# Drug Development & Delivery®

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# Company Profiles & Capabilities

The Science & Business of Pharmaceutical and Biological Drug Development

IN THIS ISSUE

INTERVIEW WITH PLUS THERAPEUTICS' CEO

**MARC HEDRICK, PHD**


**ORAL SUSPENSIONS** 20
Mary Schuster

**ORPHAN DRUG DEVELOPMENT** 30
Hibreniguss Terefe, PhD

**INJECTABLE DEVICES** 35
Tommy Schornak

**PLATFORM TECHNOLOGY** 38
Jennifer Schneider, PhD

**COMPANY PROFILES & CAPABILITIES** 46

**TECHNOLOGY & SERVICES SHOWCASES** 130


**Polla Rouf, PhD**
PharmaShell®: Enabling Once-Monthly Therapeutics With Atomic Precision Coatings

**Kyle Smith, MBA**
The Future of 3D Printing in Pharma: Aprecia's Vision for Transformative Medicine

**William Sanders, PhD**
Purification at Scale: Overcoming Chromatography Challenges for Advanced Modalities

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# Table of Contents


## Drug Delivery

14 **PharmaShell®: Enabling Once-Monthly Therapeutics With Atomic Precision Coatings**
Anders Johansson, PhD, Polla Rouf, PhD, and Joel Hellrup, PhD, review an innovative drug delivery system that uses nanometer-thin, inorganic coatings to turn short-acting drugs into long-acting injectables.

## Oral Suspensions

20 **A New Standard in Oral Suspensions: Leveraging Novel Excipients for FDA Approval**
Mary Schuster introduces a new approach to perfecting oral suspension formulations, which is centered on the strategic use of a "novel" synthetic functional excipient, magnesium aluminometasilicate (MAS).

## Executive Interview

24 **Plus Therapeutics: Advancing Targeted Radiotherapeutics for Rare & Difficult-to-Treat Cancers**
Dr. Marc Hedrick, CEO of Plus Therapeutics, discusses the company's targeted radiotherapeutic platform for central nervous system and solid tumor cancers and why internal radiation therapy offers patients a more advanced drug delivery solution compared to traditional external radiation therapy.

## 3D Printing

26 **The Future of 3D Printing in Pharma: Aprecia's Vision for Transformative Medicine**
Kyle Smith, MBA, explains how his company, a pioneer in pharmaceutical 3D printing, has a vision for distributed, patient-centric manufacturing that could re-shape the future of medicine.

## Drug Development

30 **Common CMC Pitfalls in Orphan Drug Development**
Hibreniguss Terefe, PhD, says although the unique challenges of orphan drug development are amplified by compressed timelines and limited patient populations, common pitfalls also serve as cautionary tales for other areas of drug development.

## Injectable Devices

35 **Delivering Tomorrow's Injectables to Patients Today: Responding to a New Era of Demand With Purpose-Built Capabilities**
Tommy Schornak examines how evolving therapeutic modalities, delivery systems, and regulatory expectations are reshaping the fill finish landscape.

## Platform Technology

38 **Developing Innovative Solutions to One of the Top Public Health Threats: Antibacterial Resistance**
Jennifer Schneider, PhD, believes immunotherapy holds the potential to revolutionize the treatment of "hard to treat," chronic, and often recalcitrant infections.

## Purification Strategies

41 **Purification at Scale: Overcoming Chromatography Challenges for Advanced Modalities**
William Sanders, PhD, explores the real-world challenges of scaling chromatography and highlights how contract development and manufacturing organizations (CDMOs) can help partners overcome them.

## Company Profiles

47 For each participating company, this section presents a detailed summary highlighting their core technologies, capabilities, products, and services.

## Departments

8 **Market News & Trend**
130 **Technology & Services Showcase**


## Neupulse Launches First-of-its-Kind Wearable With the Support of Ensera Design to Help People Living With Tourette Syndrome

Neurotechnology company Neupulse has announced a first-of-its-kind wearable device proven to dramatically reduce the frequency and urge of tics in people living with Tourette Syndrome, marking a major milestone in the development of drug-free, non-invasive therapy for this condition.

Developed with the design and engineering support of Ensera Design, a global healthcare innovation consultancy, the breakthrough wearable integrates Neupulse's neurotechnology expertise into a discreet, everyday device activated at the touch of a button.

Developed over four years but built on two decades of research by the team behind the product, the wrist-worn device uses gentle, rhythmic electrical stimulation of the median nerve to target brain networks associated with tics. Originating from pioneering neuroscience research at the University of Nottingham, the technology has shown promising results in clinical trials, demonstrating significant reductions in tic severity and frequency for both motor and phonic tics.

"This wearable and self-managed treatment could change the lives of people living with Tourette's. It potentially offers a flexible and accessible option for the many people who are currently struggling to access treatment." said Emma McNally, CEO of UK charity Tourettes Action.

Ensera Design's UK team, formerly Kinneir Dufort, supported the development of the device. This included the development of an early-stage prototype for use in clinical studies, and ongoing refinements to enhance real-world usability, comfort and convenience ahead of commercial launch, enabling the device to integrate seamlessly into users' daily lives. The partnership reflects a shared commitment to advancing inclusive healthcare solutions through cutting-edge device innovation.

"Ensera Design has been a critical partner for Neupulse in developing the Neupulse device. Vital to the relationship is a shared understanding and vision of changing the lives of people living with Tourette Syndrome," said Paul Cable, CEO, Neurotherapeutics Ltd.

"Turning pioneering research into a functional medical device that's ready for commercial launch is no small task," said Kerry Briggs, VP Design and Development Europe at Ensera Design. "It was essential that our design, electronics engineering and prototyping experts worked in lockstep with the Neurotherapeutics team. Getting a product to perform in real-world use calls for more than just deep technical expertise. It requires a strong sense of shared commitment to the people we're designing for – something which drove us from the outset of this important project."

"It's rare to work on an innovation that so directly improves lives," said Craig Wightman, Chief Design Officer at Ensera Design during the development of the project. "From the outset, we felt a deep responsibility to help bring this therapy from the lab to life in a form that's usable, effective, and human-centred."

The announcement comes amid growing awareness of Tourette Syndrome, partly driven by the release of the film I Swear, inspired by the real-life story of John Davidson, a long-term advocate for greater understanding and acceptance of Tourettes. The film has helped shine a light on the lived experiences of people with Tourette Syndrome and the need for accessible, evidence-based therapies that provide non-invasive relief.

Regulatory submissions for the device are currently underway, with commercial availability targeted for 2026.

"The Neupulse device is more than an engineering success, it's a cultural and clinical turning point for people with Tourette Syndrome," added Wightman.

## Enterprise Therapeutics Publishes Results of Phase 1 Study of a Novel Inhaled ENaC Blocker for Treatment of Cystic Fibrosis

Enterprise Therapeutics Ltd recently announced the publication of a peer reviewed study in the Journal of Cystic Fibrsosis. The paper, titled ETD001, a long-acting inhaled ENaC blocker, is well tolerated in a first human, healthy participant trial, describes the results of the Phase 1 trial of Enterprise's novel epithelial sodium channel (ENaC) blocker, ETD001, indicating that ETD001 is well tolerated in healthy individuals at higher doses than required to observe long-lasting improvements in mucociliary clearance in preclinical models.

The Phase 1 study to evaluate the safety, tolerability and pharmacokinetics of ETD001 followed single and multiple inhaled ascending doses, at levels predicted to be efficacious in humans. The results from the trial show that ETD001 was well tolerated at single doses and on repeat dosing twice daily, for up to 14 days. Unlike historical inhaled ENaC blockers, the pharmacokinetic profile of ETD001 following inhaled dosing was consistent with slow absorption out of the lung and into the systemic circulation, consistent with prolonged retention in the lung and the potential for extended duration of action. Furthermore, target-mediated ENaC blockade in the kidney can lead to changes in blood potassium levels. This trial demonstrated that levels of blood potassium remained within normal limits at all doses of ETD001 evaluated.

These results align exceptionally well with the pre-clinical data, which demonstrated a good safety profile and an extended duration of action in the lung for >16 hours after a single inhaled dose. Enterprise is currently conducting a Phase 2 trial (NCT06478706) investigating whether 28 days of treatment with ETD001 improves lung function in people with cystic fibrosis, with headline data expected in early 2026.

Dr. Henry Danahay, Head of Biology, Enterprise Therapeutics, and lead author of the paper, said: "There is an urgent need for new therapies to treat mucus obstruction in the lungs of people with CF, and especially those who are genetically unsuited to CFTR modulators. We are passionate about working towards treatments that will benefit all people with cystic fibrosis and are excited to publish these promising results from our Phase 1 trial. We are grateful for everyone who took part in this trial, and for the people with cystic fibrosis that are enrolled in the ongoing Phase 2 trial of ETD001."

Cystic fibrosis is estimated to affect over 100,000 people worldwide, with an average life expectancy of ~60 years. Failed mucociliary clearance and mucus congestion in the lungs leads to cycles of infection and inflammation and an ongoing decline in lung function. Inhibition of ENaC in the airways of people with cystic fibrosis represents an approach to restore airway mucus hydration and is expected to drive substantial improvements in lung function.

Cystic Fibrosis is a lethal genetic disease, with more than 100,000 patients worldwide living with the disease. The average life expectancy of a person with CF, although improving, is only ~60 years.

## Pace Appoints Ken Beyer as Chief Executive Officer

Pace, a leading science and technology company with a nationwide network of environmental and life sciences laboratories, announces the appointment of Ken Beyer as its new Chief Executive Officer. Beyer will oversee all aspects of the organization, bringing a wealth of experience across technology and logistics markets to further strengthen Pace and its mission of delivering innovative solutions and outstanding customer service.

"I am honored to join Pace and lead a team dedicated to making the world a safer, healthier place," said Ken Beyer. "Together, we will continue to innovate our services and delivery network while advancing scientific excellence for our clients and communities."

Ken Beyer joins Pace after a distinguished career leading high-growth companies in the logistics, technology, and consulting sectors. Most recently, as CEO of Transportation Insight and Nolan Transportation Group, he guided the combined company to become the 4th largest domestic transportation management provider in the U.S., generating over $5 billion in annual revenue. Beyer previously served as President of Ingram Micro Commerce & Lifecycle Services, a $4 billion global logistics business spanning 39 countries and 15,000 employees. He joined Ingram Micro after its acquisition of CloudBlue Technologies, a company he co-founded and scaled into a global leader in reverse logistics and IT asset disposition. Beyer began his career as a management consultant with Ernst & Young, holds a degree in Architectural Engineering from Kansas State University, and is an active member of the Young Presidents' Organization (YPO).

Pace, a portfolio company of Leonard Green & Partners and Aurora Capital Partners, brings decades of expertise in supporting industries, government agencies, and businesses through its state-of-the-art laboratory services. Under Beyer's leadership, the company is poised to accelerate growth, expand service offerings, and strengthen partnerships across the pharmaceutical, biotechnology, and environmental sectors.

Pace makes the world a safer, healthier place. For decades, Pace® people have been committed to advancing the science of the pharmaceutical and biotechnology industries in our Life Sciences laboratories and supporting businesses, industries, consulting firms, government agencies, and more through our Environmental and Analytical Services laboratories. Pace offers local-level service backed by a national laboratory network. For customers with in-house labs, Pace provides a range of professional services to keep their operations moving forward. Pace people work in partnership with customers by providing the service, science, and the data they need to make critical decisions that benefit us all. More at pacelabs.com.

## Kelun-Biotech & Crescent Biopharma Announce Strategic Partnership to Develop & Commercialize Novel Oncology Therapeutics

Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. and Crescent Biopharma, Inc. recently announced they have entered into a strategic partnership to develop and commercialize oncology therapeutics, including novel combinations.

The partnership involves Crescent's CR-001, a PD-1 x VEGF bispecific antibody, and Kelun-Biotech's SKB105, an integrin beta-6 (ITGB6)-directed antibody-drug conjugate (ADC) with a topoisomerase payload. Both candidates are being developed for the treatment of solid tumors and are expected to enter Phase 1/2 monotherapy clinical trials in the first quarter of 2026.

Under the terms of the collaboration, Crescent has granted Kelun-Biotech exclusive rights to research, develop, manufacture and commercialize CR-001 in Greater China (including mainland China, Hong Kong, Macau and Taiwan). In addition, Kelun-Biotech has granted Crescent exclusive rights to research, develop, manufacture and commercialize SKB105 in the United States, Europe and all other markets outside of Greater China. The partnership includes the development of these candidates as monotherapies, and also the evaluation of CR-001 in combination with SKB105.Both Crescent and Kelun-Biotech have the right to independently develop CR-001 in additional combinations, including combinations of CR-001 with proprietary ADC pipeline assets.

Under the collaboration, Kelun-Biotech will receive an upfront payment of US$80 million from Crescent and is also eligible to receive additional milestones of up to US$1.25 billion, plus tiered middle single-digit to low double-digit royalties on net sales of SKB105. Kelun-Biotech is also eligible to receive additional payment from Crescent if Crescent undergoes a near-term change of control or enters into a sublicense agreement with a third party. Crescent will receive an upfront payment of US$20 million from Kelun-Biotech and is also eligible to receive additional milestones of up to US$30 million, plus tiered low to middle single digit royalties on net sales of CR-001.

CR-001 is a tetravalent bispecific antibody being developed for the treatment of solid tumors that combines two complementary, validated mechanisms in oncology via a blockade of PD-1 and VEGF. PD-1 checkpoint inhibition is aimed at restoring T cells' ability to recognize and destroy tumor cells, and blocking VEGF is intended for reducing blood supply to tumor cells and inhibiting tumor growth. In preclinical studies, CR-001 demonstrated cooperative pharmacology with increased binding to PD-1 and signal blockade in the presence of VEGF as well as robust anti-tumor activity. CR-001's anti-VEGF activity may also normalize the vasculature at the tumor site, which has the potential to improve the localization and effectiveness of combination therapies, such as the administration of CR-001 with antibody-drug conjugates (ADCs). A global Phase 1/2 trial of CR-001 in patients with solid tumors is anticipated to commence in the first quarter of 2026.

SKB105 is a differentiated ADC targeting integrin beta-6 (ITGB6) with a topoisomerase 1 inhibitor payload. ITGB6 is overexpressed in many solid tumors, but shows minimal to no expression in most normal tissues, thereby potentially reducing the risk of systemic toxicity and off-target effects. SKB105 consists of an anti-ITGB6 fully human IgG1 monoclonal antibody conjugated via a stable, clinically validated cleavable linker. The molecule incorporates proprietary Kthiol irreversible conjugation technology, designed to enhance stability and tumor-specific payload delivery while reducing adverse effects. SKB105 demonstrated a favorable efficacy, safety, and pharmacokinetic (PK) profile in preclinical models. A Phase 1/2 clinical trial of SKB105 in patients with solid tumors is anticipated to commence in the first quarter of 2026.

## Quotient Sciences & Intrepid Labs Form Strategic Partnership to Accelerate AI-Guided Formulation Development

Quotient Sciences and Intrepid Labs recently announced a ground-breaking multi-year strategic partnership to advance the use of artificial intelligence (AI) in early drug development.

Under the new agreement, Quotient Sciences will have access to Intrepid's machine learning model, ANDROMEDA, the first AI platform to develop and optimize clinical performance of drug products.

ANDROMEDA supports rapid exploration of formulation options, helping reduce experimental burden, minimize drug substance demands, and enhance data-driven decision making. It uses an advanced, proprietary machine learning algorithm, not a large language model, and has the potential for client-specific or aggregated multi-client models for enhanced predictivity.

The partnership builds on an existing collaboration where Intrepid's AI model was incorporated into Quotient's Translational Pharmaceutics® platform to help accelerate the identification of optimal formulation compositions and reduce the time to transition new drug products into clinical development with even greater chances of success.

Customers will benefit from Quotient Sciences' extensive experience in formulation development, GMP manufacturing, and early clinical testing, alongside Intrepid Labs' deep expertise in formulation science and AI-guided approach to designing drug products.

Each project will be supported by a secure, independent AI instance, ensuring strong data protection, confidentiality, and alignment with industry standards. Initial pilot projects comparing traditional and AI-assisted methods will begin immediately, followed by a wider rollout.

Christine Allen, CEO and Co-Founder of Intrepid Labs, said: "Our goal is to help the industry design better formulations with greater confidence and speed. Working with Quotient Sciences allows our technology to have an immediate impact, reducing time, material use, and the uncertainty that often accompanies early formulation work."

This collaboration comes as the industry continues to adopt advanced digital tools to improve efficiency in R&D. Recent analysis from Boston Consulting Group suggests that AI-enabled approaches could reduce time and cost in early development by 25–50%.

Both Quotient Sciences and Intrepid Labs plan to explore additional applications as the partnership continues to evolve.

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, they save precious time and money in getting drugs to patients. Everything they do for their customers is driven by an unswerving belief that ideas need to become solutions, and molecules need to become cures, fast, because humanity needs novel therapeutic solutions, fast. Quotient Sciences has been recognized as a multi-year winner of the CRO Leadership Awards in 2021, 2022, and 2024 and of the CDMO Leadership Awards in 2023.

## Incannex Granted FDA Fast Track Designation for IHL-42X in Obstructive Sleep Apnea

Incannex Healthcare Inc. recently announced the US FDA has granted Fast Track designation for IHL-42X, the Company's oral fixed-dose combination product candidate for the treatment of obstructive sleep apnea (OSA).

The Fast Track designation was supported by promising safety, efficacy, and pharmacokinetic results from the three clinical trials completed to date within the IHL-42X development program. These include the Company's successful Phase 2 "RePOSA" study demonstrating statistically significant reductions in Apnea-Hypopnea Index (AHI), with individual reductions of up to 83%, outstanding patient-reported outcomes, and an excellent safety profile.

Fast Track designation is granted by the FDA to drug candidates that treat serious conditions and address unmet medical needs with the aim of making important new therapies available to patients sooner.

Under the Fast Track program, IHL-42X will now benefit from: more frequent, structured interactions between Incannex and the FDA to discuss clinical strategy, trial design, and data requirements, eligibility for rolling review, enabling the Company to submit completed sections of a future New Drug Application (NDA) ahead of the full submission, and potential access to Accelerated Approval and Priority Review, should relevant criteria be met

Incannex expects to receive detailed written feedback from the FDA in response to its Phase 2 data package and clinical development strategy. The Company expects to provide further updates regarding the FDA's guidance, the agreed next steps, and the proposed path toward late-stage development once it has received and reviewed this feedback.

"We are delighted with the FDA's decision to grant Fast Track designation to IHL-42X for OSA. This supports the potential for IHL-42X to address the unmet need for an oral pharmacotherapy for OSA patients. OSA is a serious disease with impacts on both short- and long-term aspects of patient health and quality of life. We look forward to continuing to work with the FDA on the development of IHL-42X," said Mark Bleackley, Chief Scientific Officer

"We believe Fast Track designation for IHL-42X is one of the most significant regulatory milestones in Incannex's history. OSA affects millions of people globally, yet there remains no approved oral pharmacotherapy, a gap we are determined to close. Following our exceptional Phase 2 results, this designation validates the strength of our data package and the potential for IHL-42X to transform the treatment landscape. We believe the designation also provides a clear, expedited regulatory pathway, allowing us to accelerate development and capitalise on the pillars we have built throughout the year, including our recent Nasdaq extension. We look forward to working closely with the FDA as we advance IHL-42X toward late-stage development and ultimately to patients who urgently need new options," added Joel Latham, President & CEO

Incannex is leading the way in developing combination medicines that target the underlying biological pathways associated with chronic conditions, including obstructive sleep apnea, rheumatoid arthritis and generalized anxiety disorder. The company is advancing three clinical-stage product candidates based on evidence-based innovation and supported by streamlined operations.

## Evonik Names New President for the Americas Region

Evonik, one of the world's leading specialty chemicals companies, has appointed long-time Evonik executive Elias Lacerda President of the Americas region, effective February 1, 2026. Lacerda will succeed Guido Skudlarek, who recently became global Head of Evonik's U.S.-based Health Care business line.

"The Americas region is crucial for Evonik's success," says Lauren Kjeldsen, Evonik's Chief Operating Officer Custom Solutions and Management Board member responsible for the Americas. "I want to sincerely thank Guido for his successful work in growing the Americas business, and I look forward to Elias leading the next phase of our growth trajectory in North and South America. We see great potential there and have ambitious goals."

A native Brazilian with degrees in chemical engineering and business administration (MBA), Lacerda has nearly three decades of experience with Evonik and its predecessors. He spent half of that time in Central and South America (CSA) managing businesses in the coatings sector and holding global leadership positions in Evonik's Silica and Animal Nutrition business lines. Most recently, he served as head of the strategically important Coating Additives business line at the company's headquarters in Essen, Germany. From 2018 to 2022, he led the CSA region as president. The CSA and North America regions were recently merged.

"Elias is the perfect choice for the Americas region. Fluent in four languages and with an extensive global network, he combines scientific and business expertise in an ideal way," says Kjeldsen.

Evonik generates 30 percent of its annual revenue in the Americas and operates more than 30 production sites in the region, along with distribution centers and commercial offices. "My focus is on people, performance, and prosperity," says Lacerda. "I look forward to working with our excellent team to expand Evonik's business in the Americas, drive key strategic projects, and strengthen the region."

Evonik is one of the world leaders in specialty chemicals. The company is active in more than 100 countries around the world and generated sales of €15.3 billion and an operating profit (adjusted EBITDA) of €1.66 billion in 2023. Evonik goes far beyond chemistry to create innovative, profitable, and sustainable solutions for customers. More than 32,000 employees work together for a common purpose: We want to improve life today and tomorrow.

## NorthX Biologics Achieves Milestone GMP Certification to Manufacture Mendus' Lead Cell Therapy Product for Acute & Chronic Myeloid Leukemias

NorthX Biologics and Mendus recently announced the successful completion of GMP manufacturing certification for Mendus' lead cell therapy product, vididencel. This milestone marks the culmination of a transformative collaboration initiated in 2023, when NorthX Biologics and Mendus entered into a strategic alliance to establish scalable, GMP-compliant cell therapy manufacturing in Sweden. The project, co-financed by leading life science investor Flerie, was designed to support late-stage clinical development and future commercialization of vididencel, Mendus' groundbreaking immunotherapy targeting tumor recurrence in AML and other cancers.

"This partnership has gone beyond traditional manufacturing," said Janet Hoogstraate, CEO of NorthX Biologics. "Through open and transparent collaboration, we've built not only a cell therapy infrastructure but also mutual capabilities. Together, we've grown stronger, technically, operationally, and strategically. Achieving GMP readiness and delivering clinical-grade material for Mendus' upcoming clinical trials is a shared success story rooted in trust and innovation."

For two years, NorthX Biologics and Mendus have collaborated closely to adapt NorthX Biologics' GMP facilities for allogeneic cell therapy production, perform tech transfer of the vididencel process, and manufacture clinical batches in accordance with stringent regulatory standards. The process development and manufacturing journey has reinforced Sweden's position as a hub for advanced therapy medicinal products (ATMPs) and enabled Mendus to accelerate its oncology pipeline.

"With the establishment of large-scale GMP production, we're delivering on an important milestone for the vididencel program," said Mendus CEO Erik Manting. "Reliable manufacturing is central to advance our clinical trials and go-to-market strategy in AML and CML. This milestone demonstrates the maturity of the vididencel production process and strength of our partnership with NorthX Biologics. It reflects the execution focus that defines Mendus, as we continue to build clinical momentum."

The successful execution of this manufacturing project positions both companies at the forefront of Europe's ATMP ecosystem. It also exemplifies how tailored CDMO alliances can unlock clinical and commercial potential for cell therapies by aligning scientific ambition with industrial excellence.

NorthX Biologics is a leading contract development and manufacturing organization (CDMO) and Sweden's national innovation hub for advanced biologics, enabling next-generation therapies beyond traditional manufacturing. With over 30 years of GMP experience, NorthX Biologics offers end-to-end services including process development, recombinant proteins, vaccines, personalized medicine, viral vectors, cell therapies, and aseptic fill & finish. Headquartered in Matfors, Sweden, NorthX Biologics also operates a facility in Stockholm and a commercial office in Boston, USA, serving customers worldwide. https://www.nxbio.com/

Mendus is dedicated to changing the course of cancer treatment by addressing tumor recurrence and improving long-term survival for cancer patients, while preserving health and quality of life. We leverage our understanding of dendritic cell biology to develop an advanced clinical pipeline of immunotherapies that combine clinical efficacy with a benign safety profile. Based in Sweden and The Netherlands, Mendus is publicly traded on the Nasdaq Stockholm under the ticker IMMU.ST. https://www.mendus.com/.

## Croda Expands Biopharma Capabilities Through Strategic Partnership

Croda International Plc recently announced a strategic supply partnership with Amino GmbH aimed at strengthening the global availability of high purity amino acids for pharmaceutical formulation and biomanufacturing.

Combining Croda's deep expertise in smart science and global market reach, with Amino's advanced capabilities in precision manufacturing of amino acids will enable Croda to deliver even more innovative, high-quality and sustainable solutions that help customers accelerate their product development and achieve greater efficiency.

"This partnership reflects Croda's strategy, to strengthen our ability to support customers in the fast-evolving biopharma landscape" said Katie Dec, Global Business Director, Croda International Plc. "Amino's strong reputation and expertise make them an ideal partner as we continue to deliver high-quality, reliable materials needed to bring new therapies to market."

"The partnership with Croda is both a milestone and a catalyst for Amino's ambitions in biopharmaceuticals. The combination of Croda's market reach and our high-purity amino acid production expertise forms a partnership dedicated to meeting specific customer demands," states Lutz Thomas, Managing Director of Amino GmbH.

This reinforces Croda's commitment to supplying the highest purity ingredients for pharmaceutical formulation and biomanufacturing and follows on from the recent launches of Virodex™ for viral inactivation and cell lysis, and Super Poloxamer 188 as a shear protectant in cell culture media.

Croda is a specialty chemicals company that creates high performance ingredients and solutions principally for Consumer Care and Life Sciences markets. Established 100 years ago in 1925 and headquartered in the UK, Croda is a FTSE 100 company with over 5,800 employees across 92 locations in 39 countries. Revenues in 2023 were £1.69bn.

As the name behind some of the world's most successful brands, we combine our knowledge, passion and entrepreneurial spirit to develop and supply innovative ingredients relied on by industries and consumers around the world. Our smart science is found in products that touch our lives every day from sun protection to life-saving pharmaceuticals and formulations that enhance crop yields.

With a shared Purpose to use Smart science to improve lives, and with around two thirds of its organic raw materials already from bio-based sources, Croda has committed to be the most sustainable supplier of innovative ingredients, becoming Climate, Land and People Positive by 2030 while providing solutions to some of the world's biggest challenges.

Croda's Pharma business is a leading partner in the development of excipients and the supply of high purity materials for pharmaceutical formulations and is committed to enabling the next generation of drug delivery systems. The business is focused on empowering biologics drug delivery, through its adjuvant systems, small molecule, protein, and nucleic acid delivery platforms.

Amino GmbH based in Frellstedt, Germany is a manufacturer of high-quality amino acids and related substances focused on pharmaceutical and nutritional applications.

# PharmaShell®: Enabling Once-Monthly Therapeutics With Atomic Precision Coatings

By: Anders Johansson, PhD, Polla Rouf, PhD, and Joel Hellrup, PhD

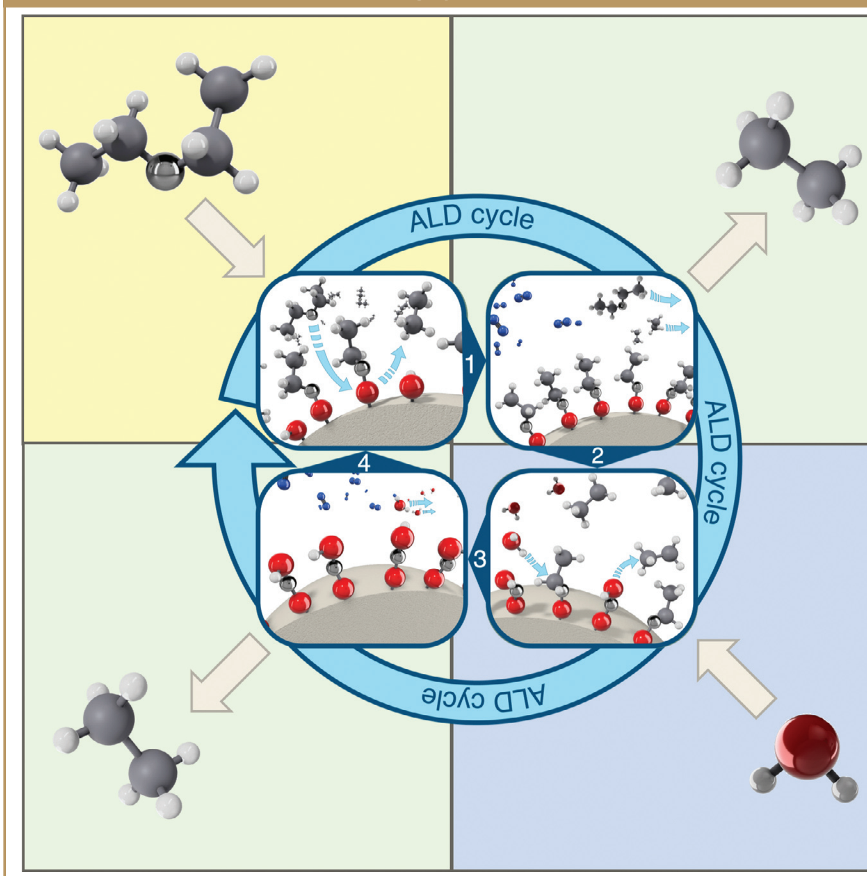
## INTRODUCTION

Effective management of many chronic diseases, such as type 2 diabetes, often requires daily injections; however, this can negatively impact patient adherence. In the case of GLP-1 analogs, changing from daily to weekly injections has been shown to significantly improve adherence – behavior that persists over time.[1]

To address this burden of frequent dosing, the Swedish company Nanexa has developed PharmaShell®, an innovative drug delivery system that uses nanometer-thin, inorganic coatings to turn short-acting drugs into long-acting injectables. By enabling a steady, extended release of medication from a single treatment, PharmaShell can dramatically reduce dosing frequency.

The following details the PharmaShell technology and its benefits, with a focus on Nanexa's recent Phase I clinical study, and its once-monthly type 2 diabetes GLP-1 receptor agonist therapy.

FIGURE 1




**Schematic overview of one ALD cycle producing one layer of a metal oxide for example ZnO. Each ALD cycle consists of four steps, introduction of metal containing precursor, purge away byproducts, introduction of non-metal containing precursor followed by a purge. The number of cycles is directly proportional to the thickness of the coating, more ALD cycles give thicker coating, resulting in atomic-level precision.**

## PHARMASHELL TECHNOLOGY: ALD-ENABLED PRECISION COATING

PharmaShell encapsulates solid drug particles within an extremely thin, uniform coating made of an inorganic compound. The coating is applied using atomic layer deposition (ALD); a technique that deposits one atomic layer at a time in a gas phase reaction, Figure 1. ALD has many established applications in the semiconductor industry – but Nanexa is pioneering its use in drug formulation.

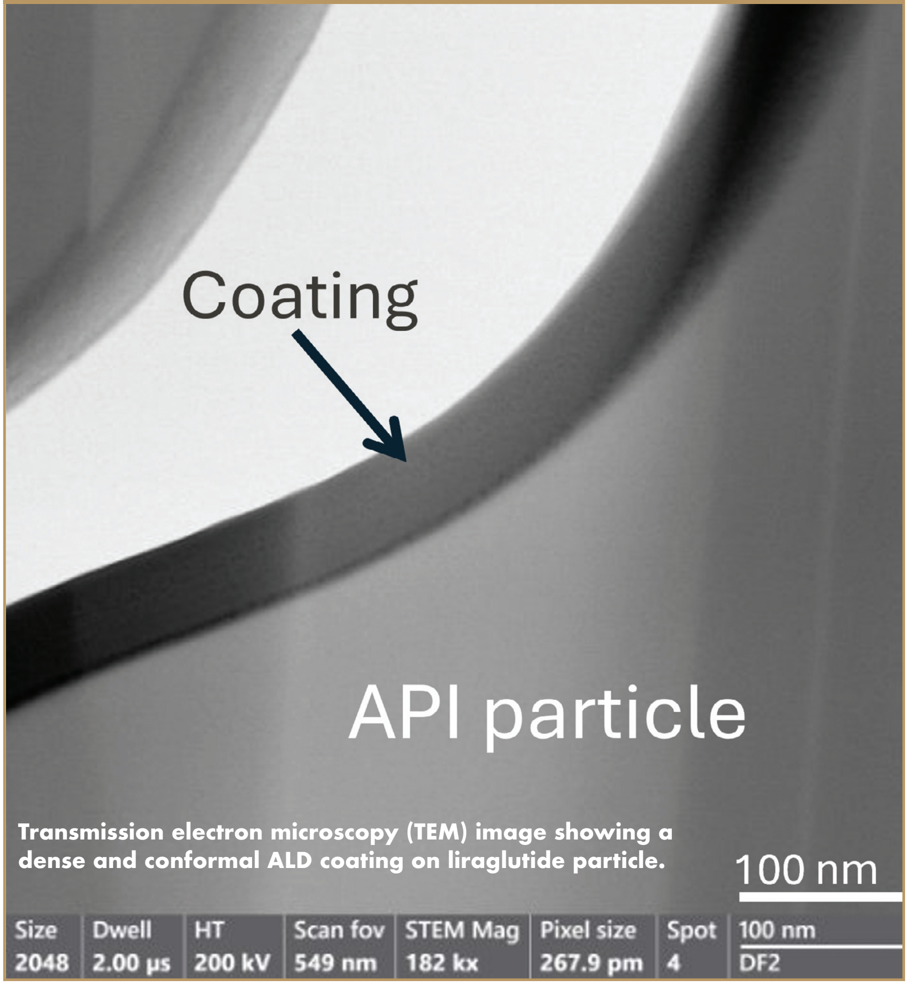
The process operates at mild temperatures, protecting sensitive drug molecules while achieving subnano-level precision in coating thickness. Each particle is coated conformally, and the coating is only tens of nanometers thick, Figure 2.

The coating acts as a release rate-controlling barrier: once the PharmaShell-coated particles are injected into the body, the coating dissolves slowly or permits the drug to be released at a controlled rate. By adjusting the ALD parameters, Nanexa can precisely tailor the release profile of the drug, from days up to several months, without altering the drug molecule itself.

Nanexa's ALD approach offers several technical advantages over conventional long-acting formulation methods. The ultra-thin coating means that each microsphere is composed mostly of the active drug, not excipient. Drug loadings as high as 80% have been demonstrated with ALD-coated pharmaceutical powders, allowing a full therapeutic dose to be delivered in a small injection volume.

The ALD coatings are also completely uniform and virtually free from imperfections.[2] This uniformity ensures a smooth, predictable release of drug, minimizing the "burst release" often seen with biodegradable polymer microspheres (where an initial surge of drug can leak out too quickly). And importantly, because ALD is a gentle, solvent-free process, it can encapsulate a wide range of molecules – including fragile peptides and proteins – without denaturing them.

FIGURE 2




**Transmission electron microscopy (TEM) image showing a dense and conformal ALD coating on liraglutide particle.**

## THERAPEUTIC BENEFITS & APPLICATIONS OF PHARMASHELL

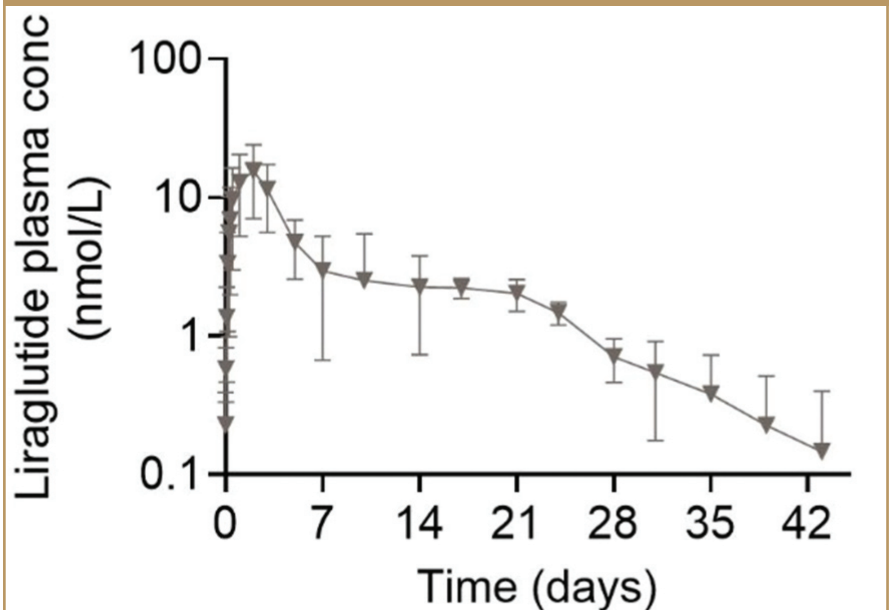
### Reduced Treatment Burden & Better Outcomes

The key benefit of transforming a drug into a long-acting injectable (known as a depot medication) is that extending the dosing interval results in more stable disease control. Fewer injections mean greater convenience for patients, enhanced adherence to medication, and improved health outcomes.[1] In diabetes management, for example, consistent use of a GLP-1 agonist leads to better glycemic control and reduced risk of long-term complications.

### Steady Therapeutic Levels

PharmaShell depots release the drug at a controlled rate, keeping plasma concentrations within the optimal therapeutic window for an extended period. This avoids the peaks and troughs associated with frequent dosing. A smoother pharmacokinetic profile can improve efficacy and tolerability. For instance, GLP-1 receptor agonists (the class including liraglutide) commonly cause gastrointestinal side effects like nausea when the therapy is initi-

FIGURE 3




**Plasma concentration time profile for the PharmaShell coated liraglutide after 30 mg single subcutaneous administration in type 2 diabetes patients (n=3) in study NEX-22-01 clinical study. A single dose sustained drug levels for up to 42 days, demonstrating a medication with less than a day's duration transformed into a once-monthly treatment. Pharmacokinetic assessment revealed no pronounced initial burst release, followed by a gradual decline over 42 days.**

ated at higher doses. With a controlled release formulation, drug levels rise gradually, potentially reducing such side effects during the initial period. In fact, in the first human trial of a PharmaShell-based therapy (NEX-22), no significant nausea or vomiting was observed even at high doses, suggesting that controlled release helped avoid the usual acute side effects.

### High Drug Load, Low Injection Volume

Thanks to the minimal bulk added by the coating, a full monthly dose can often be administered in a volume of only a few tenths of a milliliter. This small volume can be injected with a very fine needle (around 30-gauge, similar to an insulin pen needle) which improves patient comfort and acceptance. By contrast, some existing depot injections (such as certain microsphere-based therapies) require thicker needles and syringe volumes due to the substantial amount of polymer or oil carrier. A less painful injection experience can make a big difference to whether patients are willing to start and continue long-term injectable therapy.

### Broad Drug Compatibility & Stability

The PharmaShell platform has been evaluated across diverse drug classes – from small-molecule therapeutics to large peptides – and has consistently demonstrated the ability to modulate their release profiles. This suggests that the technology could be applied across a wide range of therapeutics where less frequent dosing is desired.

The robust inorganic coating also helps protect sensitive drugs from degradation until the moment of release. In cases where an active ingredient might otherwise break down quickly in the body, encasing it in a protective coating can preserve its stability and potency until it is delivered to the target site over time. In this way, PharmaShell not only extends the action of drugs but can also enhance their effective lifespan in the body.

## NEX-22: A ONCE-MONTHLY GLP-1 INJECTION

Nanexa's lead internal program, NEX-22, exemplifies the capabilities of PharmaShell technology. NEX-22 is a long-acting formulation of liraglutide, a GLP-1 receptor agonist used to treat type 2 diabetes.

Liraglutide's clinical benefits (improving blood sugar and supporting weight loss) are well established but in its standard form, but liraglutide must be injected every day due to its short half-life (~13 hours). The goal for NEX-22 is to deliver liraglutide in a single injection that maintains its therapeutic effect for about one month. Achieving this would reduce roughly 30 injections to just one, a dramatic improvement in convenience for patients.

In the PharmaShell manufacturing process, microparticles of liraglutide are coated with a precise inorganic coating to create the NEX-22 formulation. Upon subcutaneous injection, the coated microparticles form a depot in the subcutaneous tissue, slowly releasing liraglutide as the coating gradually dissolves. Early laboratory and animal studies indicated that the concept works: the coated particles released liraglutide steadily over several weeks. These promising preclinical results paved the way for human testing of NEX-22.

### Clinical Evaluation of NEX-22

The first-in-human evaluation of NEX-22 was a Phase I, single-ascending-dose trial conducted in 2024-2025. It enrolled patients with type 2 diabetes to assess safety, tolerability, and pharmacokinetics of this long-acting formulation. Small groups of patients received a single subcutaneous injection of NEX-22 at increasing dose levels (each new group getting a higher dose than the previous) under close observation. Each participant was followed for over a month to track how long liraglutide remained in circulation and to monitor any side effects.

The results were extremely encouraging. At the highest dose tested (30 mg, far above a typical daily dose), a single injection maintained serum drug levels for up to 42 days, Figure 3. In other words, NEX-22 successfully turned a medication that normally lasts less than a day into a once-per-month treatment. The pharmacokinetic data showed no large initial burst release – peak blood concentrations were reached around 1-2 days after injection, and then declined gradually over the subsequent weeks. This indicates that the ALD-applied coating functioned as intended, releasing the drug evenly over time rather than dumping it quickly.

Equally noteworthy was the tolerability of NEX-22 in this trial. Patients experienced no serious adverse events and, in fact, almost no systemic side effects. Notably, the common GLP-1 related side effect of nausea did not occur in any dose group – even at the highest dose – an outcome that underscores how the controlled release prevented the sharp peak levels that typically trigger such effects. The only side effects observed were mild, transient reactions at the injection site (such as slight redness or tenderness), which resolved within a few days. The clinical study thus provided proof-of-concept that PharmaShell can convert an immediate release drug into a long-acting injectable without new safety concerns, paving the way for the next phase of development.

## COMPARISON WITH OTHER LONG-ACTING TECHNOLOGIES

PharmaShell's approach to creating injectable depots is distinct from traditional methods. The most common technology for multi-week release has been biodegradable polymer microspheres (for example, PLGA-based microspheres used in some weekly injections). While polymer microspheres have enabled long-acting formulations for certain drugs, they often exhibit an initial burst release and can require relatively large needles due to the volume and particle size of the injection. In contrast, PharmaShell's coating provides a controlled and uniform release with essentially no burst phase, and the high drug payload relative to the coating allows use of fine needles, making injections more comfortable.

Pharmaceutical companies have also developed implantable devices or solid implants that release drugs over months or even years. Examples include contraceptive hormone implants or implantable GLP-1 pumps. Implants can provide long-term therapy but require a minor surgical procedure for insertion and removal, and they cannot be easily adjusted once in place. PharmaShell aims to hit a sweet spot: achieving multi-month drug delivery with a simple injection. There is no need for surgical removal – when the drug depot is exhausted, it simply dissolves away.

## FUTURE OUTLOOK

With the success of the Phase I study, Nanexa is now preparing to advance into the next stages of clinical development. The company is also exploring partnerships and licensing opportunities, reflecting the strong interest in the industry for long-acting injectable therapies. A once-monthly GLP-1 treatment would be a notable breakthrough in type 2 diabetes care, and other pharmaceutical companies are likewise investigating long-acting formulations for metabolic diseases.

Beyond diabetes, the PharmaShell platform is being applied to other therapeutic areas. For instance, Nanexa has engaged in feasibility studies with major pharmaceutical partners to evaluate PharmaShell on their proprietary compounds – a testament to the wider interest in this approach to drug delivery.

To prepare for future commercialization, Nanexa has begun scaling up the ALD coating process in its current GMP facility, ensuring that production can meet anticipated demand while maintaining the precision and consistency required for industrial application.

In conclusion, PharmaShell technology represents a significant innovation in the field of drug delivery. By enabling precise control over drug release through atomic-level engineering, Nanexa offers a way to dramatically extend the action of existing medications without compromising their safety or efficacy.

NEX-22, in particular, shows how a daily therapy can be reimagined as a once-monthly treatment, potentially improving patient quality of life and adherence. As this technology progresses through clinical development, it has the potential to create a new generation of long-acting injectable therapies that benefit patients, healthcare providers, and health systems alike. ◆


## REFERENCES

1. Polonsky WH, et al. (2022). "Higher Rates of Persistence and Adherence in Patients with Type 2 Diabetes Initiating Once-Weekly vs Daily Injectable GLP-1 RAs (STAY Study)." Diabetes Therapy, 13(2): 175–187.
2. Sparrow N. (2015). "Atomic layer deposition technology finds path to medical market via drug-delivery systems." PlasticsToday, July 7, 2015.
3. La Zara D, et al. (2021). "Drug powders with tunable wettability by atomic and molecular layer deposition: From highly hydrophilic to superhydrophobic." Applied Materials Today, 22: 100945.


## BIOGRAPHIES

**Dr. Anders Johansson** serves as Head of Intellectual Property, Senior Scientist, and Co-Founder at Nanexa, where he is been employed since 2009. Dr Johansson holds both an MSc and a PhD in Chemistry from Uppsala University, Sweden. Prior to joining Nanexa, he gained experience as a patent consultant at the intellectual property firm Bjerkéns KB in Sweden.

**Dr. Polla Rouf** is Head of ALD R&D at Nanexa. Dr. Rouf leads the development of atomic layer deposition (ALD) coatings that enable controlled drug release, contributing to programs such as NEX-22. He earned a PhD in Materials Chemistry from Linköping University specializing in the ALD technology, and holds a MSc in Chemical Engineering from Uppsala University.

**Dr. Joel Hellrup** is Head of Pharmaceutical R&D at Nanexa AB, leading research and development of drug formulations and quality control. He is one of the key developers of the PharmaShell® technology and is named as an inventor on several patent applications. He holds a PhD in Pharmaceutical Sciences and an MSc in Pharmacy from Uppsala University, and has received the Young Investigator Award from the Controlled Release Society.

# ORAL SUSPENSIONS

## A New Standard in Oral Suspensions: Leveraging Novel Excipients for FDA Approval

By: Mary Schuster

### WHEN ORAL SUSPENSIONS ARE THE ONLY CHOICE

Oral administration is the most common route of delivery for many therapeutic agents due to its convenience, ease of use, and non-invasiveness.[1] Liquid dosage forms are often the ideal solution to accommodate diverse patient groups such as pediatrics, geriatrics, and up to 16% of the general population with dysphagia.[2] Swallowing difficulties are also prevalent in patients with disorders resulting from various conditions like stroke or neurological diseases. In severe cases, these conditions may require enteral feeding via nasogastric (NG) or percutaneous endoscopic gastrostomy (PEG) tubes. In these settings, an oral suspension is not just a matter of preference but often the only viable means of ensuring that patients continue to receive their medications safely and consistently.

With nearly 90% of drug entities being poorly water-soluble, addressing solubility and bioavailability is a critical priority in drug development.[3] Dispersing the drug is one of the most direct approaches to dealing with a poorly soluble active pharmaceutical ingredient (API). However, this creates a new set of complex challenges. A successful suspension demands careful consideration of chemical and physical stability, palatability for oral administration, accurate and flexible dosing, and precise *in-vitro* dissolution. Viscosity especially plays a vital role for patients requiring enteral feeding, as it directly impacts both administration and drug delivery.

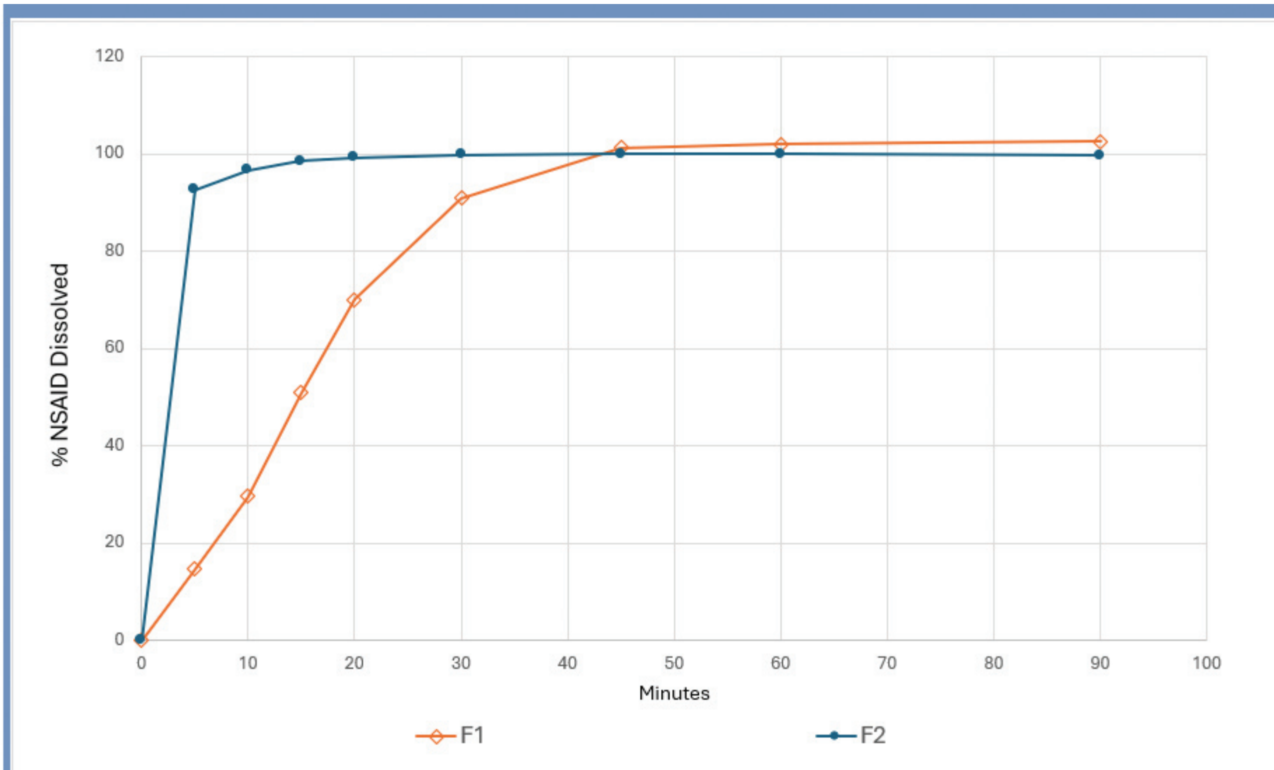
This article introduces a new approach to perfecting oral suspension formulation. It is centered on the strategic use of a "novel" synthetic functional excipient, magnesium aluminometasilicate (MAS). We explore its unique properties, its successful journey through the FDA approval process, and its application in a real-world case study on NSAIDs. By showcasing how we successfully navigated the challenges of working with a novel excipient and a complex suspension system, we aim to provide formulators with a clear pathway to overcome their most difficult challenges and drive innovation in drug development. Ultimately, our work illustrates how the deliberate choice of excipients can transform an otherwise limited formulation into a patient-friendly product with commercial longevity.

### WHY MAGNESIUM ALUMINOMETASILICATE?

MAS possesses unique functional properties that were essential for the success of our oral suspension development. Its high surface area and porous structure enable controlled dissolution rate, API dispersion, and amorphous stabilization, while its chemical composition provides additional benefits for stability and its potential to indirectly contribute to taste masking. These properties directly address the most common challenges encountered when moving from early formulation screening to late-stage development.

Their impact will be further detailed in our case study, which highlights how MAS was successfully incorporated into our FDA approved oral suspension product. The decision to include this novel material in our formulation was driven by its functional advantages, despite the complexity of the regulatory pathway. This approved product supports our formulation science and regulatory strategy to achieve a new standard in oral suspension delivery.

FIGURE 1




**Formulation 1 (F1) contains MAS with other excipients, while Formulation 2 (F2) does not contain MAS. The data illustrates that the presence of MAS in F1 leads to a more controlled and consistent dissolution rate.**

**The Core Roles of MAS**

## THE CHALLENGE & OPPORTUNITY OF A NOVEL EXCIPIENT

In the eyes of the FDA, an excipient is considered "novel" when it has not been previously used in an approved drug product in the U.S. for the intended route and dosage level.[4] A novel excipient often differs significantly from established excipients, which are typically natural or semi-synthetic. MAS fits this definition because it is a synthetic compound, unlike its counterpart, Magnesium Aluminum Silicate, which is naturally derived from purified smectite clays.[5]

The novelty of MAS and other synthetic materials can create confusion in the public domain. For instance, there are often confounding CAS numbers and misleading descriptions of natural and synthetic materials as equivalent. This lack of clarity and the absence of a defined regulatory pathway for such materials highlights the need for a rigorous strategy. While synthetic materials like MAS are often valued for their high purity and lot-to-lot consistency, they come with high regulatory barriers, which often discourage pharmaceutical companies from using excipients beyond those already approved. As a result, the adoption of novel excipients lags significantly behind scientific discovery, creating a gap between what is technically possible and what is practically implemented in commercial products.

Securing approval for a novel excipient is a rigorous and data-intensive process. Novel excipients are not listed on the FDA's Inactive Ingredient Database (IID), so their safety and performance must be thoroughly demonstrated through formal regulatory submissions. Our team successfully navigated this pathway by collaborating closely with the manufacturer/supplier of MAS, who submitted a detailed Drug Master File (DMF) to the FDA. We provided expert input and conducted a thorough review of the open portion of the DMF, which contained comprehensive data on chemistry, manufacturing, and controls. An extensive toxicological evaluation and the full toxicokinetic behavior of other MAS grades and related compounds were also presented to justify the safety and effectiveness of this excipient, leading to a positive outcome and regulatory acceptance of the material. The FDA's formal acknowledgment of MAS's approvability was a key milestone, demonstrating our expertise in managing complex regulatory processes and our ability to incorporate novel materials into new drug formulations.

## A CASE STUDY: FORMULATING AN NSAID SUSPENSION

### The Core Roles of MAS

The unique challenges of formulating select NSAIDs, which are known for their poor solubility and bitter taste, provide a compelling use case for a novel excipient like MAS. Its high surface area (300 $m^3$/gm) and porous structure facilitate the adsorption of the API at a near-molecular level, which enhances dispersion and prevents particle aggregation, thereby maximizing the drug's exposure to gastrointestinal fluids and leading to a more consistent dissolution profile. Furthermore, MAS helps stabilize the amorphous form of the drug, preventing recrystallization and maintaining the controlled dissolution properties. For these NSAIDs, this stabilization can be the difference between a formulation that delivers a consistent and reproducible release profile and one that fails to achieve reliable results.

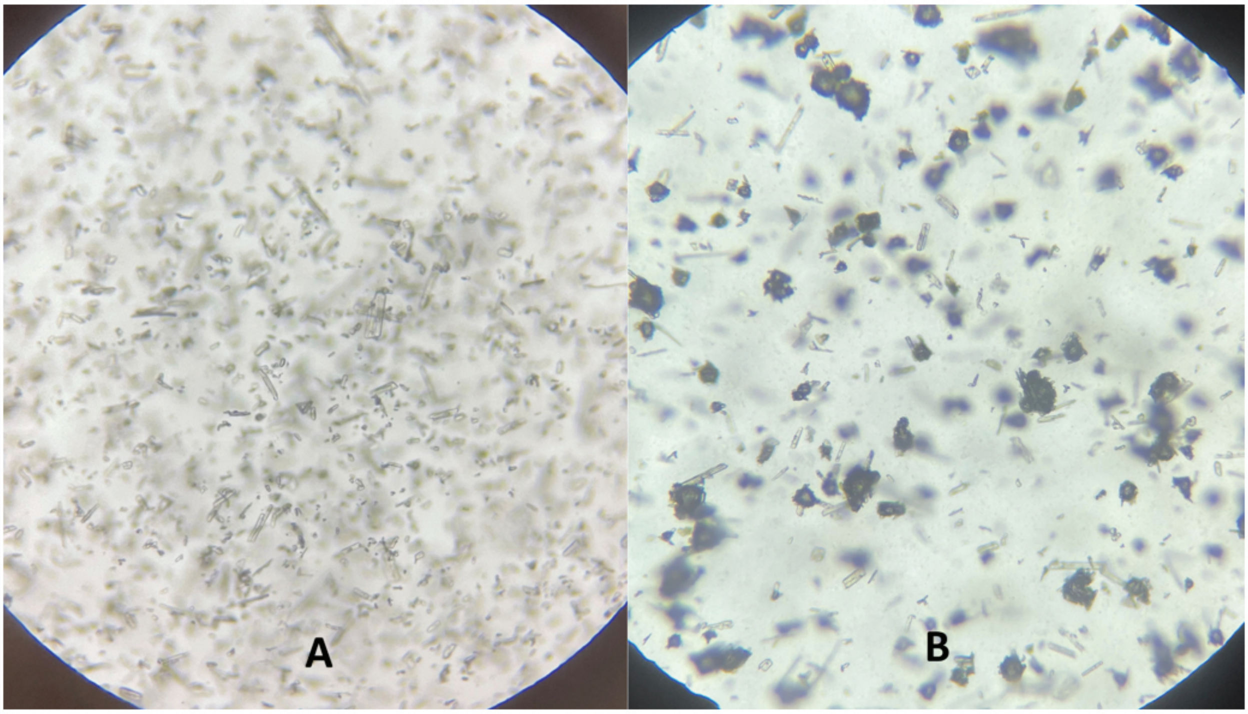
Beyond its impact on drug performance, MAS contributes significantly to product stability and patient acceptability. A key quality attribute of elegant suspensions is redispersibility: the ability to be easily and homogeneously re-dispersed with gentle shaking after sedimentation. The highly porous nature of MAS slows settling and caking of suspended drug particles, ensuring dose uniformity throughout the product's shelf-life. Its ability to effectively encapsulate drug particles and promoting fine, uniform dispersion, also indirectly contributes to taste masking. This barrier formation can shield direct contact with taste receptors in the mouth, and the improved drug dispersion can prevent localized high concentrations of bitter drug in the suspension and potentially help reduce the need for extensive flavor work. In pediatric populations especially, palatability is often the single largest driver of adherence, and the potential for MAS to help minimize bitterness offers a practical route to better compliance without relying solely on flavoring agents or sweeteners.

### Achieving an Elegant Suspension: Synergistic Excipients

By combining MAS with other carefully selected functional excipients, we optimized the *in-vitro* dissolution profile while improving overall patient experience. For example, xanthan gum (XG), a key rheol-

**FIGURE 2**

**Microscopic comparison of Suspension A, formulated with optimized excipient ratios, and Suspension B, prepared with different excipient composition.**




**Suspension A shows evenly dispersed, smaller particles with minimal aggregation, while Suspension B displays larger, aggregated particles and less uniform distribution under 100X magnification.**

**Achieving an Elegant Suspension: Synergistic Excipients**

ogy modifier, was crucial for providing long-term physical stability. When dispersed in an aqueous solution, XG forms a structured network that effectively holds drug particles in place, preventing sedimentation or caking. Its pseudoplastic behavior ensures the suspension exhibits high viscosity at rest. When subjected to shear force like shaking, pouring, or swallowing, its viscosity temporarily decreases, allowing for easy handling and administration.[6] This is a critical property for patients requiring enteral feeding, as the shear-thinning behavior allows smooth administration through a narrow tube while the high viscosity at rest prevents settling within the bottle. The rheological control also enhances swallowability and mouthfeel by providing a smooth, consistent texture and preventing grittiness, which is particularly beneficial for patients with dysphagia.

Our formulation strategy incorporated additional excipients to further refine the suspension system. Glycerin acts as humectant, co-solvent, and stabilizing agent to prevent the formulation from drying out and impacting redispersibility. The system also includes tight pH control, which is essential for product quality, shelf life, and patient acceptability. In certain iterations, we also explored the strategic use of an ion exchange resin to further enhance taste masking capabilities, particularly for actives with more pronounced bitter taste. The result is a formulation that proficiently solved the challenge of bitterness and improved chemesthetic properties, such as throat catch or burning sensation associated with select poorly soluble NSAIDs.

This carefully balanced combination of MAS with rheology modifiers, humectants, and taste masking agents demonstrates our expertise in developing elegant and effective oral suspensions. Our innovative suspension system delivers improved dose uniformity, long-term physical stability, precise *in-vitro* dissolution, and better mouthfeel and swallowability, all of which contribute to superior patient compliance.

Beyond elevating overall product quality, it creates a visually appealing, dye-free formulation. Visual aspects should not be underestimated — patients often associate clarity, color, and consistency with product quality, and a suspension that looks elegant can inspire greater trust and acceptance.

Overall, a comprehensive formulation approach reflects the reality that no single excipient, however novel, can solve every challenge. Success depends on understanding the interactions of multiple components working in sync.

## A PATHWAY FOR FORMULATION EXCELLENCE

The successful journey from a novel excipient to an FDA-approved product is a compelling testament to the blend of expert formulation science and regulatory understanding. This case study demonstrates that excipients like MAS are powerful tools, but their full potential is unlocked through the strategic use of a complete excipient system. By successfully leveraging magnesium aluminometasilicate's unique capabilities, this approach has shown that it is possible to create innovative, patient-centric suspensions that are both therapeutically effective and commercially viable. This experience highlights the critical role of expert formulation in a complex environment and offers a pathway for formulators seeking to accelerate their product development with new materials and methodologies. ◆

## REFERENCES


1. Alqahtani, M.S., Kazi, M., Alsenaidy, M.A., et al. Advances in Oral Drug Delivery. Front Pharmacol. 2021 Feb 19;12:618411. doi: 10.3389/fphar.2021.618411. PMID: 33679401; PMCID: PMC7933596.
2. Mittal, R.K., Zifan, A. Why so Many Patients With Dysphagia Have Normal Esophageal Function Testing. Gastro Hep Adv. 2024;3(1):109-121. doi: 10.1016/j.gastha.2023.08.021. Epub 2023 Oct 5. PMID: 38420259; PMCID: PMC10899865.
3. Xie, B., Liu, Y., Li, X., et al. Solubilization techniques used for poorly water-soluble drugs. Acta Pharm Sin B. 2024;11:4683-4716. doi:10.1016/j.apsb.2024.08.027.
4. U.S. Pharmacopeia. Quality Matters. Novel Excipients: New Hope for Therapeutic Innovations. Accessed August 7, 2025. https://qualitymatters.usp.org/novel-excipients-new-hope-therapeutic-innovations.
5. Vanderbilt Minerals, LLC. VEEGUM® EZ Magnesium Aluminum Silicate. Accessed August 14, 2025. https://www.vanderbiltminerals.com/products/veegum-ez/rx-veegum-magnesium-aluminum-silicate.
6. Layek, B. A Comprehensive Review of Xanthan Gum-Based Oral Drug Delivery Systems. Int J Mol Sci. 2024;25(18):10143. doi:10.3390/ijms251810143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## BIOGRAPHY

**Mary Schuster** earned her degree in biochemistry from the Georgia Institute of Technology in Atlanta, GA, and has built a career spanning nutraceuticals, molecular biology, and pharmaceuticals. She began her journey in the pharmaceutical industry as a scientist at Kiel Laboratories, where she gained hands-on experience in drug formulation and analytical method development. This foundational experience gave her a deep understanding of pharmaceutical operations and laid the groundwork for her current role as a Business and Innovation Strategist, where she bridges the gap between innovation and market-ready solutions.

# Drug Development EXECUTIVE

Dr. Marc Hedrick

CEO

Plus Therapeutics

## Plus Therapeutics: Advancing Targeted Radiotherapeutics for Rare & Difficult-to-Treat Cancers

Radiation has been a primary treatment in oncology for over 100 years. With advancing technology, cancer clinical research and treatment options have continued to evolve. Targeted radiotherapeutics, a class of drugs that combines a radioactive isotope with a novel delivery technique to directly irradiate cancer cells, are one example of a new and advanced approach to drug delivery in oncology. Plus Therapeutics is a US clinical-stage pharmaceutical company developing targeted radiotherapeutics designed to deliver a safe and effective dose of radiation directly to the tumor of adults and children with rare and difficult-to-treat cancers. Plus' lead drug candidate, REYOBIQ™ (rhenium re186 obisbemeda), is based on the radioactive isotope rhenium-186.

*Drug Development & Delivery* recently interviewed Dr. Marc Hedrick, CEO of Plus Therapeutics, to discuss the company's targeted radiotherapeutic platform for central nervous system cancers and why internal radiation therapy offers patients a more advanced drug delivery solution compared to traditional external radiation therapy.

**Q: Can you tell us a little bit about Plus Therapeutics and how your targeted radiotherapeutics work?**

**A:** Plus Therapeutics is a Houston-based clinical-stage pharmaceutical company developing targeted radiotherapeutics designed to deliver a safe and effective dose of radiation directly to the tumor of adults and children with rare and difficult-to-treat cancers. Plus Therapeutics has developed a promising lead radiotherapeutic, REYOBIQ (rhenium Re186 obisbemeda), which is designed to treat central nervous system (CNS) cancers by leveraging a rhenium radioisotope used to both image and shrink the cancer patient's tumor.

**Q: Why radiotherapeutics?**

**A:** Radiation therapy is an important and effective treatment for cancer and the gold standard for CNS cancers. However, traditional external radiation beam therapy (EBRT) is limited by low doses to minimize potential damage to healthy tissues and organs and the need for frequent treatment sessions, which are inconvenient and time-consuming for the patient. Plus Therapeutics has developed a targeted radiotherapeutic that addresses the limitations of EBRT, utilizing a delivery system designed to maximize toxicity to cancer cells while minimizing radiation exposure to healthy cells.

**Q: How can Plus Therapeutics' solution change patient care and management of diseases like glioblastoma, and other cancers of the central nervous system?**

**A:** The key difference with our radiotherapeutics is the precision with which they target cancer cells. We believe that by delivering our radiotherapeutic directly to the tumor with extreme precision using a catheter, we can mitigate the risk of damage to other healthy cells in a patient's body. Most people are aware of the side effects of external beam radiation therapy, like hair and appetite loss, and other complications that stem from toxic radiation levels in the body. By limiting exposure to radiation to sites directly within or adjacent to the solid tumor, we aim to enhance patient care overall by shielding the body from unnecessary radiation exposure.

**Q: What is REYOBIQ and what makes it different from existing treatments?**

**A:** REYOBIQ (rhenium Re186 obisbemeda) is a novel injectable radiotherapy specifically formulated to deliver direct, targeted high-dose radiation to CNS tumors in a safe, effective, and convenient manner to optimize patient outcomes. With this radiotherapeutic drug, the goal is to inject high doses of radiation into or adjacent to brain and other CNS cancers, which act on the tumor, break down slowly to sufficiently destroy tumor tissue, and stay localized while sparing healthy tissues until fully cleared.

We believe that REYOBIQ has the potential to improve outcomes for CNS cancer patients, compared to currently approved therapies, with a more targeted and potent radiation dose. Rhenium-186 is an ideal radioisotope for CNS therapeutic applications due to its short half-life, beta energy for destroying cancerous tissue, and gamma energy for real-time imaging. REYOBIQ is being evaluated for the treatment of recurrent glioblastoma (GBM), leptomeningeal metastases (LM), and pediatric brain cancer (Ependymoma and High Grade Glioma) in the ReSPECT-GBM, ReSPECT-LM, and ReSPECT-PBC clinical trials, respectively. These cancers are aggressive and challenging, occurring throughout the central nervous system with limited treatment options.

**Q: Can you further discuss the ReSPECT clinical trials?**

**A:** Earlier this year, we shared positive trial data for the now complete Phase 1 ReSPECT-LM dose escalation trial. The data showed it was well tolerated and demonstrated high radiation doses effectively delivered to tumors, with no significant safety issues. The findings provided evidence of prolonged survival and improved patient outcomes.

Enrollment is currently available through the ReSPECT-LM dose optimization trial. Our ReSPECT-GBM trial is currently enrolling in Phase 2, and our ReSPECT-PBC will soon be enrolling for Phase 1.

**Q: Can you share some background on Plus Therapeutics' subsidiary company, CNSide Diagnostics, LLC?**

**A:** Plus Therapeutics' subsidiary, CNSide Diagnostics, has launched the CNSide® Cerebrospinal Fluid (CSF) Assay Platform, consisting of a highly sensitive, CSF-based, laboratory-developed tests (LDTs) for patients with LM from carcinomas and melanomas. This proprietary test platform is designed to assess tumor cells that have spread from a primary carcinoma or melanoma to the central nervous system (CNS) by collecting a patient's CSF. The CNSide CSF Assay Platform is the leading precision oncology diagnostic product emerging from CNSide Diagnostics, offering an advancement in clinician understanding of LM by assisting diagnosis, identifying biomarkers, supporting treatment decisions, and monitoring the disease and effects of LM treatment. CNSide empowers physicians to "Achieve Clarity and Act with Certainty." ◆

# The Future of 3D Printing in Pharma: Aprecia's Vision for Transformative Medicine

By: Kyle Smith, MBA

## INTRODUCTION

As the pharmaceutical industry stands at the intersection of innovation and urgency, the need for transformative solutions has never been more critical. Global supply chain disruptions, rising demand for personalized therapies and the limitations of traditional manufacturing methods have exposed systemic vulnerabilities. Patients are waiting longer for essential medications and manufacturers are under pressure to deliver safer, more effective treatments with speed and precision.

Aprecia, a pioneer in pharmaceutical 3D printing, has a vision for distributed, patient-centric manufacturing that could reshape the future of medicine. With proprietary platforms that offer flexible oral dosage forms with tailored functionalities and a range of API compatibility, Aprecia is not just responding to industry challenges; it's redefining how drugs are formulated, produced, and delivered.

The COVID-19 pandemic brought to light the limitations and challenges of global pharmaceutical supply chains. From active pharmaceutical ingredient (API) shortages to delays in packaging and distribution, the ripple effects were felt across continents. Even beyond the pandemic, climate-related disruptions and increasing regulatory complexity continue to strain traditional manufacturing models.

At the same time, the rise of personalized medicine driven by advances in diagnostics and patient data is demanding a shift from mass production to tailored therapies. Patients with rare diseases, pediatric populations, and those with complex dosing needs require medications that are effective and can be customized to their physiology and lifestyle.

Traditional manufacturing, with centralized facilities and rigid batch processes, can struggle to meet these evolving demands. The industry is waiting for a shift that embraces flexibility, precision and resilience.

## 3D PRINTING IS REVOLUTIONIZING MEDICINE

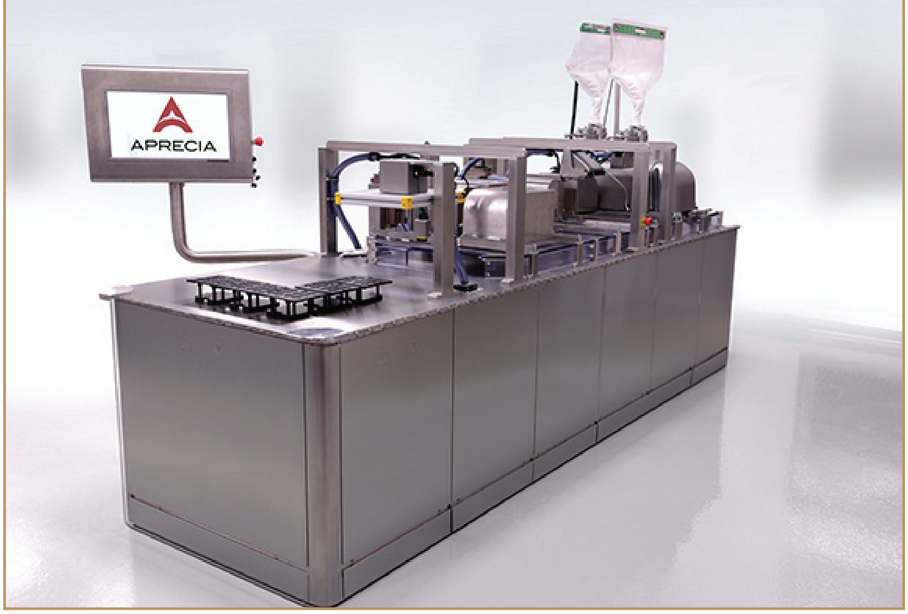
Aprecia's response to these challenges is rooted in its mastery of binder jet 3D printing, a technology that enables the creation of oral solid dose medications with unprecedented control and customization.

- 3DP binder jetting technology allows for high-dose, fast-dissolving tablets that are beneficial for patients with swallowing difficulties, including children, the elderly, and those with neurological conditions.
- Precision formulation with 3DP development expertise builds on this by enabling tailored mechanical properties, taste masking, and enhanced bioavailability, all within a single dosage form.
- At the heart of Aprecia's innovation is its in-blister binder jetting platform that prints dosages layer-by-layer directly into blister packaging. This continuous manufacturing process supports real-time quality monitoring and batch release, eliminating the need for separate packaging steps and reducing production timelines.

The in-blister 3DP-Tablet Production Platform is designed for scalability without altering the manufacturing process or sacrificing rigor and precision. This flexibility supports distributed manufacturing, allowing production to occur closer to the point of care, reducing transportation costs and mitigating supply chain risks.

Aprecia's distinct, patent-protected 3DP production platforms extend well beyond prototyping and are built for commercial-scale production. The company's Open Bed racetrack-style 3D printing configuration delivers breakthrough binder jetting innovations that can deliver capacity at scale. Each platform can produce clinical supplies suitable for Phase I-III trials, accelerating development timelines and market entry.

Aprecia's In-Blister 3DP-Tablet Production Platform




## APRECIA'S STATE-OF-THE-ART TECHNOLOGY

Aprecia's state-of-the-art technologies prioritize speed, flexibility, and precision, setting new standards for reliable medication production and distribution. Aprecia's technology takes a comprehensive approach to prioritize and deliver:

- Efficiency and Risk Reduction: Aprecia's continuous 'racetrack' 3D printing configuration eliminates wait times, boosts efficiency and ensures precise medication dispensing while minimizing risk.
- Flexibility and Market Entry: Our pioneering 3DP technology platform optimizes development processes and expedites market entry.
- Prototyping and Clinical Supplies: In-Blister 3DP-Tablet production platform enables quick development of prototypes and early clinical supplies, reducing investment risk and allowing faster go/no-go decisions in clinical trials.
- Enhanced Clinical Trial Efficiency: Aprecia's technology enhances clinical trial efficiency and cost-effectiveness, reducing delays and improving responsiveness to protocol changes.
- Proprietary Powder Handling Technologies: Precise powder and liquid deposition at clinical and commercial scales enable rapid design, prototyping and manufacturing of novel dosage forms.
- Accelerated Product Development: The technology accelerates product development through Phase 1 and 2 programs, streamlining product development and enabling rapid screening and elimination of non-viable prototypes.

For pharmaceutical partners, this means faster go/no-go decisions in clinical trials, reduced investment risk, and the ability to respond quickly to protocol changes.

## THE ADVANTAGES OF ADVANCED DISTRIBUTED MANUFACTURING

Aprecia's advanced platforms offer significant advantages in the realm of distributed manufacturing. These technologies enable pharmaceutical companies to manufacture complex tablet structures, providing the freedom and flexibility to design novel dosage formulations that address unmet patient needs.

- **Complex Tablet Structures:** Aprecia's technology enables the manufacturing of tablets with varying degrees of hardness and mechanical strength, allowing for the creation of novel dosage formulations that incorporate embedded functionalities.
- **Dosage Solutions:** The platform solves common dosage challenges by producing pill structures that dissolve effortlessly in a patient's mouth with just a sip of water, improving ease of administration and patient compliance.
- **Customizable Medications:** Aprecia supports the production of highly customizable, patient-specific medications with precise dosing, offering both cost and logistical advantages for pharmaceutical partners.
- **Flexible Administration:** The system provides flexible oral administration options and dosage forms, including em-

Primary Packaging Shuttles Where 3D-Printed Tablets Are Formed

bedded features for taste masking and enhanced bioavailability, while maintaining broad API compatibility to meet diverse dosing needs.

Aprecia is setting a new benchmark for pharmaceutical innovation by combining speed, flexibility, and precision in commercial-scale 3D printing. Our platforms streamline formulation timelines, support real-time batch release and enable the rapid development of complex, patient-friendly dosage forms. By producing entirely in the US, we're not only addressing supply chain vulnerabilities but also empowering pharmaceutical partners with on-demand, distributed manufacturing capabilities that unlock personalized medicine and accelerate clinical success.

## REAL LIFE SUCCESSES

In 2015, Aprecia made history with Spritam®, the first FDA-approved 3D-printed medication used to treat partial-onset seizures in patients aged four and older. This milestone validated 3D printing as a viable pharmaceutical manufacturing method and opened the door for broader regulatory acceptance.

Since then, Aprecia has secured over 126 patents and continues to collaborate with regulatory bodies to advance agile manufacturing standards. Aprecia's work with ZipDose® and other platforms demonstrates a commitment to meeting regulatory requirements but helping to shape and redefine them as well.

Over the past year, Aprecia has been collaborating with one of our strategic partners in a government funded research program to investigate how a drug substance synthesis platform, combined with Aprecia's revolutionary solid oral dose 3D printing technology can accelerate US drug production to deliver high quality drug products. Under this program:

- Aprecia is developing two drug products for registration with the FDA which are categorized by the US government as essential medicines for the US population.
- Aprecia will produce both the active pharmaceutical ingredients and the finished pharmaceutical dosage forms at the same location, significantly shortening the pharmaceutical raw material supply chain while also lessening supply chain risk for commercial product distribution.
- Aprecia will generate key scientific data needed to demonstrate that agile manufacturing can meet FDA drug product registration requirements and be utilized to produce safe and effective pharmaceutical products.

These types of government research programs enable us to contribute toward important public health initiatives while facilitating broader adoption of advanced manufacturing technology, such as Aprecia's 3D printing technology, unlocking private and public capital for commercialization of innovative pharmaceutical technology and propel the agile pharmaceutical manufacturing technology into the marketplace.

The potential impact of this work is far reaching. Aprecia will use agile pharmaceutical manufacturing technology to address critical drug shortages more rapidly, enable point-of-need manufacturing to support military operations and medical countermeasure applications, enhance the overall resilience of the pharmaceutical supply chain and develop the foundation for more personalized medicine success.

Aprecia's technology also addresses common barriers to medication adherence. Tablets that dissolve effortlessly improve ease of administration, especially for patients with dysphagia or those requiring high-dose therapies. Customizable dosing ensures that each patient receives the exact amount needed, reducing side effects and improving outcomes.

The ability to embed functionalities, such as taste masking, controlled release, and multi-API combinations, within a single tablet offers pharmaceutical companies new avenues for innovation. These features are particularly valuable in pediatric and geriatric care, where traditional dosage forms often fall short.

## BENEFITS BEYOND RELIANT & FAST MANUFACTURING & PRECISION DOSING

Distributed manufacturing not only enhances resilience but also reduces environmental impact. By decentralizing production, Aprecia minimizes transportation emissions and packaging waste. On-demand printing reduces overproduction and inventory costs, aligning with sustainability goals and lean manufacturing principles.

For pharmaceutical companies, this translates into lower operational costs, faster time to market and improved responsiveness to demand fluctuations.

Our innovative approach to medicine production not only addresses current supply chain vulnerabilities but also supports efforts to widen manufacturing capabilities in the US. Aprecia manufactures pharmaceuticals solely in the US, and our platform streamlines manufacturing in two keyways. First, it enables us to create unique products that conventional technologies can't — like SPRITAM and a range of other dosage forms from orally disintegrating tablets to extended-release and suspension formats. Second, our process supports distributed and flexible manufacturing, which opens the door to onshoring, personalized medicine and on-demand production. We've shown that 3D printing isn't just for prototyping — it's a viable commercial manufacturing solution.

The global market for pharmaceutical 3D printing is projected to grow significantly over the next decade, driven by demand for personalized medicine and advanced manufacturing technologies.

## LEADING THE FUTURE OF PHARMACEUTICAL PRODUCTION

Aprecia is the only advanced additive manufacturer with an FDA-approved product and commercial-scale capabilities.

With a focus on oral solid dose medications, combined with deep expertise in formulation science and regulatory strategy, Aprecia is a category leader. Competitors may offer prototyping tools or niche applications, but Aprecia's end-to-end platform — from development to distribution — sets it apart.

As we look ahead, Aprecia's commitment to innovation, speed, and precision positions it at the forefront of pharmaceutical transformation. Its platforms enable flexible, localized production models that support onshoring, personalized therapies, and rapid response to emerging health needs.

3D printing is no longer a future promise — it's a present-day solution. At Aprecia, we've proven that additive manufacturing can deliver scalable, patient-centric therapies with speed, precision and resilience. Our platforms are built not just to meet today's challenges, but to redefine what's possible in medicine tomorrow.

By combining advanced 3D printing with strategic partnerships and regulatory leadership, Aprecia is not just changing how medicine is made — it's changing what is possible.

## TRANSFORMING PHARMA WITH SCALABLE 3D PRINTING

The pharmaceutical industry must evolve to meet the demands of a changing world. Aprecia's vision for distributed, patient-centric manufacturing offers a blueprint for that evolution. With proven technology, regulatory milestones and a track record of innovation, Aprecia invites pharmaceutical partners, policymakers, and healthcare providers to join in shaping the future of medicine. ◆

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

## BIOGRAPHY

**Kyle Smith** is President & COO of Aprecia Pharmaceuticals, where he leads strategic operations and innovation in 3D-printed drug manufacturing. With over a decade at Aprecia, he's held roles from Operations Engineer to VP of Operations, driving advancements in pharmaceutical technology and GMP compliance. He also serves on the Board of Directors at BAMF Health, a leader in cancer imaging and theranostics. He earned a Chemical Engineering degree from Georgia Tech and an MBA from Miami University.

DRUG DEVELOPMENT

# Common CMC Pitfalls in Orphan Drug Development

By: Hibreniguss Terefe, PhD

## INTRODUCTION

Orphan drug development addresses the high unmet needs of small populations of patients living with rare diseases, bringing hope in the form of new treatments. Spurred by regulatory incentives, such as the US Orphan Drug Act and similar frameworks worldwide, this landscape has expanded rapidly over the past two decades.

The driving force in this expansion is largely small, emerging sponsors. These companies are often agile and innovative but lack the extensive internal resources and institutional knowledge of larger pharmaceutical organizations. The resulting reliance on a fragmented network of external partners can lead to a lack of full process visibility, where critical oversights create downstream problems. According to a 2023 industry report, manufacturing and supply chain challenges are among the top concerns for emerging biopharma companies.[1] Many have learnt that "more haste, less speed" is the key to navigating the complex world of Chemistry, Manufacturing, and Controls (CMC).

Although the unique challenges of orphan drug development are amplified by compressed timelines and limited patient populations, the common pitfalls in this article also serve as cautionary tales for other areas of drug development. Seemingly small missteps can not only compromise product quality, but also delay or derail a promising therapy. Where every batch matters, every patient counts, and success means exclusivity, robust CMC execution is essential.

## REGULATORY SCRUTINY SETS A HIGH BAR

Orphan drug development is not, and should not be, exempt from the high bar for pharmaceutical quality and safety. While these programs benefit from expedited pathways like the FDA's Breakthrough Therapy and Regenerative Medicine Advanced Therapy (RMAT) designations, or the EMA's PRIME scheme, these accommodations apply primarily to the review timeline, not to the fundamental expectations for product quality, safety, and manufacturing process robustness. Regulators require sponsors to meet the same ICH guidelines for pharmaceutical development (ICH Q8), quality risk management (ICH Q9), and drug substance development (ICH Q11).[2,3] There is no "wiggle room" on safety.

The challenge is that orphan drugs are often supported by limited clinical data and produced in small batches, which constrains a sponsor's ability to conduct full-scale process validation or extensive stability programs. This makes it all the more critical to work meticulously within these constraints to avoid costly re-evaluation. Without end-to-end understanding, scientifically sound development, and a strong risk management framework, sponsors can fall foul of any of the pitfalls outlined below.

## PITFALL 1: PRIORITISING PATIENTS BUT UNDERPLAYING PROCESSES

Racing through early development to the first-in-human milestone can prove to be a costly efficiency. Sponsors who use non-optimized processes, minimal characterization, and temporary formulations risk compromising a product's long-term usability and scalability. This approach, while it may expedite a clinical trial, often leads to expensive and time-consuming remedial work once the program matures.

### Data Scrutiny or Rejection

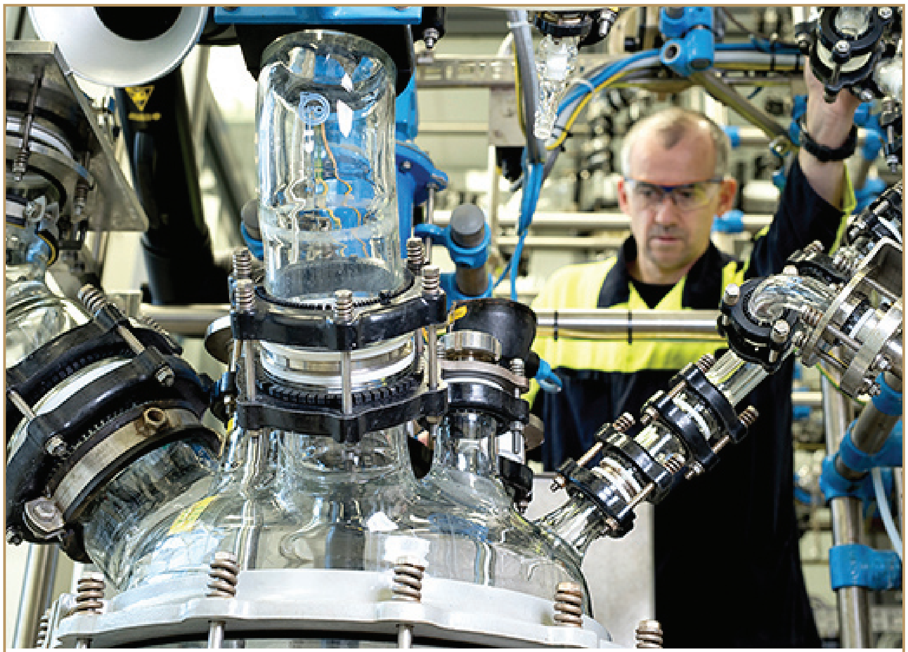
The rush to the clinic often means using materials and processes not fit for later-stage development. This can create a critical disconnect between early and pivotal trial data. For example, one gene therapy sponsor's use of research-grade plasmid DNA and non-GMP AAV vectors in early trials resulted in a lack of comparability data when the program transitioned to a GMP process. This oversight, a key concern outlined in FDA guidance on CMC information for human gene therapy, prompted regulators to question the integrity of the clinical data, forcing the sponsor to repeat toxicology studies and causing a significant delay.[4]

### Unanticipated Impurities

Neglecting fundamental development work can also lead to unanticipated product quality issues. A small molecule sponsor learned this when its early solution formulation exhibited recrystallization during stability testing. The sponsor had not performed polymorph screening or excipient compatibility studies upfront. The resulting reformulation introduced new impurities and required extensive bridging work, further delaying the program.

## PITFALL 2: FAULTY ANALYTICAL PROCESSES

Ongoing patient safety and efficacy rely on quality control. If the analytical methods used to assess a product are flawed, incomplete, or poorly validated, it sets the stage for significant downstream complications. Journal articles on the manufacturing of gene and cell therapies highlight that the complexities of these products can lead to challenges with quality control assays.[5] In the rush to meet timelines, many orphan drug programs proceed with methods that lack the robustness required for regulatory scrutiny, jeopardizing product integrity and delaying development.



**Drug Substance Reaction Process**

### Inappropriate Reference Standards

A robust analytical method requires appropriate controls, including a well-defined reference standard. In a cell and gene therapy program, a critical potency assay lacked reproducibility because the sponsor had failed to establish a proper reference standard. As a result, the assay failed during a key comparability test, forcing regulators to request a new method and additional clinical data to bridge the gap.

### Storage & Stability Issues

Analytical methods must be capable of accurately measuring a product's quality over its shelf-life. A small molecule program faced a major challenge when its UV-based HPLC method failed to resolve a critical degradant that formed under long-term storage conditions. By the time the issue was discovered, several clinical batches had been released using a method that was not stability-indicating. This raised serious questions about the integrity of the product and highlighted the consequences of not investing in robust stability-indicating analytical tools upfront.

## PITFALL 3: FLAWED CONTROL STRATEGIES

Generic or poorly justified specifications fail to instill confidence in product quality. While orphan drug programs often deal with a low number of batches, they must still demonstrate an adequate control strategy to ensure safety and efficacy. A lack of process knowledge, a common point of failure noted in ICH Q11, can be the root cause of issues.[6] Without this understanding, specifications can be generic and poorly justified.

### Challenges & Pushback

A common issue arises when sponsors apply generic specifications from a different product type. In one biologic program, a fusion protein was assigned monoclonal antibody specifications. Regulators challenged these assumptions, pointing out that the protein's degradation pathways and immunogenicity risks were fundamentally different. This oversight required the sponsor to perform additional characterization and caused a several-month delay, highlighting how a one-size-fits-all approach is insufficient.

### Missing Toxicological Assessments

In the small molecule space, sponsors face similar issues with impurity limits. In one instance, an uncharacterized impurity approached the ICH Q3A threshold, but the sponsor had not performed structure elucidation or toxicological assessment. The FDA requested a full ICH M7 evaluation, including genotoxicity data, that had not been generated. This oversight stalled the regulatory review and forced the sponsor to halt progress until the required data could be produced.

## PITFALL 4: UNJUSTIFIED CHANGES

Changes, even positive improvements, must be managed carefully. A seemingly minor change in formulation, process, or site can trigger unintended consequences and raise regulatory concerns if it is not supported by robust comparability data. European regulatory agencies, such as the EMA, provide specific guidance on the quality documentation required for biological products.[7]

### Better Yield, Different Glycosylation Pattern

Changes intended to improve a process can have unexpected effects. In one biologics program, a purification change introduced to improve yield unintentionally affected the product's glycosylation pattern. Because the change had not been thoroughly studied and the assays lacked sensitivity, regulators required the sponsor to generate new clinical bridging data, postponing the drug's approval.

### New Polymorph, Same Dissolution & Bioavailability?

A new polymorph may improve manufacturability, but it must be proven not to affect the drug's performance. A sponsor introduced a new polymorph but did not adequately characterize its impact on dissolution or bioavailability. Without an *in vitro in vivo* correlation to justify the change, regulators requested additional pharmacokinetic data. This misstep resulted in a significant delay while the required data was generated.

## PITFALL 5: PROBLEMS OF SCALE

Scaling up is an exciting stage of development, but minimizing issues requires a deep understanding of how new equipment and different process dynamics can

**Spray Drying Process of a Highly Potent Compound**

impact a product. The need for a life-cycle approach to process validation is a well-established principle in the industry, as detailed in both PDA technical reports and EMA guidelines.[8,9] Without this foresight, the transition from lab to clinical or commercial scale can be more costly than it is a cause for celebration.

### Insufficient Sensitivity

A lack of robust analytical methods or defined process parameters at a larger scale can lead to a failure to detect critical changes. In one viral vector program, a change in chromatography resin during scale-up unexpectedly altered the ratio of empty to full capsids. Because the sponsor lacked sufficiently sensitive release assays, they only discovered the issue after the clinical material failed potency testing. This oversight resulted in wasted material and a costly delay.

### Process Change Impurities

Even seemingly minor changes to a process during scale-up can introduce new impurities. A small molecule program experienced an undesirable change in its impurity profile during scale-up crystallization. The increase in mixing speeds and thermal gradients introduced new stress points. The new impurity required a toxicology reassessment and repeat validation, demonstrating that simply replicating a lab-scale protocol without understanding the new process dynamics can have expensive consequences.

## PITFALL 6: WEAK LINKS IN A SUPPLY CHAIN

For many orphan drug programs, a single vendor for a critical raw material or intermediate represents a weak link in the supply chain. While this reliance can be manageable in early development, it creates a serious point of failure as a program scales toward regulatory approval.


Tablet Coating Process

### Lost Certification

For a drug to be manufactured under cGMP, its raw materials must come from a qualified source. In one gene therapy program, the sponsor's single-source plasmid supplier lost its GMP certification, halting vector production. Without a qualified backup, the sponsor faced a six-month delay while it had to revalidate a new supply chain.

### Discontinued Production

A supplier can also stop production for business reasons, leaving a sponsor without a critical material. A small molecule program encountered a similar issue when its supplier of a specialized intermediate discontinued the product line due to cost concerns. The sponsor had not developed a backup plan, so regulatory filings could not proceed until a new material source was requalified.

## PITFALL 7: PAPER TRAIL PROBLEMS

Even with brilliant scientific breakthroughs, inconsistencies raise questions. Documentation could be considered a regulatory product pitch. Inconsistencies, gaps, or ambiguity undermine even the most robust science, eroding regulatory confidence and stalling a program. Guidance on Drug Master Files underscores the need for clear and complete documentation, as this information is used by regulatory agencies to assess the manufacturing process.[10]

### Unjustified Impurity Limits

One NDA was delayed when reviewers found inconsistencies between batch records and process descriptions. In this case, impurity limits were not adequately justified, and the history of excipient sourcing was ambiguous. These inconsistencies created enough regulatory doubt to prompt a formal delay.

### Incomplete Traceability

The ability to trace every component of a drug to its source is non-negotiable for patient safety. In another case, a BLA was refused at filing due to incomplete traceability of raw materials used in pivotal clinical batches. Despite the batches passing all release testing, the lack of robust GMP documentation created regulatory uncertainty that could not be resolved after the fact.

## STRATEGIES FOR NAVIGATING THE CMC LANDSCAPE

The seven pitfalls outlined above are not insurmountable. They are, in fact, entirely avoidable with a few key strategic shifts.

**1. Proactive Planning and Cross-Functional Alignment**

The goal is to design a CMC plan that is not just a collection of discrete tasks but a coherent, risk-based strategy. Decisions made in preclinical development should anticipate their impact on Phase 3 and commercialization, for instance, by selecting a scalable formulation or establishing a preliminary control strategy.

**2. The Value of Experience**

The choice of a development partner is an impactful decision. Whether a single CDMO or multiple organisations, experience of the unique nuances of orphan drug development meaningfully contributes to control strategy design, impurity risk assessments, and regulatory authoring.

**3. Leveraging Risk Management and Data**

Since orphan drug programs are often data-poor, sponsors must compensate with rigorous, science-based risk management. This involves using orthogonal analytics, in silico modelling, and process knowledge to build a robust justification for specifications and process parameters. Regular, proactive meetings with regulators can help clarify expectations and align on strategy, preventing surprises at submission.

Engaging with regulators is also beneficial. FDA guidance on CMC information for biotech products outlines the types of data that are needed to ensure a smooth review.[11]

## METICULOUS WORK, CHANGES LIVES

While clinical innovation and investor attention are the engines of drug development, the true driver of ambition in this space is the human element: the unmet needs of patients previously marginalized by medical advances. It is the why that fuels the work. But ambition alone is not enough. A well-executed CMC strategy is the how that transforms that ambition into a tangible reality. It is the framework that turns a scientific breakthrough into a reliable, safe, and available treatment, ensuring that the promise of a drug is ultimately fulfilled for the patients who need it most.◆

## REFERENCES


1. BioPlan Associates. 15th Annual Biopharma Manufacturing Report. 2023.
2. ICH. Pharmaceutical Development Q8(R2). 2009.
3. ICH. Quality Risk Management Q9. 2005.
4. U.S. FDA. CMC Information for Human Gene Therapy INDs. Guidance for Industry, 2020.
5. Kumar M, et al. CMC Challenges in Gene and Cell Therapy. Mol Ther Methods Clin Dev. 2020;17:523–530.
6. ICH. Development and Manufacture of Drug Substances Q11. 2012.
7. EMA. Quality Documentation for Biological IMPs. 2022.
8. PDA. Technical Report 60-2: Process Validation Lifecycle. 2021.
9. EMA. Process Validation for Finished Products. 2016.
10. U.S. FDA. Drug Master Files: Guidance for Industry. 2022.
11. FDA. CMC Information and Establishment Description for Biotech Products. 2023.




## BIOGRAPHY

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# INJECTABLE DEVICES

## Delivering Tomorrow's Injectables to Patients Today: Responding to a New Era of Demand With Purpose-Built Capabilities

By: Tommy Schornak

### INTRODUCTION

The global injectable drug delivery market is projected to reach $1.11 trillion in 2030, driven by the surge in chronic diseases, the growing adoption of biologics, and the desire for patient-centric administration routes.[1] At the same time, therapeutic innovations like RNA-based platforms and gene therapies are testing the technical limits of conventional fill finish infrastructure.

What was once a system designed for large-volume vial fills must now accommodate prefilled syringes, autoinjectors, cartridges, and small-batch, high-value therapies. These diverse formats require different container components, production volumes, processing speeds, and sterility considerations. Contract development and manufacturing organizations (CDMOs) are also facing rising expectations around regulatory compliance, operational sustainability, and early phase technical collaboration.

For manufacturers, this means designing facilities and teams that are fast, compliant, and flexible. That flexibility must extend across container types and fill volumes, through late-stage scale-up, and across development models. Meeting this challenge requires investment in automation, data systems, and isolator-based design, but it also demands something less tangible: a shift in mindset. In this environment, the most effective CDMOs are those structured to solve, not just supply.

The following examines how evolving therapeutic modalities, delivery systems, and regulatory expectations are reshaping the fill finish landscape. It explores how CDMOs can adapt infrastructure, sustainability practices, and early development engagement to meet rising complexity with confidence. Each section highlights the strategic decisions manufacturers must make to build flexible, future-ready operations that can support a broader range of therapies and delivery formats.

### BRIDGING TOMORROW'S THERAPIES THROUGH FUTURE-READY FACILITIES

Adapting to today's demands means designing infrastructure for what comes next. Demand is shifting away from uniform, high-volume runs toward a mix of personalized treatments, device-integrated formats, such as autoinjectors or microneedle array patches (MAPs) and rapid turnarounds. This shift is driven primarily by evolving patient preferences for simplified, self-administered options, with added pressure from healthcare buyers who are prioritizing simpler delivery options that are easier and safer to use.

Emerging formats like prefilled syringes, wearable injectors, and MAPs require infrastructure that can handle a range of volumes, container types and sterility conditions without compromising operational efficiency. Facilities built around a small number of dedicated lines for specific formats are no longer sufficient on their own. Those optimized exclusively for a single container type will struggle to keep pace with the growing diversity of delivery systems and the operational demands they bring.

To address this, CDMOs are investing in flexible fill lines, isolator-based designs and modular cleanroom suites that support multiple formats and rapid changeovers. These approaches enable smoother transitions from development to commercial scale, support both large and small batch sizes and better position CDMOs to respond to future shifts in patient need, modality, or market urgency.

## COMPLIANCE IS A COMPULSORY DESIGN ELEMENT

The revision of Annex 1 of the EU Good Manufacturing Practice (GMP) guidelines in 2022 marked a turning point in sterile facility design. Among its most significant updates was a reinforced emphasis on contamination control through advanced technologies, including the use of isolators, restricted access barrier systems (RABS), and automation to reduce human intervention in aseptic environments. While such systems have been available for years, the revised guidance now effectively elevates them to baseline expectations for regulatory compliance in sterile manufacturing.

This is evident not only in regulatory language but in how biopharma companies approach outsourcing partnerships. There is now a clear expectation that filling lines minimize operator intervention, data integrity systems are robust and equipment can be validated to meet rigorous global standards.

With this shift in regulatory expectations, retrofitting legacy lines is increasingly seen as a short-term fix that may leave manufacturers unable to keep pace with evolving standards and competitive timelines. As facilities age, their risk of failing to meet evolving compliance standards increases.[2] By contrast, greenfield builds provide an opportunity to embed compliance from the outset by incorporating the most modern, future-ready approaches to aseptic processing and facility design to stay ahead of evolving sterility standards.

For decision-makers assessing infrastructure strategy or outsourcing partnerships, this underlines the importance of long-term regulatory alignment. Facilities designed with these expectations in mind

are more likely to earn regulatory trust, streamline tech transfers, and maintain consistent performance as product and format complexity increases.

## SUSTAINABILITY IS A SHARED RESPONSIBILITY

The growing emphasis on early alignment is mirrored in another area of expanding industry focus: sustainability. Drug developers are facing increasing pressure to account for the environmental footprint of their supply chains, from the materials used to the ways energy, water, and waste are managed during production.

This focus is prompting re-evaluation of how facilities are built and operated. Design choices that once prioritized throughput or footprint are now being reassessed for their impact on resource efficiency. Technologies such as isolators can reduce the frequency of cleaning cycles and limit waste generation, while thoughtful process design can minimize batch loss and disposable consumption.

As regulatory and market expectations continue to evolve, sustainability is becoming a strategic advantage. CDMOs that embed these considerations into their operations early are better positioned to align with client goals while also supporting the lifecycle needs of increasingly complex therapies. By reducing material usage, optimizing line cleaning requirements and enhancing energy and water efficiency, sustainability-oriented design helps improve operational efficiency and ensure manufacturing remains adaptable and cost-effective as therapies become more personalized and formats more diverse.

## HEALTHIER TOMORROWS ARE BUILT ON TODAY'S COLLABORATION

Many of the downstream challenges in injectable drug manufacturing originate from early decisions made without adequate input from those responsible for scale-up. Formulations that appear promising in small-scale trials may behave unpredictably at larger volumes. Container materials, filling equipment, or facility limitations can introduce friction or delays, especially when not factored in from the start.

As therapies become more complex

and timelines more compressed, CDMOs are expected to participate earlier and contribute technical foresight, helping developers avoid late-stage surprises. This includes evaluating how formulations will perform at scale, identifying material or equipment incompatibilities and understanding how design decisions may affect throughput or product loss.

The modern CDMO role now extends beyond production. Leading partners are expected to contribute to formulation risk assessments, advise on container closure selection, validate compatibility with fill lines, and assess scale-up viability. These inputs help drug developers avoid missteps and make decisions that support long-term manufacturability.

Successful tech transfer depends on early alignment between teams, timelines, and technical expectations. It is not a hand-off, but a continuous collaboration. When that collaboration begins early, manufacturers are better positioned to deliver a process that is robust and aligned with the goals of the overall development program.

## WHAT IT TAKES TO DELIVER TOMORROW'S INJECTABLE INNOVATION

The demands facing injectable drug manufacturing are more dynamic than ever. Infrastructure must accommodate a broader spectrum of delivery formats, regulatory expectations continue to elevate standards for contamination control and sustainability has become a core consideration rather than a secondary goal. Across every stage of development and production, alignment between stakeholders is essential.

Long-term success depends on designing flexible facilities that support diverse modalities, embedding compliance and sustainability from the outset and fostering collaboration early in the development process to reduce risk and enable scalability.

These priorities are reflected in manufacturing approaches that prioritize versatility and responsiveness across technical, regulatory and environmental domains. As injectable therapies continue to diversify and evolve, these capabilities will become even more critical to ensuring safe, timely and effective delivery to patients around the world.

Ultimately, the path forward lies in deliberate coordination. Facilities, technologies and partnerships must work in unison to support today's therapies and prepare for those yet to come.◆

## REFERENCES


1. Injectable Drug Delivery Devices Market - Growth (Size, Share), Segments, Regions, Competition & Trends Overview, Mordor Intelligence
2. Aging Facilities: An FDA Perspective, U.S. Food & Drug Administration


## BIOGRAPHY


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# Developing Innovative Solutions to One of the Top Public Health Threats: Antibacterial Resistance

By: Jennifer Schneider, PhD

## THE UNRESOLVED CHALLENGE IN TREATING BACTERIAL INFECTIONS

According to the World Health Organization 1.27 million people died in 2019 due to antibacterial resistance (AMR). AMR is commonly understood to be associated with infections which are no longer easily treatable by common antibiotics due to mechanisms of resistance in the bacteria. Additionally, elderly people, patients receiving antibody therapies, and oncology patients, amongst others are at additional risk for developing bacterial infections. Due to these complex host factors, these patients may not be effectively treated by traditional antibacterials, even when the bacteria is deemed to be susceptible. Infections are increasingly recognized as a major factor overturning the benefits of years of research, innovation and progress in modern medicine, as successful treatment for cancer, for example, may be negated by mortality due to infection.

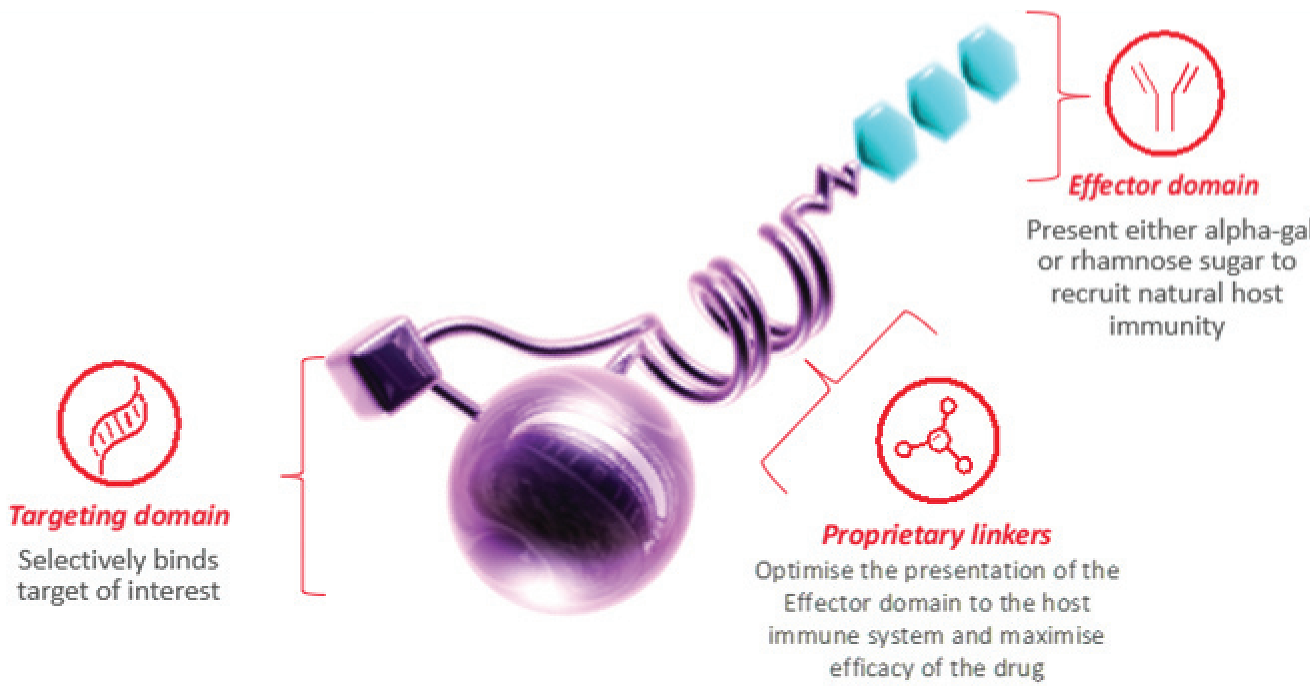
Data shows that bacterial infections develop in ~40% of individuals with blood cancers, in over 50% of CAR-T cell therapy recipients, and 13% for patients who are on long-term corticosteroids. There is therefore a clear and urgent need for the development of novel approaches to treat infections in these underserved and vulnerable populations.

Taking oncology as an example, while immunotherapy provides new lifesaving options for treating and managing some cancers, the more established modalities of radiation and chemotherapy continue to play a critical and leading role in the overall treatment paradigm. Similarly, when we look at infections, traditional antibiotics are likely to remain the primary workhorses in infectious disease management even as novel modalities are developed and become available for the treatment of more complicated cases. However, as with oncology, there will be patients and cases in infectious disease where immunotherapy transforms outcomes. Immunotherapy, therefore, holds the potential to revolutionize the treatment of 'hard to treat', chronic, and often recalcitrant infections.

## NOVEL IMMUNE THERAPY APPROACH FOR INFECTIOUS DISEASES – HARNESSING ALPHA-GAL

A robust antibody response to alpha-gal was detected back in the 1960s in the context of xenotransplantation, when the transplanted tissue was rapidly attacked and killed due to the high-density presentation of alpha-gal sugar on the surface of the pig tissue being recognized by abundant anti-alpha-gal antibodies present in the human. Because all mammals (except old-world primates) present this alpha-gal sugar epitope and humans do not, humans have developed antibodies to this sugar by way of regular exposure in the gut. Following the identification of the alpha-gal antibodies, additional research identified other anti-sugar antibodies, such as rhamnose antibodies with similar properties to alpha-gal. These very abundant polyclonal antibodies are low affinity but have high avidity, and are thus recruited within the context of a high-density glycan array.

The anti-sugar antibodies are abundant polyclonal antibodies, including IgM and IgG isotypes. These multiple isotypes leverage different aspects of the immune system and drive multiple pathways of immune engagement. Multiple research teams have been aware of the opportunity to take advantage of these ubiq-




uitous pre-existing anti-sugar antibody repertoires, and there has been much excitement about how to take advantage of these antibodies to develop novel immunotherapeutics in oncology and infectious disease, or to enhance the efficacy of vaccines.

The Alphamer® platform takes advantage of this opportunity. Based on a novel and proprietary linker technology that allows for the non-cleavable coupling of a targeting moiety to a sugar effector moiety, this rational coupling allows for the successful presentation of the selected sugar to the immune system, while remaining bound to the target cell via the targeting moiety. This binding of the molecule to the target cell while maintaining presentation of the sugar to the immune system allows for rapid immune-driven killing of the target cell.

## THE TRANSLATIONAL CHALLENGE

The fundamental aim of any anti-infective is to reduce the pathogen load sufficiently to enable the patient's immune system to clear the rest of the infection. In individuals with a less robust immune response, including the elderly and those with compromised immune systems, the anti-infective is often doing its job in terms of reducing pathogen load, but the patient isn't actually improving. This is because the immune system of the individual is unable to fully eradicate the pathogen, which may lead to chronic infections, or infections which go on to develop resistance due to significant and continued drug pressure.

One reason why antibiotic development has historically been attractive for investors and pharmaceutical companies alike is that, for traditional antibiotics, animal models of infection and other pre-clinical activities translate quite well to efficacy in otherwise healthy individuals. Identifying the optimal drug exposure which leads to bacterial clearance in the chosen animal models and then extrapolating that exposure into humans, within defined safety margins, saw a lot of early success. However, as noted above, these traditional antibiotics may have limitations when it comes to their efficacy in individuals who have some type of comorbidity, and the animal models themselves are limited in terms of what they can tell us about efficacy in hosts with varying immune status.

## PRE-CLINICAL MODELS FOR NON-TRADITIONAL ANTI-INFECTIVE MOLECULES

The Alphamer platform has enabled development of a bifunctional molecule that has both direct acting antibacterial activity as well as robust and rapid activity driven by the immune recruiting component. Because of this novel mechanism of action, new techniques are required to assess the potency and activity of the molecules, replacing the traditional, and often inadequate, animal models of infection, to capture the effect of the molecule in totality.

As previously mentioned, the vast majority of pre-clinical mammalian models have either no or very reduced anti-sugar antibodies, which means the anti-sugar antibodies must be administered as part of any model of infection in such a way to achieve the human equivalent titer. Additionally, mouse models typically used for infection studies are often neutropenic, which of course limits the ability to evaluate the role of the immune system in bacterial clearance. Finally, complement is a major player in the activity of immune recruiting molecules, but complement in mice is known to be quite different from that in humans, with levels only around 10% of those in humans.

The challenges associated with the differences in the immune systems of mice and humans are just one aspect that needs to be addressed for the evaluation of novel non-traditional molecules. It is encouraging that multiple research groups in the industry are publishing on the use of novel assays for the evaluation of anti-infectives and are working to address some of the limitations of more traditional animal models and assays. Expanding the use of more host-relevant conditions, including a whole blood assay, which has commonly been used in immunology, inflammation, and hematology, is a great starting point. Being able to demonstrate the totality of the effect of novel molecules in a relevant human assay, coupled to the data achievable in less than perfect animal models, is an exciting success.

## THE NEED FOR ONGOING EDUCATION BEYOND THE CLINIC

In addition to either developing or adapting novel assays for evaluation of immune therapies to treat bacterial infections, additional pragmatic challenges also need to be addressed.

Traditional antibacterials have, in part, their suitability for clinical use evaluated using standard and widely used susceptibility tests as noted above. These tests perform reliably and effectively for traditional antibiotics. How to adapt these susceptibility assays is a key question under discussion, whether for novel immunotherapeutics such as Alphamers, or for monoclonal antibodies or phage therapies. As the standard assays are modified to ensure utility and new technologies or tests are developed, significant education and adoption of these technologies will be required to reassure clinicians that the right drugs are being used in the right patients at the right time.

A serious risk is that powerful and important new therapeutic modalities will be undervalued or underused while efforts to understand their susceptibility lag behind. Those developing non-traditional agents must work in close collaboration with subject matter experts, funders and regulatory authorities to facilitate collective advancement in the field. Both the adaptation of current methods and the development of new approaches to minimum inhibitory concentration (MIC) testing will enable healthcare providers to confidently use drugs with novel mechanisms of action. This will be important for most, if not all, of the novel technologies working their way through development, as the traditional assays and workstreams in the microbiology lab are not well suited to emerging modalities.

## SUMMARY

Antibacterial resistance remains a critical and unresolved challenge, particularly for vulnerable patient populations. Realizing the potential of emerging therapeutics, particularly immunotherapeutics, requires addressing key translational challenges, such as developing more relevant preclinical models and adapting susceptibility assays. Tackling these challenges will help ensure that innovative anti-infective strategies reach the patients who need them most, improving the management of hard-to-treat infections and addressing a major public health threat. ◆

## BIOGRAPHY

**Dr. Jennifer Schneider** is CEO of Centauri Therapeutics. Prior, she was executive officer of North America for the Global Antibiotic Research & Development Partnership (GARDP). She has nearly 20 years of experience working with companies, universities and non-governmental organizations in the United States and around the world, providing expertise in antibiotic policy, partnering, and fundraising. She participates in US and international discussions surrounding market creation, access, and novel payment models. She earned her PhD in Molecular Biology from the University of Notre Dame and her MPH in Epidemiology and International Health from the University of Michigan.

# PURIFICATION STRATEGIES

## Purification at Scale: Overcoming Chromatography Challenges for Advanced Modalities

By: Dr. William Sanders

### THE EVOLVING ROLE OF CHROMATOGRAPHY IN DRUG DEVELOPMENT

Chromatography, first developed in the 19th century to separate plant pigments, has grown into a cornerstone of modern drug development. Today, it plays a critical role in every stage of the lifecycle, from discovery through to commercial quality control. Its importance has only increased with the rise of complex molecules and advanced modalities, where robust purification strategies are essential to meet regulatory expectations, ensure patient safety, and unlock the therapeutic potential of new drugs.

The following explores the real-world challenges of scaling chromatography and highlights how contract development and manufacturing organizations (CDMOs) can help partners overcome them.

### SCALING UP: FROM BENCH TO PLANT

Scaling chromatography from laboratory to commercial scale is rarely straightforward. Bench-scale methods often fail to translate directly because large-scale operations introduce nonlinear factors, such as resin availability, pressure drops, solvent volumes, column dimensions, flow rates, and equipment limitations. If not addressed early, these issues can create costly bottlenecks or force late-stage changes in resin strategy.

Success begins with a deep understanding of the process and foresight. A strong technology transfer strategy ensures consistency across hardware, software, and even manufacturing sites. Our optimization approach includes evaluating resin selection, buffer conditions, process order, and step necessity to drive efficiency. For example, switching to resins with improved salt tolerance can eliminate unnecessary buffer exchanges and streamline purification.

### MEETING THE CHALLENGES OF COMPLEX MOLECULES & MODALITIES

Drug development is increasingly shaped by the emergence of complex modalities designed to tackle some of today's most pressing health challenges. These new drug classes have transformed purification requirements, with each modality presenting unique challenges:

- **Antibody Drug Conjugates (ADCs):** Managing heterogeneity and maintaining tight control over drug–antibody ratio (DAR).
- **Highly Potent APIs (HPAPIs):** Ensuring operator safety through strict containment and regulatory compliance.
- **Polymers, Peptides, and Oligonucleotides:** Addressing high viscosity and broad molecular weight distributions.
- **Controlled Substances:** Navigating complex regulatory and logistical requirements across global markets (Schedule I-V).

As more of these modalities enter the pipeline, purification strategies must adapt with equal sophistication. Expertise, flexibility, and access to advanced chromatographic technologies are vital for enabling the development of these innovative therapies. It is therefore vital that CDMOs leverage these methods effectively to facilitate the release of these therapeutics into the global market.


## EXAMPLES OF COMPLEXITY IN PRACTICE

For each modality, unique challenges present themselves during development, which in turn require a specialized approach by CDMOs.

## HPAPIS & CONTROLLED SUBSTANCES

Due to their potency, HPAPIs require specialized facilities and containment procedures. Even trace exposure poses risks to personnel, making regulatory compliance and selection of appropriate containment strategies paramount. We operate to SafeBridge® 4 standards and manage controlled substances (Schedule I-V) under rigorous regulatory oversight. Our expertise and infrastructure allow us to deliver safe, compliant solutions for these challenging molecules.

Our expertise in HPAPIs and cytotoxic drugs is critical for developing the linker-payload moiety required in ADC production. Emerging trends include tighter control of DAR distributions and improved cell-type-specific payload release. These advances rely on designing larger, more complex linker-payload structures with multiple chiral centers and tunable ester cleavage sites. Use of chromatography (both normal phase and/or reverse phase) is an absolute requirement for the purification of these entities.

At Veranova, we have established the use of flash chromatography and preparative HPLC for HPAPIs under containment conditions and have the expertise and equipment to translate our expertise to the purification of cytotoxic warheads.

## POLYMERS, CONJUGATES, & OLIGONUCLEOTIDES

Polyethylene glycol (PEG) conjugation has recently gained attention as a strategy to extend the half-life of rapidly cleared biopolymers, leading to several approved drugs in recent years. The properties of PEG conjugates add complexity to the purification of the conjugated products. The physical properties of PEG in aqueous solution results in a liquid with high viscosity, and the polydisperse nature of available large molecular weight PEGs results in a conjugated material with wide molecular weight distributions:

- **Viscosity:** High viscosity induces poor flow characteristics and hinders conventional chromatographic processing.
- **MW Distribution:** Wide size ranges reduce resolution and complicate large-scale separation.

We address these challenges through cross-functional collaboration among analytical, chemical, and solid-form scientists. Method development informed by viscosity modeling and molecular weight profiling ensures scalability. In some cases, complementary approaches such as tangential flow filtration (TFF) provide effective alternatives for removing low-MW impurities.

## ANTIBODY DRUG CONJUGATES (ADCS)

ADCs combine antibody specificity with the potency of small molecules, but their complexity demands precise control. Key challenges include:

- **Heterogeneity:** Variability in payload-drug reactive sites and numbers creates broad Drug Antibody Ratio (DAR) distributions.
- **DAR Control:** Maintaining consistent, optimal DAR is critical for efficacy and safety.
- **Unreacted Linker-Payload Removal:** Residual linker–payload poses significant off-target toxicity risks and requires tight control.

We leverage advanced chromatographic techniques, including hydrophobic interaction chromatography (HIC), size exclusion chromatography (SEC), and chiral separations, within integrated analytical workflows. This holistic approach supports linker–payload design, DAR optimization, and streamlined ADC project execution.

## DEVELOPING ROBUST PURIFICATION STRATEGIES

Robust purification strategies begin with analytical alignment. Early use of HPLC, SFC, HRMS, and chiral/achiral methods provides critical insight, while predictive modeling offers faster, data-driven optimization compared to trial-and-error approaches.

Purification strategies are complemented by efficient post-separation and isolation techniques, including thin-film evaporation, solid-phase extraction (SPE), lyophilization, and crystallization to enhance overall process efficiency.

We integrate these techniques into scalable strategies, enabling consistency from screening through GMP production. Our teams bring together cross-disciplinary expertise to anticipate challenges, accelerate timelines, and deliver reliable outcomes, allowing us to deliver on even the most complex development projects with confidence.

Our ongoing investment in technology and scientific partnerships keeps clients ahead of the curve. Our commitment to innovation is evidenced by our recent expansions and announcement of new facilities.

## WHAT'S NEXT: INNOVATIONS IN CHROMATOGRAPHY & PURIFICATION

Chromatography and purification are evolving alongside drug development as a leader in contract API development, and we closely monitors the key trends shaping the future of purification, including:

- Continuous Chromatography for improved efficiency.
- Novel Resin Chemistries to enhance selectivity and reduce costs.
- Real-Time Monitoring and PAT to increase process control and robustness.

These innovations promise faster development timelines, more sustainable operations, and greater manufacturing confidence for drug innovators and their CDMO partners.

## MANAGING PURIFICATION COMPLEXITY WITH CONFIDENCE

Chromatography is central to achieving the safety, scalability, and purity required for today's advanced therapies. To realize the promise of complex modalities, CDMOs must provide both the technical expertise and infrastructure to deliver robust purification strategies.

As a fully integrated, end-to-end CDMO, we support clients from early development through commercial production. With advanced instrumentation, specialized facilities, and a track record of managing highly complex programs, we enable smarter, faster, and more reliable purification outcomes. ◆


## BIOGRAPHY

**Dr. William Sanders** is the Global Vice President of Chemical Development Operations at Veranova. With over 25 years of experience in the chemical and pharmaceutical industries, he has held senior R&D roles at Actylis and MilliporeSigma/SAFC. Dr. Sanders holds a PhD. and BS in Chemistry from the University of Wisconsin–Madison and is the author of multiple patents and publications. His work has been recognized by the ACS Division of Medicinal Chemistry and the National Institutes of Health Chemistry/Biology Interface.

## COMPANY DESCRIPTION

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

## COMPANY BACKGROUND

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

## SERVICES

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

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

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LinkedIn: linkedin.com/company/15091036/

## ABITEC CORPORATION

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

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

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

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

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

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

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

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

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

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

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

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

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

**LinkedIn:**
https://www.linkedin.com/company/1454313/admin/feed/posts
YouTube: https://www.youtube.com/channel/UC9mfJCBOstRuc-i2Asgu4VQ

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Moving medicine forward.

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

Over the past 24 years, Abzena has helped hundreds of customers ranging from emerging biotechs to the top large pharmaceutical firms achieve their regulatory and clinical milestones. With extensive scientific knowledge and technical expertise, our global teams provide customers with comprehensive support that minimizes risks and moves new medicines forward faster- with greater success. Our global locations include San Diego (CA, USA), Bristol (PA, USA), and Cambridge (UK).

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

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

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

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

**AbZelectPRO™** – high-yielding mammalian cell line development (CLD) platform for accelerating the generation of production of CHO-K1, GS Knockout or GS Knockout ADCC+ cell lines in just 10 weeks with 10g/L in high-performing titers for antibodies, bispecifics and recombinant proteins.

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

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

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

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

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

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

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

# COMPANY PROFILE


ADARE PHARMA SOLUTIONS
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## COMPANY DESCRIPTION

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

## SERVICES & CAPABILITIES

Adare Pharma Solutions provides comprehensive CDMO services, from the earliest stages of development to commercial manufacturing and packaging for both new and existing products, with expertise in complex formulations and patient-centric technologies.

## TECHNOLOGIES

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

## FACILITIES

Adare operates facilities in the US and Europe, staffed by over 750 employees. With a global manufacturing network, Adare offers integrated global and regional supply chains from state-of-the-art facilities in the US and Europe. We deliver development-scale through commercial-scale production, with a continuum of highly specialized manufacturing services and capabilities to meet any customer's oral solid dose needs.

### Drug Delivery

- Solutions to overcome formulation challenges
- Taste masking
- Customized drug release
- Solubility enhancement
- ODTs & novel dosage forms
- Easily swallowed dosage forms for patients with difficulty swallowing
- Optimize efficacy, safety, & dosing frequency
- Increase therapeutic performance & patient acceptability
- Maximize dosing accuracy, flexibility, convenience

### Development

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

### Manufacturing

- Global network of facilities
- Integrated regional supply chains
- Seamless scale-up & tech transfer
- Tableting & capsule filling
- Minitabs™
- Granulation & mixing
- Fluid bed processing
- Pan coating
- Blending (Bin and Static)
- Bilayer tablets
- Oven drying
- Small-scale GMP manufacturing

### Packaging

- Clinical & commercial contract packaging
- Packaging facilities in US and EU
- Bottle filling
- Blister packaging
- Stick pack filling
  - -Powders
- Flow wrap packaging
- Repackaging license
- Cartoning
- DEA Schedules II, 2N, III, 3N, IV, L1
- Serialization & aggregation


# YOUR PARTNER FOR SMALL MOLECULE ORAL SOLID DOSE SUCCESS

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

**TRANSFORMING DRUG DELIVERY. TRANSFORMING LIVES.**

ADARE®
PHARMA SOLUTIONS

ADAREPHARMASOLUTIONS.COM

Partnering to Advance Human Health

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### Company Description

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

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

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

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

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

## SERVICE HIGHLIGHTS

### API Services & Chemical Development

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

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

### Pharmaceutical Development

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

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

### Commercial Services

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

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

## RECENT INVESTMENTS

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

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

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

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

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

### Unparalleled Expertise in Inhalation

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

### Market-Leading Solutions for Effective Nasal Drug Delivery

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

### Best-in-Class Complete Injectable Solutions

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

### Proven Know-How in Ophthalmic Drug Delivery Devices

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

### Meeting the Growing Market Need in Dermal Drug Delivery

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

### Building Innovative Digital Device Solutions for Improved Patient Healthcare

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

### Our Sustainability Progress

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

# Complete Analytical Solutions for Biologics

**ARL Bio Pharma** is a contract testing laboratory that assists biotechnology and pharmaceutical innovators in developing safe and effective therapies. Our laboratory offers comprehensive analytical and microbiological testing to evaluate product safety, stability, and quality at every stage of drug development, from formulation to regulatory submission.

Leveraging comprehensive technologies such as high-resolution mass spectrometry, qPCR, and ELISA, we analyze the molecular structure, purity, and consistency of small molecules, monoclonal antibodies, peptides, and cell and gene therapies, empowering clients to make informed decisions and expedite their product's time-to-market.

Dr. Qiang Liu, ARL Chief Scientific Officer, emphasizes, "Our lab is an extension of our clients' research teams, delivering critical insight and support at every step of the process."

"At ARL, we view science as more than data; it is built on trust," affirms Dr. Thomas C. Kupiec, ARL President and CEO. "Our mission is to help our partners bring their therapies to patients safely and quickly."

ARL Bio Pharma is FDA-registered, DEA-licensed for Schedules I through V, and ISO 17025:2017 accredited.

## Small Molecule Analytical Services

- Stability Studies
- Compatibility Studies
- Raw Material Testing
- Dissolution Testing
- Pharmacokinetic/Pharmacodynamic Studies
- Preclinical and Clinical Analytical Testing

## Bioanalytical Services

### Characterization

- Intact Mass and Charge Variants
- Glycoform Profiling
- Peptide Mapping
- Disulfide Bond Mapping
- Residual Impurities (Host Cell Proteins)

### Structural Analysis

- ADCs and Fusion Protein Analysis
- Payload Determination
- Isomer Differentiation
- PTM Profiling

## Microbiology Testing Services

- Sterility and Rapid Sterility Testing
- Endotoxin Testing
- Microbial Identification
- Mycoplasma Testing
- Antimicrobial Effectiveness
- Container Closure Integrity Testing
- Cleaning Validation Studies

## Contact ARL Bio Pharma for a Quote

800-393-1595 info@arlok.com www.arlok.com


ASCENDIA PHARMACEUTICAL SOLUTIONS
661 US Highway One
North Brunswick, NJ 08902
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E: bd@ascendiaCDMO.com
W: www.ascendiacdmo.com

**Ascendia Pharmaceutical Solutions** is drug development teams' fast, flexible, and first time right CDMO partner. It makes the Impossible Possible through a comprehensive suite of pre-formulation, formulation development, cGMP manufacturing, and ICH stability services for a variety of dosage forms and clinical trial materials (CTM), using proprietary enabling nanotechnologies. The company built its success on its customer-centric BEST (Brilliant technology, Excellent service, Superior quality, and Trust) philosophy.

This combination of technologies, facilities, and expertise is why Ascendia Pharmaceutical Solutions can start projects and tech transfers in its U.S. facility within four weeks.

### Company Description

Located in the New Jersey Bioscience Center, Ascendia Pharmaceutical Solutions provides U.S.-based CDMO services from discovery to commercialization. It has a proven track record in developing formulations for API screening and CTM, for fast drug development.

All GRAS materials are used to streamline formulation development, for time and money savings. Ascendia Pharmaceutical Solutions is a rare U.S.-based CDMO with capabilities that include spray drying, aseptic fill finish, lyophilization, GMP-grade NETZSCH DeltaVita® 600 Gamma Vita equipment, and Precision Nanosystems systems. These expansive capabilities position it as expert in working with lipid nanoparticles (LNPs) and nanostructured lipid carriers (NLCs), among others.

### Company Background

Founded in 2012, Ascendia Pharmaceutical Solutions offers a comprehensive suite of pre-formulation, formulation development, cGMP manufacturing, and ICH stability services for all dosage forms. It built its foundation of success on its customer-centric BEST philosophy that has led to Ascendia Pharmaceutical Solutions to double in size in the past four years.

### Markets Served/Facilities

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

The CDMO can scale-up and optimize various dosage forms. In fact, Ascendia Pharmaceutical Solutions has a proven track record of developing new dosage forms that were previously unattainable. Its successes are why pharmaceutical companies have entrusted the CDMO with tech transfers that lead to cost and time benefits.

### Products, Services & Capabilities

Ascendia Pharmaceutical Solutions delivers sophisticated formulations to enhance bioavailability and solubility using four proprietary nanotechnologies – AmorSol®, EmulSol®, LipidSol™, and NanoSol®. It supports GLP and cGMP manufacturing in accordance with ICH guidelines.

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

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

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W: drugdeliverysystems.bd.com

**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 year[1]
- $2.3Bn Annual revenue 2024
- ~ 6000 PS Associates worldwide, Global headquarters with ~1800 associates
- 6 Manufacturing plants worldwide
- Global headquarters in Pont-de-Claix, France

1- BDM-PS Financial file November 2023, "Actual FY23" Perimeter

**Bespak – the specialist inhalation CDMO committed to leading the transition to low carbon pMDIs.**

Bespak® is a global Contract Development and Manufacturing Organisation (CDMO) solely focused on inhaled and nasal drug delivery. Headquartered in Holmes Chapel, UK, the company develops and manufactures inhaled and nasal drug products, drug delivery devices and components for the global pharmaceutical industry. Bespak provides a specialist, fully integrated service to support customers from early-stage feasibility, analytical and formulation development, product development and clinical supply, through to full-scale cGMP batch production.

With a long history in the development and commercial supply of pressurised Metered Dose Inhalers (pMDIs), Bespak is the first CDMO with commercial capacity for manufacturing low carbon pMDIs using both low Global Warming Potential (GWP) propellants, HFA-152a and HFO-1234ze. Bespak supplies a major proportion of the world's pMDI metering valves and actuators, including the trusted, market approved BK357 valve, which has now been optimised for reliable compatibility with next-generation propellants and is the first and only valve approved for this use. Leveraging established capabilities, ongoing manufacturing expansions, and collaborations across the supply chain, Bespak is leading the transition to low carbon pMDIs.

Bespak also specialises in the industrialisation and high-volume manufacture of complex Dry Powder Inhaler (DPI) devices, as well as unit dose and multi dose nasal sprays, offering industry-leading contract manufacturing services at all scales.

Across drug-device combination product development and manufacturing, Bespak delivers industry-leading quality supported by continuous improvement. Investing in the long-term capabilities of its workforce, , the company's unique Injection Moulding Academy enables technological innovation through expert-led training in inhalation device manufacture. Bespak also recognises the complexity of regulatory pathways for drug-device combination products and provides specialist support to help de-risk and streamline development.

Through a joint venture with Medspray, Bespak offers Resyca® Soft Mist Inhalers (SMIs) and nasal soft mist atomisers. These harness proprietary spray nozzle technology to efficiently deliver sensitive formulations, including biologics, to the lungs or nasal cavity.

Bespak's expanding capabilities are strengthened by significant investment and strategic collaborations. Working alongside its partners, Bespak is helping to lead the inhalation industry to a more sustainable future and supporting continued patient access to life-saving treatments.

Built on established expertise but ready for the future, Bespak is a long-term innovation partner committed to driving sustainability in the industry. This commitment extends across its operations, as Bespak prioritises strong environmental, social and governance (ESG) strategies to build responsible business practices and establish itself as a trusted partner for its customers.

BESPAK
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BIOVECTRA

A part of Agilent

BIOVECTRA

*We care about making better therapeutics.*

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

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

Our Facilities:

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

**Accelerate the Success of Your mRNA Therapeutics with BIOVECTRA**

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

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

Our experienced team excels in custom lipid manufacturing. With more than 50 years of expertise in fermentation, small molecule production, and quality management for regulatory compliance, we ensure scalability and precision at every production stage.
As a full-service CDMO, BIOVECTRA offers analytical testing, QA release, regulatory support, project management, and more.

**Learn more at www.BIOVECTRA.com.**

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CAPTISOL, BROUGHT TO YOU BY LIGAND
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www.captisol.com

## CAPTISOL LEGACY

Captisol® is a patent-protected, chemically modified beta cyclodextrin (specifically, sulfobutylether beta-cyclodextrin, or SBECD) designed to optimize the solubility, stability, and bioavailability of drugs that are otherwise difficult to deliver. Invented by scientists at the University of Kansas' Higuchi Biosciences Center for drug development and formulation, Captisol has enabled 16 FDA-approved products – including Gilead's VEKLURY® (remdesivir), Amgen's KYPROLIS® (carfilzomib), Baxter International's NEXTERONE®, Pfizer's VFEND IV®, Sage Therapeutics' ZULRESSO®, Novartis' MEKINIST® (approved March 2023), and most recently SQ Innovations' Lasix® ONYU (furosemide). Manufactured by CyDex Pharmaceuticals (a Ligand Company), Captisol stands out as the leading pharmaceutical-grade SBECD, recognized for its excellent safety and consistency record. Many Captisol-enabled products are currently in various stages of development.

We maintain a 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. 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 formulations 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 has successfully completed or assisted with orphan designations and approvals, preclinical, CMC and clinical development for ANDA, 505b2 and traditional NDA programs.

**Contact us today to learn more or request a sample!**

# Celanese

The chemistry inside innovation™

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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.

The Celanese Development & Feasibility Lab
*Accelerating your Drug Delivery Programs*


## 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

VitalDose® Delivery Platform for Long-Acting Therapies


## ABOUT CELANESE

Celanese is a global leader in chemistry, producing specialty material solutions used across most major industries and consumer applications. Our businesses use our chemistry, technology and commercial expertise to create value for our customers, employees and shareholders. We are committed to sustainability by responsibly managing the materials we create for their entire lifecycle and are growing our portfolio of sustainable products to meet increasing customer and societal demand. We strive to make a positive impact in our communities and foster inclusivity across our teams. Celanese is a Fortune 500 company that employs approximately 12,200 employees worldwide with 2024 net sales of $10.3 billion.

INNOVATION WITHOUT CHANGE

CREDENCE MEDSYSTEMS, INC.
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**Credence MedSystems, Inc.**

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

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

**Companion® Product Family**

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

**Dual Chamber Reconstitution or Sequential Liquid Delivery**

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

**Credence Isolation Valve™ System**

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


**Credence Connect™ Auto-Sensing Injection System**

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

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

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

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

**Preserve.** Differentiate without disruption.

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

**Stand out among the competition.**

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

# CRODA | Pharma

SMART SCIENCE TO IMPROVE LIVES™

**More than just your ingredients provider**

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

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

**About Croda Pharma: www.crodapharma.com**

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

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

**A Selection of Our Recent Launches**

**Virodex™:** Sustainable, compendial, cGMP, REACH compliant detergents for viral inactivation and cell lysis.
**Super Refined™ Poloxamer 188:** Highly purified poloxamer 188, optimised for mammalian cell culture with exceptional batch-to-batch consistency.
**Amino Acids:** High purity amino acids for bioprocessing and drug formulation - COMING EARLY 2026.
**Sustainable Squalene:** Synthetic biology and purification excellence enable a highly purified alternative to shark-derived squalene.
**Sustainable Saponins:** QS 21 based on plant tissue culture making a more efficient process with sustainable sourcing.
**Natural Phospholipids:** Highly purified phosphatidylcholine products originated from soybean and egg yolk.

Avanti Research
A CRODA BRAND

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

**Contact Croda Pharma**

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DDL

Testing Experts. Service Specialists.

For over 35 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. DDL now also offers package testing in its GMP Laboratory located in Minnetonka, MN.

### 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.

### 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 80,000 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.

### Industrial CT Scanning

From dimensional inspection of small-bore connectors to first article inspections on assemblies, DDL utilizes custom fixtures and programming to meet the measurement needs of various types of medical device parts. We leverage our equipment to run inspections on parts to ensure assemblies do not have defects, evaluate porosity and ensure additive manufactured parts do not have voids or issues given their design / purpose. Each project is unique and will be evaluated upon request.

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Dyhydromatics®

*Your Partner For High Pressure Homogenizers*


## COMPANY DESCRIPTION

Dyhydromatics designs and manufactures advanced ShearJet® high-pressure homogenization systems and partners with clients to integrate and scale high-pressure processes from R&D through commercial production. With a focus on precision, reliability, and exceptional customer service, Dyhydromatics helps global leaders in pharmaceuticals, biotech, chemicals, food, personal care, and more to develop innovative formulations, achieve nanoscale particle size reduction, and scale seamlessly to commercial success.

## COMPANY BACKGROUND

Dyhydromatics was founded by David Hunter, whose career spans the US Navy, technical leadership at Microfluidics Corporation, and advanced machine-building in Germany. Building on decades of global field service and process engineering, David and his team have made Dyhydromatics synonymous with high-performance equipment and world-class support. As a global, family-led organization, the company combines industry-leading technical standards and operational excellence with the agility and personal commitment of a dedicated team.

With headquarters in Massachusetts and a growing international presence, Dyhydromatics continually invests in innovation - including its proprietary Diamond Reaction Chamber® technology - and in the professional development of its expert team.

## TECHNOLOGY & SERVICES

- High-Pressure Homogenizers: Lab, pilot, and small-scale production systems (up to 30,000 psi)
- Formulation & Application Support: From proof-of-concept to scale-up
- Global Service, Components & Maintenance
- Proprietary Diamond Reaction Chamber® for ultra-fine particle and droplet sizes

## INDUSTRIES SERVED

- Pharmaceuticals & Biotech
- Chemicals
- Food & Nutraceuticals
- Personal Care
- Cannabis

## APPLICATIONS

- Nanoemulsions
- Liposomes
- Cell disruption
- Polysaccharides
- Nanoencapsulations
- Suspensions & dispersions
- Gene therapy
- Bioavailability enhancement

## RESOURCES

ShearJet® High-Pressure Homogenizers: (https://dyhydromatics.com/equipment/)

Proof of Concept & Formulation Development: (https://dyhydromatics.com/resources/proof-of-concept-testing-and-formulation-development/)

Whitepapers and Case Studies: (https://dyhydromatics.com/resources/articles-case-studies/)

Parts & Services: (https://dyhydromatics.com/services/)

Industries & Applications: (https://dyhydromatics.com/industries-applications/)

Contact Dyhydromatics: (https://dyhydromatics.com/contact-us/)

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Dyhydromatics®
Your Partner for High Pressure Homogenizers
High-Shear Homogenizers & Expert Formulation Services
Specializing in Nanoemulsions, Nanosuspensions, Liposomes & Encapsulation, Cell Lysis, and Polysaccharides
Introducing
ShearJet® HL60 V2
Now Available in 110 VAC
Learn More at
dyhydromatics.com

## GATTEFOSSÉ CORPORATION

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## Company Description:

Gattefossé provides innovative excipients to the human and animal pharmaceutical industries, as well as the dietary supplements industry. We manufacture our products in France, Singapore, and our new EXCiPACT-certified production site in Lufkin, Texas, providing customers around the world with reliable quality and supply chain security.

At Gattefossé, we innovate with care, guided by our Gatt'Up&Act roadmap—25 goals to be met by 2035 across three core pillars: Environment, Employees, and Society. Recognized with EcoVadis Gold and ISO 14001:2015 certification, our Sustainable vision continues to inspire trust worldwide.

## Company Background:

Since 1880, Gattefossé has developed and manufactured high-quality lipid excipients for human and animal health. With a service and distribution network that spans over 12 affiliates, 40 distributors, and 90 countries, Gattefossé prides itself on its history of innovation tailored to formulators' needs.

## Products, Services & Capabilities:

Gattefossé takes pride in enhancing your formulations with a broad portfolio of excipients and a consultative approach to solving your drug delivery challenges.

**For the oral route:** solubility/bioavailability enhancers, lubricants for tablets and soft gel capsules, sustained- release matrices, taste-masking solutions, and API protection.

**For the topical route:** solubilizers, penetration enhancers, emulsifiers, emollients, and viscosity modifiers.

**For the rectal and vaginal routes:** ready-to-use bases for suppositories and pessaries.

**Gattefossé's Technical Center of Excellence in Paramus, NJ** helps you screen, optimize, and de-risk your lipid-based formulations. Our data-driven approach to pre-clinical screening ensures you select the right excipients for your needs. We also regularly provide training sessions, webinars, and publications to advance lipid-based formulation development.

Genizer

SOLUTION FOR NANO

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HTTPS://WWW.YOUTUBE.COM/RESULTS?SEARCH_QUERY=GENIZER+

**Genizer LLC** is headquartered in Irvine, CA with an East Coast presence just outside Boston, MA, and we've been in business nearly 15 years. Our mission is to advance nanotechnology.

WE PROVIDE SCALABLE HIGH PRESSURE HOMOGENIZERS, MICROFLUIDIC NANO MIXERS, A FULL LINE OF LIPOSOME EXTRUDERS, DIAMOND INTERACTON CHAMBERS, HEAT EXHANGERS, AND AN ASSORTMENT OF GAUGES.

**Key products:**

- **High-Pressure Homogenizers:** Including the compact NanoGenizer for laboratory use and the larger ProdGenizer for production scales and our ManuGen series for full on production.
- **Liposome Extruders:** Tools like the HandExtruder and Jacketed Liposome Extruder for preparing uniform liposomes, used in drug delivery and cosmetics.
- **Diamond Interaction Chambers:** The core component of our homogenizers, available in Y-type and Z-type configurations.

Our world renowned **DIAMOND INTERACTION CHAMBERS** are made solely by Genizer LLC; they are compatible with most other brands of high pressure homogenizers and high pressure pumps. These chambers give you best quality, the same processing results/efficiencies as other brands, at a fraction of the cost.

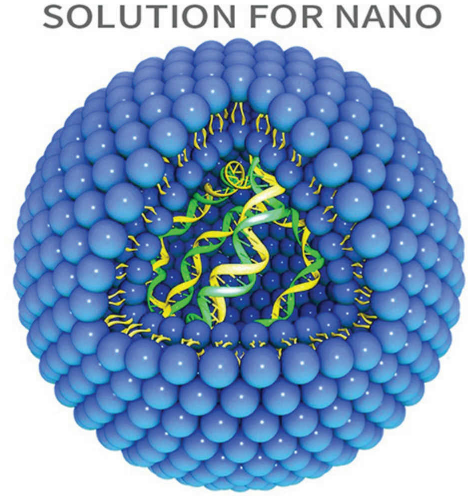
- **Laboratory Microfluidics Mixer** - Description: Laboratory Microfluidics Mixer for mRNA/DNA lipid/polycation nanoparticle preparation (max. pressure 500 psi)
- **Other Equipment:** We also offer sanitary heat exchangers, high-pressure gauges, and sanitary pumps.

**Applications**

Genizer's solutions are used across various industries, including but not limited to pharmaceuticals and biotechnology (vaccines, cell lysing, gene delivery systems, liposomal drug delivery).

Genizer

SOLUTION FOR NANO



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## On Drug Development & Delivery

HCmed Innovations is a CDMO specializing in inhalation drug delivery systems. Leveraging our proprietary vibrating mesh technology, we provide an integrated platform for the development of drug-device combination products, offering customized solutions for pharmaceutical partners.

## Mesh Nebulizer Platforms

- **AdheResp®** - The first US FDA 510(k) cleared breath-actuated mesh nebulizer is equipped with built-in connectivity, and uniquely ready for large-scale manufacturing to support pharmaceutical partners in clinical trials — accelerating new drug development. Its characteristics enhance drug delivery efficiency and reduce fugitive aerosol emissions.
- **Pulmogine®** - A continuous-delivery vibrating mesh nebulizer that efficiently aerosolizes liquid medications. With its compact size and quiet operation, it offers a comfortable and user-friendly nebulization experience.

## Flexible Customization Options

- **Level 1 Mesh** - We offer a wide selection of mesh membranes to optimize aerosol performance for your formulation needs.
- **Level 2 Firmware** - Our customizable firmware empowers you to tailor the functional features precisely to your requirements. Define the optimal triggering span for each breathing cycle, and include other features such as NFC-based activation and Bluetooth connectivity to provide to monitor adherence
- **Level 3 Hardware** - Our customizable hardware platform empowers the tailoring of the device's aesthetic design, components, and usability from technical specifications in the board to precise usability requirements, delivering a truly personalized solution.


Through our tailored services, we optimize aerosol delivery across a broad range of therapeutic formulations — from small molecules to complex biologics. With the capability to nebulize a wide array of high-value therapeutic drugs, we conquer limitations for inhaled medications.

## End-to-End Development for Combination Products

HCmed provides full-spectrum support from early-stage feasibility through clinical trials and commercial supply. Our integrated approach ensures alignment between drug formulation and device performance, allowing seamless transition across development phases. Whether optimizing aerosol characteristics or supporting regulatory submissions, we help partners de-risk development and shorten timelines for bringing combination products to market.

## Your One-stop Partner

Combining technical expertise and flexible solutions, we help deliver high-performance inhalation systems tailored to each pharmaceutical partners' needs — from small molecules to biologics. HCmed is your trusted partner in developing and commercializing inhaled combination products.

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

## ABOUT US

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

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

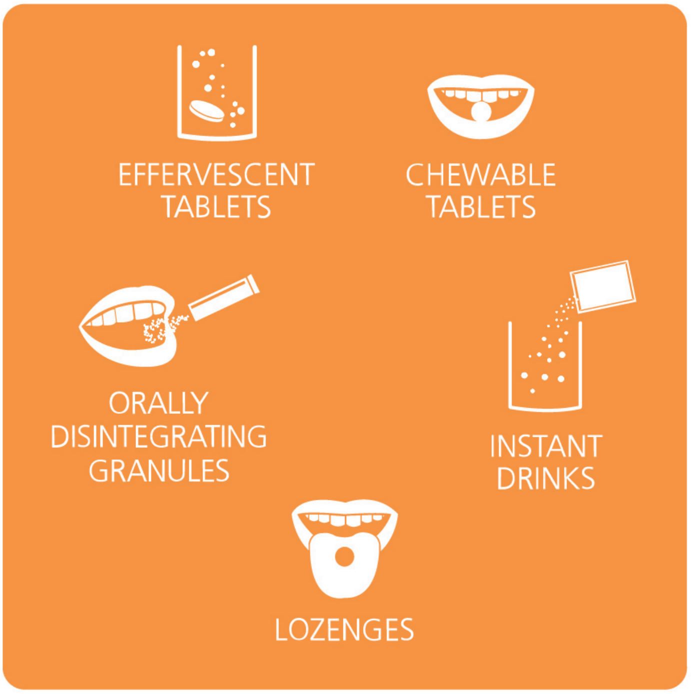
## PRODUCTS & SERVICES

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

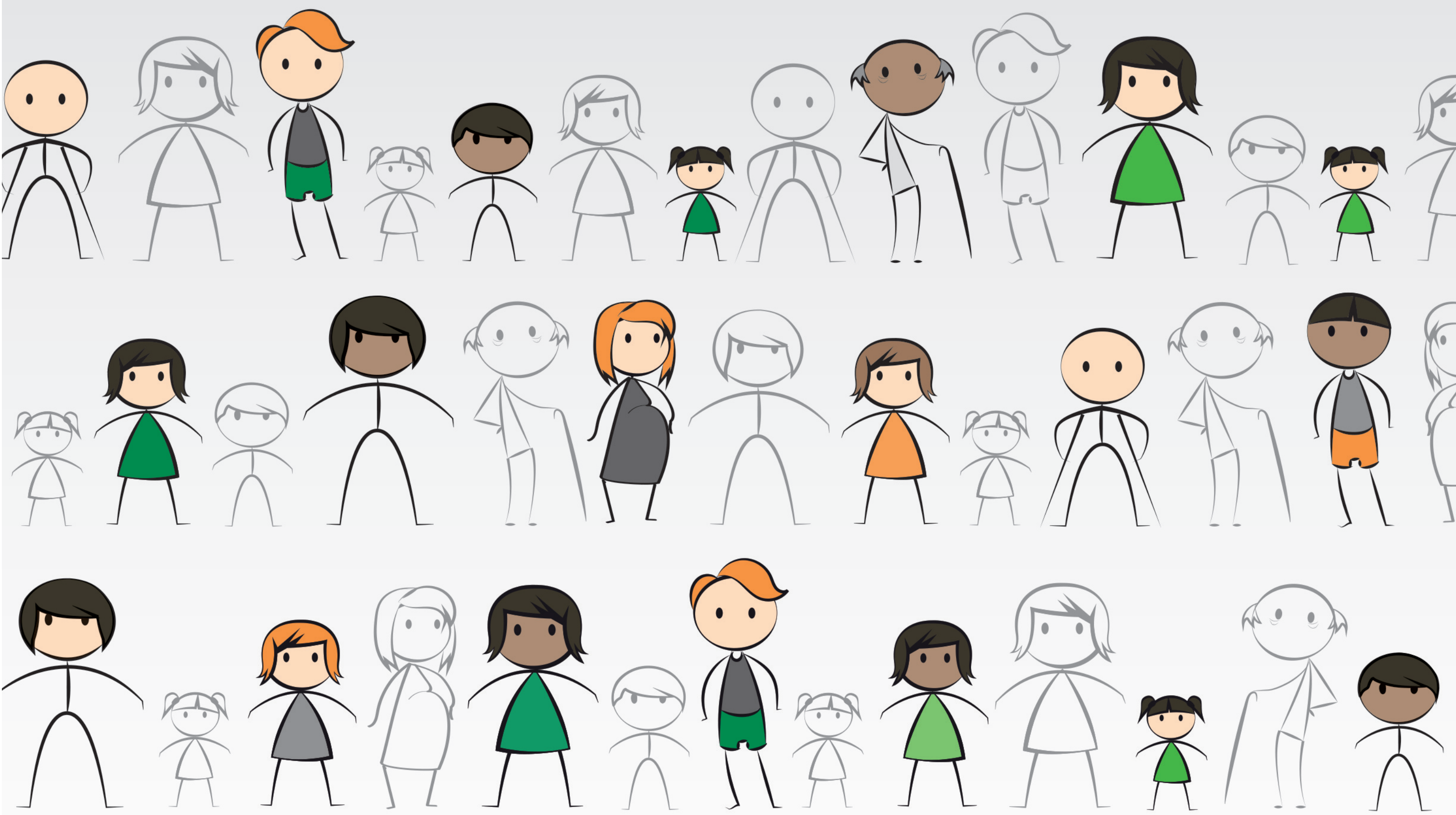
Our effervescent and chewable tablets, lozenges, instant drinks, and orally disintegrating granules are user-friendly alternatives to conventional tablets and capsules. They provide an added value to patients and consumers as they:

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

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



# TAKING A PILL IS AS EASY AS PIE?
# 50% OF YOUR CUSTOMERS WOULD DISAGREE ...



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

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

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

HERMES PHARMA
*Get the dose right®*

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**Kenox Pharmaceuticals** is a contract development, manufacturing, and testing organization specializing in innovative aerosol-based drug delivery for inhalation, nasal, eye and other applications. Over the years, we have partnered with pharmaceutical and biotechnology companies to bring life-changing inhaled and intranasal therapies to the clinic faster and more efficiently.

### Aerosol/Spray Technology

We offer extensive expertise in orally inhaled and nasal drug product (OINDP) and opthalmic product design, development, manufacturing, and testing. Kenox expansion to Good Manufacturing Practice (GMP) facilities enables seamless transition of projects to clinical manufacture and testing of OINDPs for first in human (FIH) studies. Partner with Kenox to accelerate your OINDP and ophthalmic programs.

### Why Work With Kenox?

Drawing upon many years of experience within the pharmaceutical industry, we combine large-company know-how with small-company agility to ensure unparalleled project and customer focus.

### LARGE PHARMA EXPERIENCE

- 100+ collective years
- Hands on drug - device comb experience
- Small and biologic molecules
- Diverse formulation technologies
- Regulatory pathways

### SMALL PHARMA AGILITY

- Highly focused
- Nimble & Efficient
- Creative & Collaborative
- Cost effective
- Short turnaround times

LATITUDE Pharmaceuticals Inc.

CLEARSOL
A Broad-Spectrum Drug Solubilizer

## LATITUDE Pharmaceuticals: Turning Complex Challenges into Clinical Reality

For over two decades, LATITUDE Pharmaceuticals Inc. has been helping biotechnology and pharmaceutical clients overcome complex formulation challenges and accelerate early-phase development for both human and animal health products. As a client-centric CDMO, we bring innovation to every formulation and GMP manufacturing program — supported by more than 1,250 successful projects. LATITUDE has established a reputation for transforming difficult molecules into stable, bioavailable, and clinic-ready drug products.

### Expertise in Complex Formulations

Our team of experienced formulation scientists are known for their creativity, technical rigor, and responsiveness. Their expertise spans a wide range of dosage forms and delivery routes, addressing issues such as poor solubility, instability, low bioavailability, and undesirable in vivo performance. LATITUDE is particularly recognized for its proficiency in complex injectables, including nanoemulsions, liposomes, microspheres, and nanoparticles, that demand both innovation and precision.

### Innovative Drug Delivery Platforms

LATITUDE's in-house technologies provide clients with unique solutions to accelerate development and improve the drug product profile:

- **ClearSol®:** A solubilization platform for oral or injection formulations that outperforms cyclodextrins for a wide range of actives, using only GRAS and FDA-approved excipients.
- **PG Depot:** A phospholipid gel depot enabling customizable, sustained release for subcutaneous or intramuscular delivery over 1–7 days, with up to 20% drug loading.
- **Nano-E:** A versatile nanoemulsion technology enhancing solubility for oral and injectable products while minimizing vein irritation.
- **ARTSS:** Converts lyophilized or cold-stored formulations into room-temperature-stable aqueous solutions, simplifying storage and distribution.

### GMP Manufacturing & Analytical Support

Complementing our R&D strengths, LATITUDE provides GMP-compliant manufacturing and analytical testing for Phase 1 through non-pivotal Phase 3 clinical trial materials. The company's quality system, experienced staff, and efficient project management enable rapid delivery of sterile injectables, ophthalmic drugs, oral solids / liquids, and topical drug products. LATITUDE excels at manufacturing complex liquids and controlled-release systems, ensuring consistency, compliance, and clinical readiness.

With its blend of scientific creativity, technical depth, and operational agility, LATITUDE Pharmaceuticals continues to help clients advance promising drug candidates from formulation concept to clinical reality.

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LinkedIn: https://www.linkedin.com/company/lifecore-biomedical

Unsure your filling needs will be fulfilled? Have a complex injectable product or process? We say, "Bring it."

**Lifecore** is a U.S.-based Contract Development and Manufacturing Organization specializing in the development, fill/finish, and commercialization of sterile injectables.

With a 40+ year regulatory track record and 20+ commercial products, Lifecore offers end-to-end services with experience spanning straightforward to complex formulations. We support organizations of all sizes across pre-clinical, clinical, and commercial stages.

Lifecore is also a leading producer of pharmaceutical-grade, non-animal-sourced sodium hyaluronate which is used as an API and excipient.

### Why Choose Lifecore?

We're creative problem solvers who enjoy helping our customers find solutions to complex products and processes.

We don't have limitations on what we're willing to consider. We're flexible when onboarding customer processes, methods, and equipment at our facilities.

### Process Development & Fill/Finish Services

- Development, fill and finish of sterile injectables
- Syringes, vials, and cartridges
- Expertise in highly viscous (exceeding 100,000 cP) and complex formulations
- Proven QMS supports drugs, biologics, medical devices, and combination products

### Additional Services

- Extensive on-site microbiological, analytical, and physical testing with redundant labs
- ICH stability studies
- Range of labeling, packaging, and serialization options

### Sodium Hyaluronate

- Research-grade, pharmaceutical-grade, hydrogels, and custom modifications
- Broad range of average molecular weights for use in R&D, animal/tox studies, clinical studies, and commercial applications
- US DMF approved, EP-certified, and JP-compliant


Unsure your filling needs will be fulfilled?
Bring it.
Development
Lifecore INJECTABLES CDMO
U.S.-based
Annex 1 compliant
40+ year track record
Isolator filling
lifecore.com
Lifecore® INJECTABLES CDMO

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**Lonza** is one of the world's largest contract development and manufacturing organizations (CDMOs), dedicated to serving the healthcare industry. We work alongside a broad range of customers – from emerging biotechs to global pharmaceutical companies – to transform their therapeutic discoveries into life-saving and life-enhancing treatments for their patients. Our vision is to be the pioneer and world leader in the CDMO industry, setting the pace with cutting-edge science, smart technology and lean manufacturing.

Founded in 1897 in the Swiss Alps, our business has embraced innovation and kept pace with a fast-changing world for more than 125 years. As the first and the original CDMO, we have been manufacturing medicines for more than four decades. Today we offer one of the largest Western CDMO networks with a global team of 19,000 colleagues working across more than 30 sites in five continents. Our people are united by a common purpose: to turn our customers' breakthrough innovations into viable therapies and manufacture the medicines of tomorrow.

Our business is structured to meet our customers' complex needs across three synergistic Business Platforms: Integrated Biologics, Advanced Synthesis and Specialized Modalities. Our services span from early development to drug substance and drug product manufacturing, and we lead in both established and emerging technologies including mammalian biologics, small molecules, highly potent active pharmaceutical ingredients (APIs), bioconjugates, mRNA, microbial, and cell and gene. Across technologies, we deliver integrated solutions to meet our customers' needs throughout the entire treatment lifecycle.

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## WHO WE ARE

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

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

## MAJOR MARKETS

Biotechnology and pharmaceutical organizations spanning virtual companies to large multi-national corporations, along with universities and research institutes have engaged our services in successful collaborations for a variety of projects. These projects span initial product design and process engineering for new entities right out of drug discovery through Phase 3 clinical supplies, to technology transfer to commercial manufacturing with regulatory approval. Gaining a global reputation, LTI has been sought after and completed projects with clients in the European, Middle East, and Asian Pacific regions, as well as Canada and the Americas.

## SERVICES OFFERED

### Capabilities

- Pre-clinical through Phase 3 Clinical Supplies
- Bulk Lyophilization
- Dedicated/disposable equipment
- Batch sizes: up to 75L
- Vials: 2 to 160 mL
- Dual Chamber devices 1 to 20 mL
- Novel delivery systems
- Nucleation On-Demand Technology
- DEA license
- US/EU compliant

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

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

### Development Sciences

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

- Product Design
- Formulation Development
- Thermal Analysis
- Process Engineering
- Product Characterization
- Pilot Plant Scale-up
- Isolation/Containment
- Dual Chamber Devices

### Clinical Supplies Manufacturing

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

- Aseptic compounding
- Pre-clinical through Phase 3
- Toxicology Material Processing
- Small to medium batch sizes
- Liquid/diluents
- Dual Chamber Devices

### Technical Services

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

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

## Company Description

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

## SERVICES & CAPABILITIES

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

## TECHNOLOGIES

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

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

## FACILITIES

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

## MIKART EXPERTISE

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

## AREAS OF EXPERTISE

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

## PROCESSING CAPABILITIES

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

## DEDICATED DOSAGE FORMS

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

## ANALYTICAL SERVICES

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

## COMPREHENSIVE PACKAGING CAPABILITIES

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


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MITSUBISHI GAS CHEMICAL

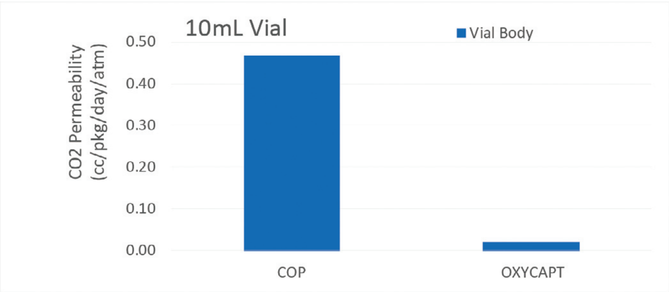
**Mitsubishi Gas Chemical (MGC)** is a leading company in the field of oxygen barrier and absorbing polymers. Based on these technologies and experiences, MGC launched new multilayer plastic vial named OXYCAPT™ in 2019. It has achieved an excellent oxygen, carbon dioxide, ultraviolet (UV) barrier, high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

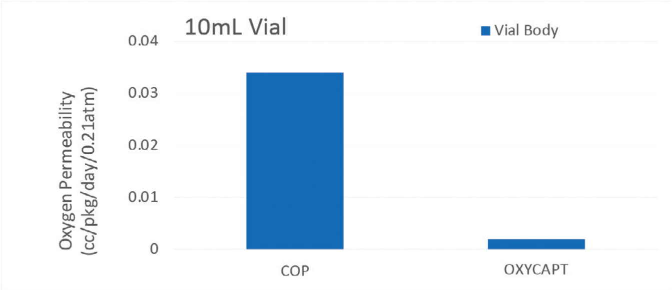
## Products

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

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

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

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

## COMPANY DESCRIPTION

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

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

## STATES SERVED

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

Pace® LIFE SCIENCES

**Pace® Life Sciences – People Advancing Science™**
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1311 Helmo Avenue North
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T: 610-279-7450
W: www.pacelifesciences.com

**Additional CRDMO network site locations:**
Boston, MA
Salem, NH
Norristown, PA
Ann Arbor, MI
Lebanon, NJ
Research Triangle Park, NC
San German, PR

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

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

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

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

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

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

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

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

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

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

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

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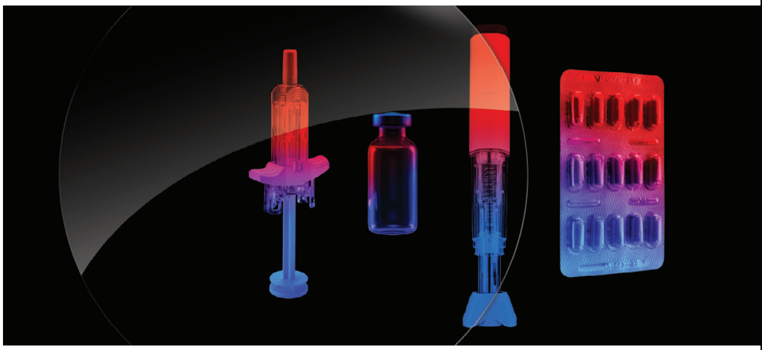
E: talkfuture@pci.com - W: www.pci.com



**PCI Pharma Services** provides world-class solutions through intelligence, ingenuity and innovation, together, delivering life-changing therapies. With integration from inception and quality at our core, PCI's development, manufacturing, clinical trial services, advanced drug delivery and packaging capabilities combine to minimize time-to-market and maximize opportunities for commercial success. PCI serves as an extension of its customers' value chains, toward the shared goal of improving patients' lives.

### PCI Facts & Figures

- 50+ years of healthcare sector service
- 90+ successful product launches per year
- 38 facilities across North America, Canada, UK, Ireland, Germany, Spain & Australia
- 8,500+ highly skilled personnel
- Emissions reduction goals validated by Science Based Targets initiative

Leveraging state-of-the-art technology and ongoing investment, PCI steers pharma products through their entire lifecycle via four key business segments:

### Development & Manufacturing

From early clinical batches to worldwide commercial supply, PCI's aseptic manufacturing, lyophilization and high potent oral dose manufacturing capabilities are trusted across formats and dosage forms. Through fully integrated formulation, analytical development and scalable manufacturing, PCI's expertise in the science delivers the reproducibility required to take products from the earliest stages of clinical development to commercial launch. Excelling in complex modalities, PCI's ever-evolving services meet emerging needs for cutting-edge sterile injectable filling and high-potency targeted therapies.

### Advanced Drug Delivery & Drug-Device Combination Products

From prefilled syringes and needle safety devices to autoinjectors and pens, PCI provides unsurpassed capabilities in advanced drug delivery and drug-device combination products. Industry-unique clinical to commercial scale device assembly, testing and packaging are performed in unified, single-space environments, ensuring seamless continuity and expedited pathways. With the expertise to assemble devices from multiple micro-engineered components and global capacity for low-volume, high-mix and large-scale production, PCI pioneers solutions that set standards for dosing accuracy and patient-centricity.

### Clinical Trial Services

Transparent and collaborative from first dose to final phase, PCI's clinical trial services ensure investigational drugs achieve accurate assessment and expedience through-phase advancement. Robust networks provide comprehensive oversight from specialized packaging to global logistics, with drug device integration, parallel work flows and built-in stability testing maintaining momentum toward approval. A dedicated Supply Management and Readiness Team (SMART™) reduces financial and resource risk, while pre-commercial consultancy and planning services serve as guideposts for client partners. Throughout, the award-winning pci | bridge™ platform provides our global client base with real-time data for faster, intelligent decision making.

### Commercial Packaging Technology

Offering a deep bench of solutions for oral dosages, injectables and other dosage forms, PCI's commercial packaging services prioritize quality, safety and precision. From proprietary systems and bespoke labeling modules to entirely new engineering approaches, PCI brings the extensive background and expansive footprint to meet countless end-of-line needs. Industry-leading and extensive labeling, printing, primary and secondary packaging capabilities developed over 5 decades combine with exacting visual inspection and traceability systems to protect products, supply chains and patients.

# PharmaCircle™

## The Difference is in the Details

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

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

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

Key content and capabilities include:

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

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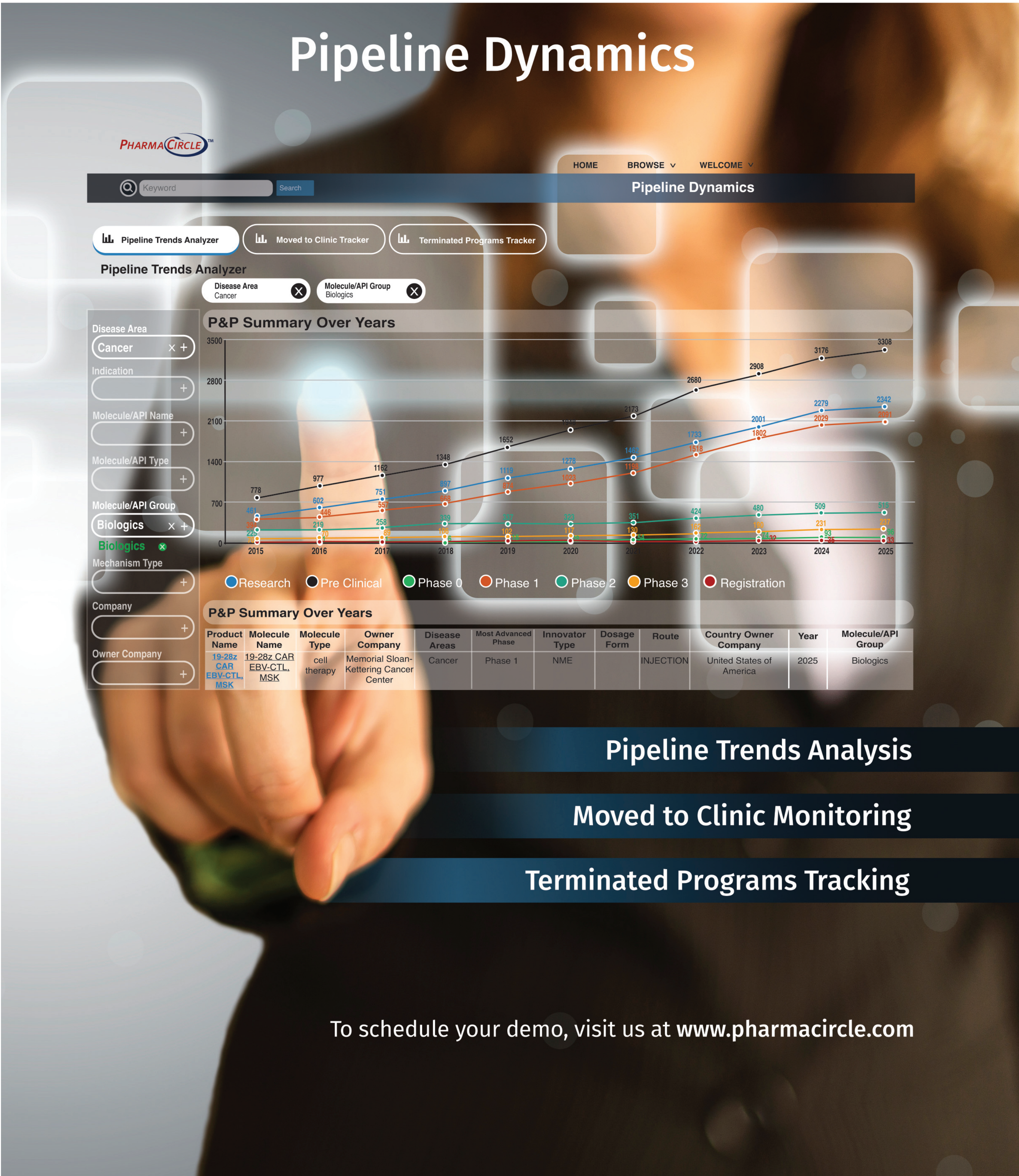
PharmaCircle™



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## Your CDMO Partner for Complex, Long-Acting Dosage Forms

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

## Markets & Applications

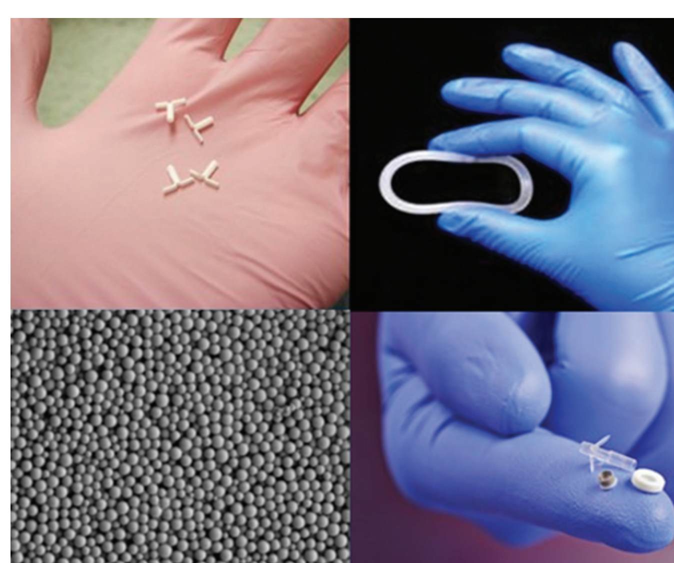
Key markets for our services include women's health, ophthalmology, oncology, and ENT. Representative drug-device applications include steroid-eluting pacing and defibrillation leads, implantable sensors, antimicrobial eluting devices, and sinus stents. ProMed also supports pharmaceutical companies developing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

## Drug Product Capabilities & Facilities

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

## Quality Control & Quality Assurance

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



# COMPANY PROFILE

Quotient Sciences

Molecule to cure. Fast.™

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

With trusted scientific insight brought to every program, Quotient Sciences is a drug development & manufacturing accelerator helping clients bring molecules to cures, fast.

With drug product development, manufacturing, and clinical testing facilities located in both the US and the UK, Quotient Sciences has worked with customers as a trusted CRDMO partner for over 35 years. Our approach to program design and delivery saves time in getting new therapies to market, without compromising quality and control of the product, data, and processes along the way.

Our comprehensive drug product (CDMO) services span a variety of dosage forms across early and late stage development, covering formulation development, clinical trial, and commercial manufacturing. We specialize in technologies for solubility enhancement, modified release, pediatric products, HPAPIs, and oral peptides.

Our clinical (CRO) services are focused on early phase, including Phase I studies from first-in-human (FIH), single and multiple ascending dose (SAD/MAD) to regulatory and exploratory clinical studies including human ADME, TQT, DDI, and bioavailability. For all projects, the customer experience is paramount, with expert project managers leading every aspect – from project start-up through to reporting.

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

We pioneered the integration of CRO and CDMO services with Translational Pharmaceutics® — a disruptive platform to enable greater efficiency in drug development. This unique approach integrates drug product manufacturing & clinical testing to reduce costs, improves decision making and accelerate development timelines by up to 12 months.

A closer look at our services:

- **Formulation development** – expertise in complex formulation development in areas including modified release, solubility enhancement, and pediatrics.
- **Clinical pharmacology** – rapid study startup and recruitment through our clinical units in Miami, FL, US and Nottingham, UK, with a database of over 30,000 healthy volunteers. Over 1,300 Phase I studies completed with a proven track record delivering across a range of drug formulations and indications.
- **Clinical trial manufacturing** – a streamlined approach to drug product supply that reflects your clinical study design and timeline.
- **Commercial drug product manufacturing** – trusted, global services for reliable commercial supply, including support for high-potency compounds and niche products with small volumes, such as pediatrics.
- **Data sciences** – providing fast access to reliable data to improve decision making during a study.
- **Modeling & simulation** – PBPK modeling, FIH predictions, quality-by-design assessments, *in-vitro/in-vivo* correlations, bioequivalence assessments.

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## COMPANY DESCRIPTION

Resilience is a North American contract development and manufacturing organization (CDMO) focused on delivering high-quality, scalable manufacturing solutions for advanced therapies. With capabilities spanning biologics drug substance, cell-based therapies, and aseptic drug product manufacturing for both small and large molecules, Resilience partners with leading biopharma companies to bring complex medicines to market faster and more reliably.

## COMPANY BACKGROUND

Resilience delivers therapeutics manufactured with excellence, quality, and reliability to their partners and the patients whose lives depend on them providing the agile manufacturing of life-changing therapies, delivered with speed, uncompromised quality, and purpose.

We were founded with a straightforward yet bold purpose: to broaden access to complex medicines and to protect biopharmaceutical supply chains against disruption. At the heart of our approach is a network of high-tech, end-to-end drug substance and drug product manufacturing solutions that can help ensure the medicines of today and tomorrow can be made quickly, safely, sustainability, and at scale.

## MARKETS/FACILITIES

Resilience serves customers worldwide through its network of facilities in North America. Their regulatory expertise spans across markets and supports customers in the EU, Asia, the Middle East, and North America.

## PRODUCTS/CAPABILITIES

With a current portfolio of 65+ clients across its network, ranging from large pharma to small and mid-size pharmaceutical and biotechnology companies, Resilience has manufactured 175 clinical batches and 100M+ commercial drug product units annually. With four core capabilities sets, including large molecule biologics development and manufacturing, cell therapy development and manufacturing, aseptic drug product manufacturing, and device assembly and packaging, Resilience was built for complexity, defined by quality, and delivers with reliability.

RESILIENCE

# In a world of change, our purpose stands firm.

## Change is constant.
## Quality is unwavering.
## So is our commitment.

- North American facilities built for reliability, regulatory excellence, and speed.
- End-to-end biologics manufacturing and injectables, built on a right-first-time culture.
- High-performance fill/finish, packaging, and logistics with seamless supply chain integration.
- A partner that evolves with the market, but never compromises on quality.

Discover why we're the right partner for your next program.

Resilience.com

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**Serán BioScience, LLC** is a science-based CDMO that specializes in a variety of drug delivery and formulation approaches suited to optimizing bioavailability. Serán's experienced formulation team will work with clients to identify an appropriate technology and formulation strategy to meet your program's unique needs. Our comprehensive approach to formulation design considers the physiochemical properties of the API, the target product profile, and your program's objectives and constraints to develop scalable formulations using efficient and material-sparing approaches.

Serán provides tablets (from minitablets to large format caplets), capsules (enteric or IR), multi-particulates (coated beads), and powder-in-bottle formulations. Our solid dosage forms are engineered for a wide range of formulation approaches such as overcoming solubility challenges and to enable extended-release.

## OUR SERVICES

### Preformulation & FIH Formulation Design

From discovery to commercial, our formulation design team has you covered. With the evolution of enabling technologies, low solubility no longer limits the advancement of molecules from discovery to clinical candidacy.

### Formulation Development

For early discovery and toxicology studies, we utilize a variety of suspension and solution approaches to obtain desired *in vivo* exposure, especially at high doses. As you advance to the clinic, our solid dosage form approaches are designed to achieve your preferred performance and are engineered for scalability.

### cGMP Manufacturing

Serán provides clinical manufacturing capabilities for a broad range of oral solid dosage forms including unit operations in particle size reduction, spray-dried dispersions, dry granulations, tablet compression, tablet coating, encapsulation, and clinical packaging and labeling.

### Spray Drying & Particle Engineering

Serán has extensive spray drying capabilities. Our team has decades of experience developing spray drying processes, related formulations, and analytical methods and techniques. We have leveraged our core knowledge of particle engineering and formulation requirements to design and build optimum spray drying systems for pharmaceutical applications.

### Solid Dosage Forms

Serán specializes in developing versatile solid dosage forms including tablets, capsules, and powder-in-bottle formulations, and a wide variety of other engineered solutions tailored for optimal *in vivo* exposure and scalability from discovery to clinical trials.

### Analytical & Quality Control

At Serán, our culture of high quality science drives us to provide top-tier analytical services that meet the rigorous demands of our clients' projects. Our team, led by respected industry veterans, operates under a unified approach that de-risks each project from the outset. Our comprehensive suite of analytical services includes method transfer, development, qualification, and a cutting-edge QC lab designed to support cGMP release testing and stability assessment and storage.

# Stevanato Group

## 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 5,500 people in 15 sites in 10 countries and generated around 1.1 billion euros of revenues in 2024. 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 and Testing Services

Stevanato Group boasts unique expertise in providing advanced pharmaceutical containers from glass tubing. Its comprehensive portfolio covers every customer need, from those related to small molecules to highly sensitive drugs. Stevanato Group produces vials, syringes, and cartridges for different applications, such as vaccines, RNA-based drugs, GLP-1 and peptides, monoclonal antibodies (mAbs) and Antibody-Drug Conjugates (ADCs). 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 and testing services through its Technology Excellence Centers.

## Offering Integrated Capabilities for Your Drug Delivery Devices Programs

Over the past few years, Stevanato Group has broadened its offering to include contract manufacturing of devices and proprietary drug delivery devices, including:

- Alina® a user-friendly, disposable pen injector platform for variable and multi-dose treatments.
- Aidaptus®, 2-step, single-use auto-injector accommodating both 1mL and 2.25 mL pre-filled glass syringes.
- Vertiva®, a pre-filled and pre-loaded on-body delivery system platform suitable for a wide range of therapies.

## Vision Inspection, Assembly & Packaging Technologies: A Modular & Flexible Approach

Stevanato Group capabilities range from modular assembly platforms and packaging lines to advanced vision inspection machines, including manual, semi-automatic, and automatic. Stevanato Group equipment can inspect a wide range of liquid, emulsions, viscous, gel-like, powder, and lyophilized drugs, catering to the needs of both small firms or big pharma companies producing blockbuster drugs.

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DISCOVER OUR
INTEGRATED
SOLUTIONS
Analytical
Services
ADDRESSING
THE FULL
VALUE CHAIN
Drug
Containment
Solutions
Drug
Delivery
Systems
Inspection
& Assembly
Equipment
Reduced Time to Market
Reduced Supply Chain Risk
Reduced TCO
Consistent Quality
SG Stevanato Group
MANAGING COMPLEXITY, DELIVERING VALUE
stevanatogroup.com

TERUMO
MEDICAL CARE SOLUTIONS

**As Part of Terumo Medical Care Solutions, the Pharmaceutical Solutions Division develops patient-oriented parenteral delivery solutions for therapeutic performance and safety.**

Globally trusted for quality and precision, we offer pharmaceutical and medical device manufacturers around the world comprehensive product design and development services.

We have decades of experience collaborating with pharmaceutical companies from the earliest phases of drug development to product commercialization to optimize critical aspects of parenteral drug delivery.

Innovation and creativity are central to our value proposition. Our expert teams lead the industry in developing and manufacturing advanced, high-performing infusion and injection technologies, including our expanded offering of integrated Contract Development and Manufacturing Organization (CDMO) services and innovative drug delivery devices.

With flexible, tailored solutions and true end-to-end support, we provide the expertise you need to bring your drug products to patients — whether you're seeking speed to market, reduce project risk, low total cost of ownership, scalability, or specialized technical capabilities.

**We listen. We question. We deliver.**

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ThermoFisher
SCIENTIFIC
15
Vi
Vision


UPM
CRDMO

**UPM Pharmaceuticals** is a U.S.-based CDMO with more than 30 years of experience supporting early development through later-stage clinical and commercial manufacturing of oral solid dosage forms. We combine deep scientific expertise with a customer-focused operating model to provide reliable, agile solutions for sponsors seeking a high-quality U.S. manufacturing partner. UPM specializes in technology transfer and scale-up, often onboarding products that begin outside our walls. Our teams work collaboratively to understand project history, clinical and commercial objectives, and the most efficient path to successful manufacturing. Whether supporting a new formulation or advancing an existing program, we focus on building robust analytical frameworks and optimized process designs to ensure strong performance at scale.

Our R&D scientists and formulation experts have advanced numerous complex products from concept to commercialization. Capabilities include analytical method development, formulation design for tablets, capsules, and comprehensive characterization such as dissolution profiling, stability assessments, flow and compressibility evaluations, friability, disintegration, and particle-size testing. UPM is also fully licensed for DEA Schedule I–V handling and provides compliant, secure management of controlled and potent compounds.

## FACILITY

UPM operates a 475,000-sq-ft cGMP facility in Bristol, Tennessee, offering the infrastructure of a large-scale manufacturer with the responsiveness of an independent, family-owned CDMO. Customers benefit from proven quality, reliability, and personalized service seldom seen in larger organizations.

## DEVELOPMENT SERVICES

- Formulation development for IR, MR, ODT, and combined technologies
- QbD-based development with formal DOE
- Clinical batch manufacturing for IND and Phase I–III programs, as well as generic bio-study batches
- Registration batch manufacturing
- Comprehensive analytical services including CU, potency, dissolution, stability, and microbiological testing
- Topical formulation development

## MANUFACTURING SERVICES

Blending, granulation (wet and dry), drying (FB & tray), coating, compression, encapsulation, tableting across a broad scale range.

## TECHNOLOGY TRANSFER & SCALE-UP

- Transfer from bench → pilot → commercial
- Site transfer for existing products
- Full process development and optimization
- Analytical transfer, qualification, and validation
- Program management, technical writing, regulatory filing support
- Validation strategy development and commercial readiness planning

## PACKAGING & SERIALIZATION

- Three solid-dose bottle lines (50–100 BPM)
- Nitrogen blanketing, desiccants, oxygen absorbers, thick-wall bottles
- Automated tube and jar packaging for semi-solids
- Vibratory line and low-humidity solutions
- Offline serialization, DSCSA-compliant, all code formats supported

## CONTROLLED SUBSTANCE CAPABILITIES

- Schedule I–V approvals
- Method and process development, stability, and degradation testing
- 3,200 sq ft of combined DEA-approved storage

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### Company Description

Upperton is a UK-based CDMO providing integrated contract development and manufacturing services. Specialising in oral, nasal, pulmonary and sterile dosage forms, Upperton offers a comprehensive range of services designed to support the progression of a molecule from early feasibility through to formulation development, clinical trial manufacture and commercial manufacture.

With over 25 years of experience, Upperton excels in rapid product introductions. Our project delivery is unparalleled and designed specifically to align with the values and innovation of small to mid-sized pharma companies.

We are flexible and nimble, enabling rapid decision-making, problem-solving, collaboration, and product introduction within 4-6 weeks.

With subject matter experts and leadership team oversight on every project, you can trust our project delivery and expertise covers all layers of our operations.

For small molecules and biologics, our clinical manufacturing process trains support batch sizes from grams to kilograms.

### Integrated CDMO Services

- Formulation Development
- Phase 1, 2 & 3 Clinical Supply
- Process Scale-Up & Optimisation
- Registration Activities
- Analytical Development & Validation

### Experts in Oral, Nasal, Pulmonary & Sterile Dosage Forms

Upperton offers expertise in developing a range of small molecule and biologics dosage forms, providing support from early feasibility studies through to clinical and commercial manufacture.

**Oral Solids:** Upperton specialises in the development of both simple and complex oral dosage forms, including powders, capsules, and tablets (IR, MR, SR, Minitabs)

**Nasal:** Supporting both liquid and dry powder formulation, the development platform, UpperNose™, streamlines and accelerates the process of developing nasal dosage forms for clinical trial studies.

**Pulmonary:** Through expertise in formulation development, particle engineering and device selection. Upperton offers both dry powder and liquid formulation options, addressing factors such as solubility, stability, and target dose delivery into the lungs.

**Sterile:** Our team can support you with aseptic and terminally sterilized small volume liquids and powders for parenteral, nasal and pulmonary delivery.

### Our Manufacturing Capabilities at a Glance

- Up to 1,000,000 tableting capacity per day
- 500g-205kg blending capacity
- Up to 2,000 blister packaging units per day
- Up to 50kg tablet coating per batch
- Up to 350,000 capsule filling (powder) capacity per day
- Up to 1000kg dry granulation capacity per day
- 0.5g-10kg spray drying batch sizes (aqueous and solvent)
- 20 litres solution preparation vessels capacity with overhead mixing
- 10 state-of-the-art GMP manufacturing suites

### Our Approach to Project Delivery

Upperton tailors projects to fit specific client timelines and requirements, prioritizing effective communication and collaboration in project delivery. Each project is assigned a project manager who coordinates all activities and ensures that transparency is maintained through regular updates.

Project teams at Upperton are composed of experts from various disciplines, including development, GMP, analytical, QA, and technical transfer. The inclusion of an Executive Leadership Team member in every project, ensures that decisions are made under expert guidance.

# WEST PHARMACEUTICAL SERVICES, INC.

## BY YOUR SIDE FOR A HEALTHIER WORLD™

West is a leading provider of innovative, high-quality injectable solutions and services. As a trusted partner to established and emerging drug developers, West helps ensure the safe, effective containment and delivery of lifesaving and life-enhancing medicines for patients. We are guided by our core values of Passion for Customers, Leadership in Quality and One West team and these values underpin our purpose to improve patient's lives. With a century of experience, we work together with our customers to support patient health and fuel a brighter future with product innovation.

West works by the side of customers from concept to patient to develop products that promote the efficiency, reliability and safety of the world's pharmaceutical drug supply.

- **Stoppers and seals for injectable packaging systems:** help ensure drug compatibility and stability and protect drugs from environmental impact to help maintain quality and safety while also supporting operational efficiency.
- **Syringe and cartridge components:** enable a more consistent injection rate to help patients receive accurate dosing with their treatment regimens, minimize drug overfill and microbial contamination.
- **Self-injection systems:** offering innovative, patient-centric technologies that are easy to use, which have the potential to improve the self-injection experience for patients while mitigating risks.
- **Containment and delivery systems:** West's historical experience provides the knowledge and understanding the importance of selecting the correct packaging system with the patients' health, operational efficiency, drug compatibility and drug stability in mind.

**WEST CONTRACT MANUFACTURING TEAM** is focused on serving the needs of healthcare companies by providing a single-source solution from product conceptualization through manufacturing and final packaging. West's team harnesses a powerful combination of innovation, technology, infrastructure and expertise to serve the pharmaceutical, medical and consumer industries. West contract manufacturing harnesses a powerful combination of innovation, technology, infrastructure and expertise to serve the pharmaceutical, medical and consumer industries. Along with more than 50 years of experience, we bring customers quality, safety and reliability in injection molding, contract assembly and finished packaging from our eight locations throughout North America and Europe.

**WEST ANALYTICAL SERVICES:** has a vast expertise and experience in extractables and leachables, particle analysis, container closure integrity, and performance and packaging/delivery systems among other methodologies. The team's understanding of materials and delivery systems and their compatibility with the drug product can assist customers in designing studies and in navigating the challenging and evolving regulatory landscape.

- **NYSE: WST**
- **10,000+ GLOBAL TEAM MEMBERS**
- **FOUNDED IN 1923**
- **2024 SALES: $2.89 BILLION**
- **OVER 41 BILLION COMPONENTS AND DEVICES SHIPPED ANNUALLY**

# ENVIRONMENTAL, SOCIAL, AND GOVERNANCE (ESG)

As a company with the mission to improve patient lives, it stands to reason that we are equally committed to a sustained investment in creating a healthier environment. West believes that, as a global organization, we have a duty and obligation to contribute to building a healthier world and that each of us, working together, can make a difference. We strive to be stewards of a sustainable future by factoring environmental considerations into every aspect of our business. We believe that sustainable practices are directly related to sustainable economic performance and the creation of healthy communities.

# A COMMITMENT TO QUALITY

An integral part of the healthcare industry, West is committed to delivering quality products that meet the exact product specifications and quality standards customers require and expect. This focus on quality includes excellence in manufacturing, scientific and technical expertise and management. A Patient-First Focus is part of West's DNA, and we take our responsibility to maintain patient safety very seriously. The slogan of "Every Dose, Every Time – 100% Commitment" is visible throughout West's manufacturing sites, a constant reminder of our commitment to quality.

# A CARING CORPORATE CITIZEN

West has a long and distinguished history of giving back to our communities, and a commitment to philanthropy is embedded in all that we do. The Company contributes to a wide range of organizations working to improve our world. The Herman O. West Foundation, an independently managed 501 (c) (3) entity sponsored by West, is committed to giving to children with special needs in the areas and communities where West employees live and work. Additionally, the West without Borders employee-led fundraising campaign encourages active participation at every local West site.

## HEADQUARTERED IN EXTON, PENNSYLVANIA, USA, WEST OPERATES ACROSS 50 LOCATIONS, INCLUDING 25 MANUFACTURING FACILITIES WORLDWIDE:

ARGENTINA | AUSTRALIA | BRAZIL | CHINA MAINLAND | COLUMBIA | DENMARK | ENGLAND FRANCE | GERMANY | INDIA | IRELAND | ISRAEL | PUERTO RICO | SERBIA | SINGAPORE | SPAIN | SOUTH KOREA | TAIWAN REGION | UNITED STATES

West Pharmaceutical Services, Inc. I 530 Herman O. West Drive, Exton, PA 19341

Important product and safety information and warnings available at: https://www.westpharma.com/products/self-injection-platforms/smartdose/smartdose-3-5, https://www.westpharma.com/products/self-injection-platforms/selfdose, and https://www.westpharma.com/products/vial-adapter-systems/vial-adapters.



For complete contact information please visit www.westpharma.com.



#11800 • 0425

## 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 Excipients

**ABITEC** manufactures lipid-based excipients to enhance the bioavailability of poorly water-soluble and poorly permeable APIs, in accordance with cGMP and IPEC guidelines in ISO-certified facilities. Lipids for LNP Therapeutics - With a catalogue of over 3000 lipid chemistries and the ability to customize and manufacture GMP lipids at scale. ABISORB-DC™ is ABITEC's co-processed excipient system for the direct compression of liquid lipids. The ABISOL™ Emulsion Preconcentrate Kit is a series of preconcentrates for the formulation of self-emulsifying drug delivery systems. CAPTEX medium chain triglycerides, CAPMUL mono- and diglycerides, and ACCONON pegylated esters formulate self-emulsifying drug delivery systems. ABITEC lipid excipients are the ideal starting point when formulating BCS Class II & IV (poorly water soluble) and BCS Class III & IV (poorly permeable) molecules. For more information, visit ABITEC at **www.abiteccorp.com.**

## CDMO+CRO Services

**Abzena** is the leading end-to-end CDMO + CRO for bioconjugates (ADCs, AOCs, RDCs), bispecifics & complex biologics. From discovery through commercial, we support customers with integrated programs and individual services designed to de-risk and streamline the development of new treatments for patients in need. Our comprehensive services for biopharmaceuticals include antibody discovery & design, protein engineering & developability, lead candidate selection, analytics & bioassays, immunogenicity, mammalian cell line development, bioconjugation & complex chemistry, linker-payload design & synthesis, analytical method development, formulation development, process development & cGMP manufacturing, technology transfer & scale-up, master cell banking, and regulatory support. Discuss your program with our experts today and discover how Abzena can help move your program forward faster. For more information, visit Abzena at **https://abzena.com/about/why-abzena/** or contact **info@abzena.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.**

## Global CDMO

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

## Analytical Solutions for Biologics

**ARL Bio Pharma** is a contract testing laboratory that assists biotechnology and pharmaceutical innovators in developing safe and effective therapies. Our laboratory offers comprehensive analytical and microbiological testing to evaluate product safety, stability, and quality at every stage of drug development, from formulation to regulatory submission. Leveraging technologies such as high-resolution mass spectrometry, qPCR, and ELISA, we analyze the molecular structure, purity, and consistency of small molecules, monoclonal antibodies, peptides, and cell and gene therapies. Our laboratory is an extension of our clients' research teams, delivering critical insights that empower clients to make informed decisions and expedite their product's time-to-market. ARL Bio Pharma is FDA-registered, DEA-licensed for Schedules I through V, and ISO 17025:2017 accredited. For more information, visit **www.arlok.com.**

## Manufacturing Facility


**Ascendia® Pharma's** expanded state-of-the-art 60,000 sq./ft. R&D and manufacturing facility provides cGMP manufacturing formulation development, processing and scale-up along with toxicity and clinical trial materials with commercial supply for sterile and non-sterile dosage forms, including ophthalmic, parenteral, topical, and oral. Its facility includes the Netzsch Vakumix for state-of-the-art aseptic processing, and a complete suite of Precision NanoSystems equipment to provide comprehen-sive lipid nanoparticle manufacturing. For more information, visit Ascendia at **www.ascendiapharma.com.**

## KinetiSol™ Technology

AUSTINPx™
PHARMACEUTICS / MANUFACTURING

**AustinPx's** KinetiSol™ Technology, offering superior sustainability, scalability, and performance, is revolutionizing amorphous solid dispersion development and manufacturing. A fusion-based, solvent-free process, KinetiSol rapidly transitions crystalline drug and polymer into an amorphous solid dispersion in as little as seven seconds. With its significantly smaller ecological footprint, broader formulation design space, faster processing times and wider application, KinetiSol is enabling the development of challenging APIs and setting new standards in sustainability, scalability, and performance. For more information, visit AustinPx at **www.austinpx.com.**

## Quality Excipients & APIs

BASF
We create chemistry

**BASF Pharma Solutions** is a leading provider of innovative and high-quality excipients and APIs for the pharmaceutical industry. Our dedicated team of industry experts, supported by our cutting-edge digital solutions, works closely with customers to develop efficient and reliable formulations. Based in Florham Park, United States, our operations span across the globe, with production facilities that spread across multiple continents, we are able to provide support and solutions to pharmaceutical industries worldwide. At BASF, we prioritize the production of pharmaceutical ingredients in accordance with the highest quality standards. With over 75 years of experience, we offer the expertise and continuity necessary to meet the diverse needs of your pharmaceutical business. For more information, visit BASF Pharma Solutions at **https://pharma.basf.com/general-contact.**

## Global CDMO

BESPAK

**Bespak** is a global CDMO solely focused on inhaled drug development. It specializes in inhaled drug products, drug delivery devices, and components for the global pharmaceutical market. Headquartered in Holmes Chapel, UK, Bespak provides a specialist, fully integrated services to support customers from early stage feasibility, analytical and formulation, product development, and clinical supply, through to full-scale cGMP batch production. With a long history in the development and commercial supply of pMDIs, Bespak supplies a major proportion of the world's pMDI dosing valves and actuators. It also specializes in the industrialization and high-volume manufacture of complex DPI devices, offering industry-leading contract manufacturing services at all scales. Through a joint venture with Medspray, Bespak offers Resyca Soft Mist Inhalers and nasal soft mist atomizers. For more information, visit Bespak at **www.bespak.com.**

## Global CDMO

BIOVECTRA
A part of **Agilent**

**BIOVECTRA**, now part of Agilent Technologies, is a global biotech and pharmaceutical CDMO that specializes in clinical-to-commercial-scale production capabilities for biologics, small molecules, bioreagents, pDNA and mRNA manufacturing, and fill/finish. Flexibility, creativity, process optimization, and compliance are at the heart of our method. With more than 50 years of experience and cGMP facilities in Canada we assure our programs advance on time and with the highest quality outcomes. Our teams leverage a proven track record of excellence to optimize, adapt, and perfect innovative technologies and drug substance development approaches to deliver world-class solutions for pharmaceutical manufacturing. Learn more at **www.BIOVECTRA.com.**

## Formulation Technology

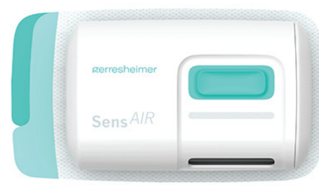
CAPTISOL®
BROUGHT TO YOU BY LIGAND PHARMACEUTICALS

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.**

## Advanced Nanotechnology Equipment

**Genizer LLC** provides robust and elegantly engineered capital equipment for all your nano development or production needs. Genizer LLC is located in Technology Link in Greater Los Angeles. We also have an office just outside Boston, MA, along with a strong network of global distributors and partners. For 15 years, we have been dedicated to advancing NANOTECHNOLOGY. We offer scalable solutions from very small R&D amounts to large manufacturing amounts across all our technologies. Genizer LLC manufactures a full line High Pressure Homogenizers, Liposome Extruders (in both on-line and off-line versions), Sanitary Heat Exchangers, Diamond Interaction Chambers, and High Pressure Gauges; of which, most are compatible with other brands of high-pressure homogenizers and high pressure pumps. We offer qualified product testing services and demo units upon request. For more information, visit Genizer LLC at **https://www.genizer.com/.**

## On-Body Drug Delivery




**SensAIR** is a platform for on-body drug delivery that can deliver drugs of higher viscosity, such as monoclonal antibodies. The aim is to provide patients with the best possible support in the subcutaneous delivery of large-volume biologics. The ready-to-use SensAIR On-Body Delivery Device is easy to use and enables patients to start medication in a self-determined manner in familiar surroundings. The SensAIR On-Body Delivery Device can be adapted to medications of different viscosities and with different requirements. This applies to the size of the medical device as well as to the needle used, variable cartridge sizes and possible connectivity, for example to the patient's smartphone. Together with Gerresheimer's One-Stop-Shop quality promise, which includes a solution from the cartridge to the drug delivery device from a single source, SensAIR enables optimized delivery of biologics. For more information, visit Gerresheimer at **www.gerresheimer.com.**

## Pharmaceutical Services

**Halo Pharma** is a leading provider of pharmaceutical services, including contract dosage form development, commercial manufacturing and analytical services. Our capabilities in the areas of tech transfer, process and pharmaceutical product development, formulation development, production, scale-up and validation, and analytical method development allow us to partner with clients from development through commercialization or at any point along the way. Our expertise across many dosage forms, including complex oral solids, topicals, oral solutions and suspensions and the manufacture of controlled substances is unmatched in North America. Halo Pharma serves a growing global customer base across multiple regulatory environments. These attributes allow Halo Pharma to be a partner of choice for many of today's large pharma, generic pharma and biotech pharma companies. For more information, visit Halo Pharma at **www.halopharma.com.**

## CDMO Specialist

**HCmed** is a CDMO specializing in drug–nebulizer combination products. Leveraging proprietary mesh nebulizer technologies, we provide cost-efficient, low-risk, and fully customizable development solutions. From concept to commercialization, HCmed collaborates with pharmaceutical partners to create world-class inhalation therapies, optimizing aerosol delivery for both small molecules and biologics. Our mission is to provide tailored, high-performance nebulizer solutions that break the limits of inhaled drug development and help bring innovative treatments to patients worldwide. For more information, visit HCmed at **https://www.hcmed-inno.com.**

## Contract Development, Manufacturing & Testing

**Kenox Pharmaceuticals** is a specialty contract development, manufacturing, and testing organization focused on advancing nasal, inhalation, and ophthalmic drug products. We provide comprehensive support from early-stage research, formulation development through GMP fill-finish and analytical testing, enabling the successful execution of Phase I and II clinical trials. Our expertise spans both non-sterile and sterile drug-device combination products, ensuring quality and reliability across diverse development programs. What sets Kenox apart is our deep technical knowledge, broad industry experience, and proven flexibility in managing complex device technologies. From conventional inhalers to advanced platforms such as Soft Mist inhalers, we deliver tailored solutions that meet the evolving needs of innovative drug delivery. For more information, visit Kenox Pharmaceuticals at **https://www.kenoxpharma.us/.**

## Client-Centric CDMO

Founded in 2003, **LATITUDE Pharmaceuticals Inc.** is a client-centric CDMO specializing in innovative drug formulation, analytical testing, preclinical supplies and GMP manufacturing to support drug programs in human and animal health. With more than 1,250 projects completed, LATITUDE is recognized for overcoming challenges in solubility, stability, bioavailability, and in vivo tolerability. Our experienced scientists excel in challenging formulations such as complex nanoemulsions, lipid nanoparticles, oral peptide tablets, PLGA microspheres, high-loading suspensions and high-loading peptide solutions, while our GMP facility enables rapid production of sterile injectables, ophthalmics, oral, and topical formulations for Phase 1 through non-pivotal Phase 3 trials. Through scientific creativity, technical depth, and operational agility, LATITUDE Pharmaceuticals continues to help clients transform challenging molecules into stable, clinic-ready drug products. Visit **www.latitudepharma.com** for more information.

## PREMIER CDMO

**LGM Pharma** is a premier CDMO specializing in Active Pharmaceutical Ingredient (API) sourcing, analytical testing, drug product development and GMP commercial manufacturing for pharmaceutical, biotech, and compounding pharmacy industries. We support clients through every phase of drug development, from API sourcing to commercialization. Our global network of qualified API partners ensures optimized supply chain management and distribution. Core services include API procurement, formulation development, method validation, ANDA/NDA submissions, stability studies, and testing. With a strong regulatory track record and expert market intelligence, LGM Pharma delivers tailored solutions that reduce risk, enhance efficiency, and accelerate commercialization. Committed to quality and customer service, we partner with clients to meet their unique needs while driving innovation in pharmaceutical manufacturing. For more information, visit LGM Pharma at **lgmpharma.com.**

## U.S.-BASED CDMO


Unsure your filling needs will be fulfilled? Have a complex injectable product or process?We say, “Bring it.” We’re creative problem solvers who enjoy helping our customers find solutions. **Lifecore** is a U.S.-based Contract Development and Manufacturing Organization specializing in the development, fill/finish, and commercialization of sterile injectables. With a 40+ year regulatory track record and 20+ commercial products, Lifecore offers end-to-end services with experience spanning straightforward to complex formulations. We support organizations of all sizes across pre-clinical, clinical, and commercial stages. Lifecore is also a leading producer of pharmaceutical-grade, non-animal-sourced sodium hyaluronate which is used as an API and excipient. For more information, visit Lifecore at **https://www.lifecore.com/.**

## GLOBAL DEVELOPMENT PARTNER

**Lonza** is one of the world’s largest contract development and manufacturing organizations (CDMOs) dedicated to serving the healthcare industry. Working across five continents, our global team of around 18,500 colleagues works alongside pharma and biotech companies to turn their breakthrough innovations into viable therapies. We support our customers in bringing life-saving and life-enhancing treatments to patients worldwide with a combination of cutting-edge science, smart technology and lean manufacturing.Our business is structured to meet our customers’ complex needs across three synergistic Business Platforms: Integrated Biologics, Advanced Synthesis and Specialized Modalities. Our services span from early development to drug substance and drug product manufacturing, and we lead in both established and emerging technologies including mammalian biologics, small molecules, highly potent active pharmaceutical ingredients (APIs), bioconjugates, mRNA, microbial, and cell and gene. For more information, visit Lonza at **www.lonza.com.**

## 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.

## TAILORED DRUG DELIVERY

**Mikart**, a CDMO specializing in pharmaceuticals, provides comprehensive solutions for formulation development, manufacturing, packaging, and regulatory support for solid oral dosages, liquids, semi-solids, and more. Mikart specializes in tailoring drug delivery technologies, optimizing processes, and ensuring compliance with industry regulations. Mikart operates from a state-of-the-art 150,000-sq-ft facility in Atlanta, GA, which boasts cutting-edge equipment and technologies for pharmaceutical development and manufacturing across various dosage forms. It includes specialized areas for formulation development, analytical laboratories, multiple manufacturing suites equipped for different types of drug products, packaging capabilities, and storage areas compliant with industry standards and regulatory requirements. Mikart's facility is designed to accommodate the diverse needs of clients in the pharmaceutical industry. Bringing innovative pharmaceutical products to market requires a reliable partner like Mikart. For more information, visit Mikart at **let-mikart-support-your-drug-development-and-manufacturing-needs.**

## FUNCTIONAL CHEMICALS

**Mitsubishi Gas Chemical (MGC)** is a leading company in the field of functional chemicals, such as oxygen barrier and absorbing polymers. MGC established the Advanced Business Development Division in 2015 for tackling a variety of today’s problems, and the division created OXYCAPTTM 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.**

## Excipient & API Manufacturing

**Nanjing Well Pharmaceutical Group Co., Ltd.,** a high-tech enterprise from China specializing in R&D, manufacturing, and supplying pharmaceutical excipients and APIs. Our factory is located in Nanjing National New Materials Technology Park. We are currently one of the largest suppliers of pharmaceutical excipients for solid, semi-solid, and liquid preparations in China, with annual sales of more than 10,000 tons and sales of more than 40 million US dollars. We maintain long-term and stable cooperation with more than 1,000 pharmaceutical companies at home and abroad, such as Johnson & Johnson, GSK, Novartis, Bayer, and other multinational pharmaceutical companies. For more information, visit **http://en.well-js.com/.**

## Patient-Focused Delivery Devices

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

## Research Chemical Supplier

**Oakwood Chemical** wants to be your research chemical supplier of choice. Since our founding 30+ years ago as a research chemical supplier specializing in fluorine and sulfur chemistry, we have remained focused on providing our customers the chemicals needed to advance science. Our catalog of over 45,000 chemicals includes a comprehensive collection of the essential chemicals needed to perform the broad range of reactions that enable discovery research. In addition, we have increased our in-house production capacity to provide support for both catalog products and custom synthesis projects, while also increasing our overall scale to support development efforts. Our experience in manufacturing, sourcing, and handling a wide range of chemicals enables us to respond quickly and efficiently to your research chemical needs. For more information, visit Oakwood Chemical at **www.oakwoodchemical.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.**

## Global End-to-End CDMO

With over 4300 customer-centric employees and commercial operations across the US, EU, and China, **Porton J-STAR** provides pharmaceutical and biotech companies with innovative, reliable, end-to-end process R&D and GMP manufacturing services for Drug Substance and Drug Product across Small Molecules, Tides, Biologics and Conjugates. Porton J-STAR is recognized for our process innovation, supply chain performance and compliance with global Quality and EHS standards. Constantly striving for excellence and enabling the public's early access to good medicines. Porton has steadily added and continues to expand in the areas of Process Chemistry, Analytical R&D, QC/QA, GMP delivery, Crystallization R&D, Solid State and Catalysis Screening, Enabling Technologies, High Potent Compound Handling (HPAPI), Impurity Isolation and Structural Elucidation, Pre-formulation, Drug Product Formulation R&D, and Oral Solid Drug Product GMP manufacturing. For more information, visit Porton J-STAR at **https://www.portonpharma.com/.**

## Specialized CDMO

Since our founding 20 years ago, **ProMed Pharma** has endeavored to be your preferred development partner for long-acting injectable and implantable dosage forms. Our proficiency spans molding, extrusion, and microencapsulation techniques, leveraging polymeric excipients, including silicones, thermoplastics, and biodegradables. Key markets for our services include women's health, ophthalmology, oncology, and neurological disorders. Representative drug-device applications include steroid-eluting pacing and defibrillation leads, implantable sensors, antimicrobial eluting devices, and sinus stents. ProMed also supports pharmaceutical companies developing extended-release formulations utilizing subcutaneous implants, intratumoral pellets, intrauterine devices, intravaginal rings, and ophthalmic inserts. Whether you represent an emerging biotech venture or a global pharmaceutical entity, entrust us as your CDMO partner, as we diligently translate scientific concepts into finished dosage forms. For more information, visit ProMed Pharma at **www.ProMedPharmaLLC.com.**

## Integrated Drug Product, Manufacturing, & Clinical Services

**Quotient Sciences** is a pharmaceutical development & manufacturing accelerator offering fully integrated programs and tailored services from candidate selection through commercial manufacturing. Our seamless integration of drug product development, manufacturing, and clinical testing services, results in a more efficient and accelerated development plan. Integrating all activities under a single organization in an entirely non-siloed way encourages close relationships between multidisciplinary experts, creating a more agile approach to pharmaceutical development. The ultimate benefit is a significant cost savings & shortening of the timeline from candidate selection to clinical development, which in turn allows us to get medicines to patients faster. For more information, visit Quotient Sciences at **www.quotientsciences.com.**

## Technology-Focused Biomanufacturing

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

## Excipients & Ingredients

**Roquette Health & Pharma Solutions** offers a broad and versatile portfolio of reliable excipients designed to enhance productivity, cost efficiency, and supply stability across the pharmaceutical and nutraceutical value chain. Our plant-based, high-quality, and multi-compendial excipients support a wide range of applications, from prescription and OTC drugs to generics, nutraceuticals, and biopharmaceuticals. With a strong focus on innovation, Roquette also delivers specialty ingredients that help customers optimize formulations and maintain consistent performance while meeting stringent global standards. By combining robust sourcing capabilities with scientific expertise, we help our partners improve development speed, strengthen supply security, and advance patient outcomes. For more information, visit Roquette Health & Pharma Solutions at **www.roquette.com/pharma.**

## Science-First CDMO

**Serán BioScience** is a science-based CDMO specializing in a variety of drug delivery and formulation approaches suited to optimizing bioavailability. Serán's experienced team works with you to identify an appropriate technology and formulation strategy to meet your program's unique needs. Our comprehensive approach to formulation design considers the physiochemical properties of the API, the target product profile, and your program's objectives and constraints to develop scalable formulations using material-sparing approaches. Serán provides capsules, tablets, multi-particulates (coated beads), and powder-in-bottle formulations. Our solid dosage forms are engineered for a wide range of formulation approaches, such as overcoming solubility challenges and to enable extended release. We complement industry-best production practices with the finest manufacturing equipment available to produce dosage forms that perform predictably and reliably. For more information, visit Serán Bioscience at **www.seranbio.com.**

## Contract Service Provider

**Singota** is a cGMP-compliant contract service provider to the life sciences industry, offering outsourcing partnerships for formulation development, testing, labeling and kitting, and supply chain services. Headquartered in Bloomington, IN, Singota has more than 50 employees with many years of valuable experience in the pharmaceutical and biotechnology industries. Singota Solutions is a dba of BioConvergence, LLC. For more information, visit Singota at **www.singota.com.**

## Accelerate Drug Development

Small molecule drugs currently account for over 90% of approved medicines on the market, forming the foundation of the pharmaceutical industry. At **Thermo Fisher Scientific**, we offer integrated, end-to-end CDMO and CRO services for oral solid dose (OSD) forms — the gold standard in drug delivery. From early phase drug formulation to late-phase process optimization, we help you save time, money, and active pharmaceutical ingredients (APIs). And with nine state-of-the-art facilities worldwide, we provide global expertise in OSD development and manufacturing, including for high-potency APIs. Let's turn your vision into reality. For more information, visit Thermo Fisher Scientific at **www.thermofisher.com.**

## CDMO Services


**UPM Pharmaceuticals** is CDMO with 30+ years of US based experience in development to later-stage clinical and commercial manufacturing of oral solid and semi-solid dosage forms. Beyond our expertise and technology, UPM is a contract manufacturing organization that has a passion for propelling our customers' journeys from early-stage development to the market, even when the journey doesn't begin with us. As a large-scale CDMO, technology transfer and scale-up are our specialties; we welcome the opportunity to sit down with you to create a pharma solution by understanding the evolution of your project, your clinical and commercial goals, and how we can work together to get your product across the finish line. For more information, visit UPM Pharmaceuticals at **www.upm-inc.com.**

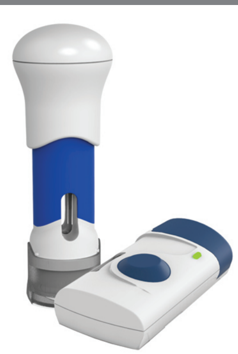
## Integrated Services

**Upperton** is a UK-based CDMO providing integrated contract development and manufacturing services. Specializing in oral, nasal, pulmonary, and sterile dosage forms, Upperton offers a comprehensive range of services designed to support the progression of a molecule from early feasibility through to formulation development, clinical trial manufacture and commercial manufacture. For more information, visit Upperton at **www.upperton.com.**

## Full-Service CDMO

**Vetter** is a leading independent contract development and manufacturing organization (CDMO) specializing in clinical and commercial aseptic filling and packaging as well as the assembly of syringes, cartridges, and vials. With extensive expertise in biologics and other complex compounds, Vetter collaborates with pharma and biotech companies worldwide to support their unique products from preclinical development through to global market supply. With state-of-the-art facilities in the US and Europe, the CDMO provides comprehensive support for early stage products, transfer to Phase 3, and commercial supply for large-scale production. Vetter's commitment to quality and innovation results in reliable and efficient solutions tailored to meet the needs of each customer. For more information, visit **www.vetter-pharma.com.**

## Injectable Solutions & Services



**West** is a leading provider of innovative, high-quality injectable solutions and services. As a trusted partner to established and emerging drug developers, West helps ensure the safe, effective containment and delivery of lifesaving and life-enhancing medicines for patients. With over a century of experience, we work together with our customers to support patient health and fuel a brighter future with product innovation: stoppers and seals for injectable packaging systems, syringe and cartridge components,self-injection systems, containment and delivery systems, and contract manufacturing and analytical services. West works by the side of customers from concept to patient to develop products that promote the efficiency, reliability, and safety of the world's pharmaceutical drug supply. For more information, visit West at **www.westpharma.com.**

## Sterile Solutions

**Woodstock Sterile Solutions** is a global provider of best-in-class sterile development and manufacturing solutions – with a decades-long track record of helping healthcare companies advance molecules through clinical development into full-scale commercial production. Throughout our 50-year history, Woodstock has been a leader in developing and deploying advanced aseptic blow-fill-seal delivery products. For more information, visit Woodstock Sterile Solutions at **www.woodstocksterilesolutions.com.**

# Nov/Dec 2025 Advertiser Index

| COMPANY | PAGE | CONTACT | WEBSITE |
|---|---|---|---|
| AbbVie Contract Manufacturing | 2, 46, 47 | abbviecontractmfg@abbvie.com | www.abbviecontractmfg.com |
| ABITEC Corporation | 48, 49 | | www.abiteccorp.com |
| Abzena | 50, 51 | info@abzena.com | www.abzena.com |
| Adare Pharmaceuticals | 52, 53, 140 | BusDev@adareps.com | www.AdarePharmaSolutions.com |
| Almac | 56, 57 | almacanalytical@almacgroup.com | https://www.almacgroup.com/analytical-solid-state/ |
| Aptar Pharma | 58, 59 | info.pharma@aptar.com | https://www.aptar.com/pharmaceutical/ |
| ARL Pharma | 60, 61 | info@arlok.com | www.arlok.com |
| Ascendia Pharma | 7, 62, 63 | bd@ascendiaCDMO.com | www.ascendiacdmo.com |
| BD Medical Pharmaceutical Systems | 64, 65 | US: 800-225-3310 EU: +33 4 76 68 36 36 | www.drugdeliverysystems.bd.com |
| Bespak | 66, 67 | +44 (0) 1477 537 112 | https://bespak.com/ |
| BIOVECTRA | 68, 69 | solutions@biovectra.com | https://www.biovectra.com/ |
| Captisol (Ligand) | 3, 70, 71 | (858) 550-5632 | www.Captisol.com |
| Celanese | 72, 73 | healthcare@celanese.com | www.vitaldose.com |
| Credence MedSystems | 74, 75 | info@CredenceMed.com | www.CredenceMed.com |
| Croda | 76, 77 | | www.crodapharma.com |
| DDL | 9, 79 | ddlinforequests@ddltesting.com | https://www.ddltesting.com |
| Dissolution Testing Handbook | 13 | | www.dissolutiontech.com |
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| Gattefosse | 82, 83 | infopharma@gattefosse.com | www.gattefosse.com |
| Genizer "Solutions for Nano" | 84, 85 | 949-932-0294 | https://www.genizer.com/ |
| Hcmed Innovations Co. | 86, 87 | info@hcmed-inno.com/chris.vernall@hcmed-inno.com | https://www.hcmed-inno.com |
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| Kenox | 90 | bd@kenoxpharma.us | https://www.kenoxpharma.us/ |
| Latitude Pharmaceuticals Inc. | 11, 91 | Info@latitudepharma.com | www.latitudepharma.com |
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| Mitsubishi Gas Chemical | 100, 101 | +81 3 3283 4913 | www.mgc.co.jp/eng/products/abd/oxycapt.html |
| Oakwood Chemical | 102, 103 | sales@oakwoodchemical.com | www.oakwoodchemical.com |
| Pace Life Sciences | 104, 105 | (610) 279-7450 | www.pacelifesciences.com |
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