharmaceutical Systems	72,73	bd@ascendiapharma.com	www.drugdeliverysystems.bd.com
Bora Pharmaceuticals USA	74,75	US: 800-225-3310 Europe: +33 4 76 68 36 36 – info@bora-corp.com	www.boracorpcdmo.com
Captisol	5,76,77	(858) 550-5632	www.Captisol.com
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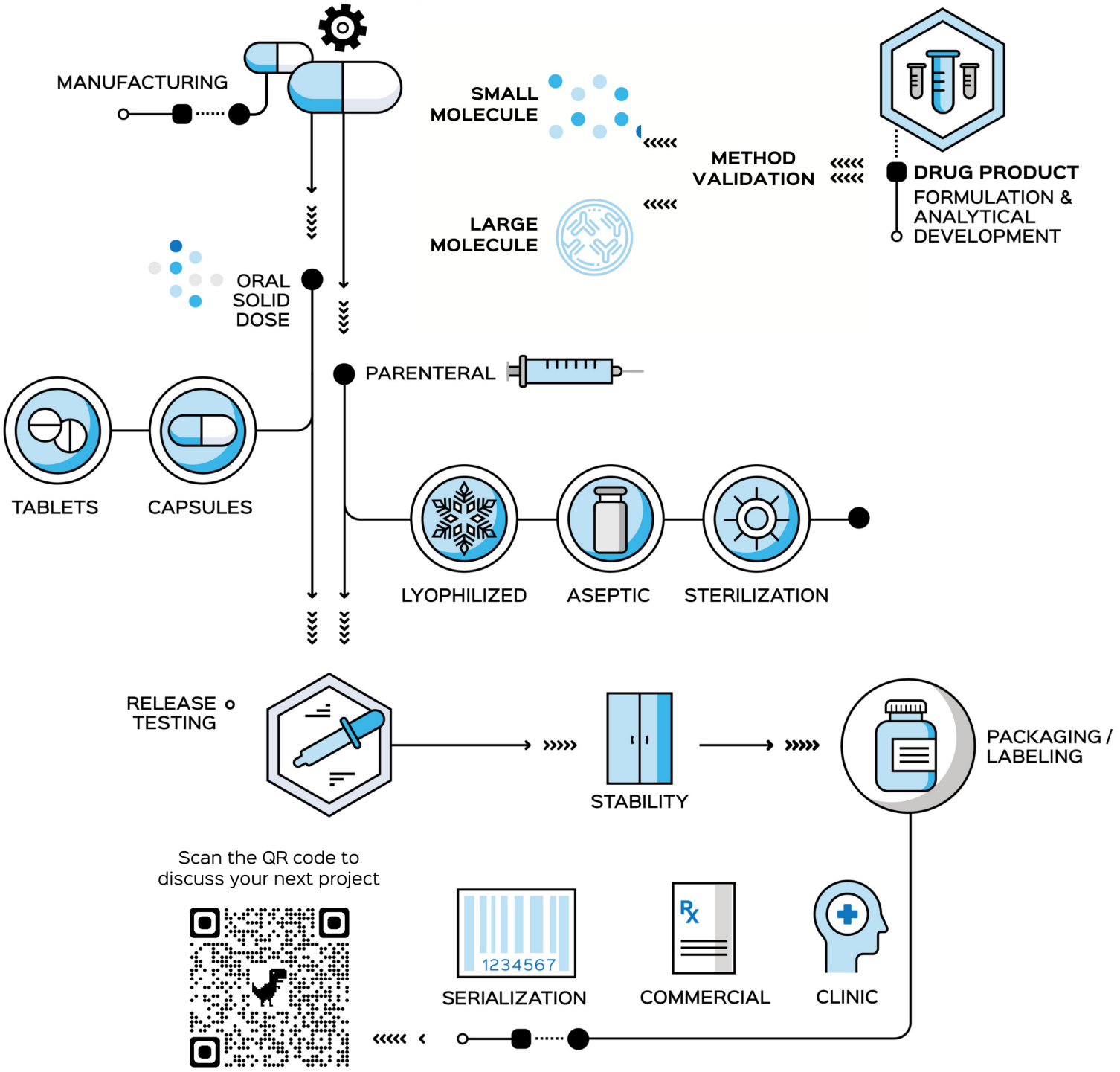

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