Drug Development® & Delivery

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Company Profiles & Capabilities

The science & business of drug development in specialty pharma, biotechnology, and drug delivery

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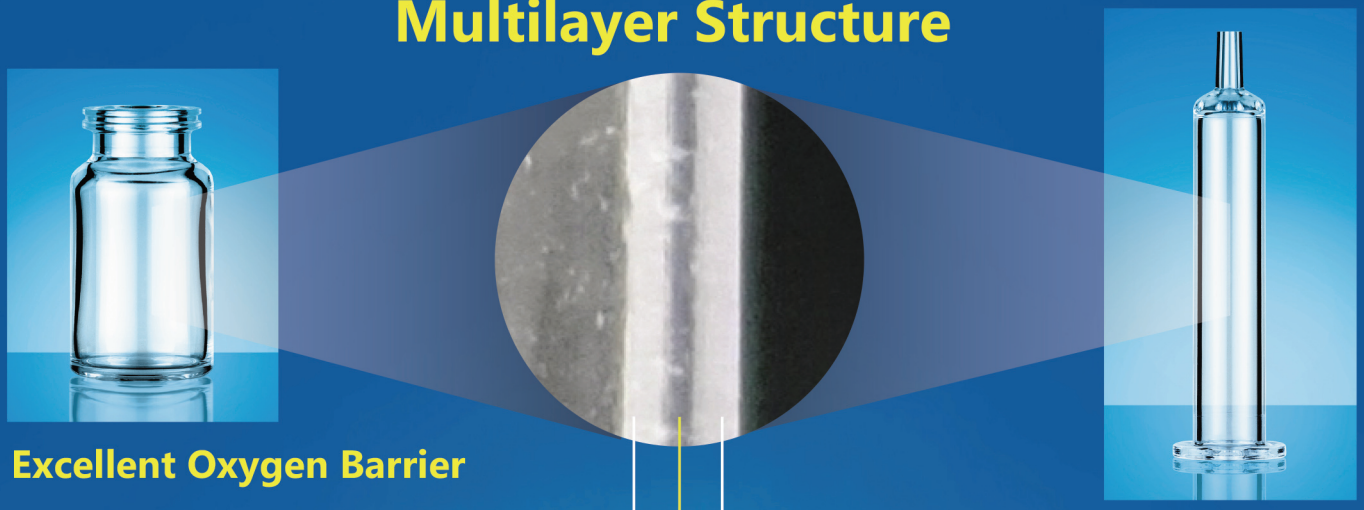

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Real World Challenges
in *Drug Delivery and Formulation*

The Objective

Need to understand the changing dynamics of clinical-stage pipelines by indication, molecule type and most advanced phase to present to senior management

The Challenge

How do I obtain this information in a format that will allow me to quickly evaluate overall trends in pharmaceutical development?

The PharmaCircle Solution

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Atlas Nanotech Targets the World's Largest Consumer Health Products Companies

Costas, Inc. DBA/Atlas Nanotech, (the Company) is currently in discussions to license their proprietary nanotechnology vitamin a (retinol) based crystalline eye drops known under the trade name NANO CLEAR A, to the leading eye drop manufactures, by licensing Nano Clear A to existing top tier eye drop manufactures it will allow the product to be widely used at a rapid pace.

Atlas Nanotech's business model is to develop and patent unique nanotechnology products. These unique proprietary products are then licensed to leading manufactures to enhance the performance of existing product offerings. The Company's scientific team is confident in its ability to license existing products and continue to develop additional nanotechnology products that the company will license to some of the world's leading biotechnology, pharmaceutical and consumer products manufacturers.

The Company is dedicated to offering their proprietary NANO CLEAR A to all industry leaders in the eyedrop and lubricants market. This approach will allow each licensee to brand and market this revolutionary nanotechnology to fit within their existing brands and product offerings. Industry leaders in the global eye drops and lubricants market include Novartis International AG (Alcon, Inc.), Akorn Consumer Health (Thera Tears), Johnson & Johnson (Visine), Pfizer, Similasan Corporation USA, Sager Pharma Kft., Prestige Consumer Healthcare, Inc., Allergan PLC. and Valeant Pharmaceuticals International, Inc. (Bausch & Lamb, Inc.) just to name a few. The Company is currently establishing communications with a number of industry leaders in this market.

The development to be known as NANO CLEAR A represents the culmination of research initiated by Dr. Aldo Oregon Miranda an ophthalmologist surgeon and member of the scientific advisory board of Atlas Nanotech, in collaboration with Professor David De La Mora Atlas' Chairman.

The global eye drops and lubricants market size was valued at $1.8 billion for 2018 and is projected to register substantial growth through 2025. The growth within this segment will be driven by the aging demographics across the globe and the prevalence of ophthalmic disorders worldwide. Management is confident with strategic licensees' NANO CLEAR A will become the standard in the industry driving top line revenue at a rapid pace.

Costas Inc. has been trading under the symbol CSSI since the year 2014. With the recent acquisition of the Guadalajara-based nano-medical firm Atlas Nanotech, it now enters the new dynamic market of nanotechnology development and manufacturing. For more information, visit Atlasnanotech.com.

CURE Pharmaceutical Takes First Step to Acquire Coeptis Pharmaceuticals

CURE Pharmaceutical recently announced it purchased a $200,000 convertible promissory note issued by Coeptis Pharmaceuticals, Inc., a biopharmaceutical company engaged in the acquisition, development and commercialization of branded 505(b)(2) pharmaceutical products. This note represents an initial step toward a potential acquisition of the company and the exclusive rights to Coeptis' approved drug Consensi, the first fixed-dose combination drug for the treatment of comorbid osteoarthritis and hypertension.

"The planned acquisition has the potential to accelerate our 505(b)(2) drug pipeline and expedite our growth with a planned 2020 launch of Consensi," said Rob Davidson, CEO of CURE Pharmaceutical. "Consensi's potential to reduce pill burden for patients fits our core mission to improve drug delivery and medication adherence."

CURE and Coeptis entered into a non-binding term sheet in furtherance of an acquisition for which the final terms and valuation are to be determined. Additional information concerning this acquisition can be found in the Company's Form 8-K filed with the Securities and Exchange Commission on November 14, 2019.

CURE Pharmaceutical is a vertically integrated drug delivery and development company committed to improving drug efficacy, safety, and the patient experience through its proprietary drug dosage forms and delivery systems. CURE has a full-service cGMP manufacturing facility and is a pioneering developer and manufacturer of a patented and proprietary delivery systems (CURE-form™), including CUREfilm® one of the most advanced oral thin film on the market today. CURE is developing an array of products in innovative delivery platforms and partners with wellness brands, dietary supplement, biotech and pharmaceutical companies. CURE has positioned itself to advance numerous therapeutic categories, including the pharmaceutical cannabis sector with partnerships in the U.S., Canada, and Israel. The company's mission is to improve people's lives by redefining how medicines are delivered and experienced. For more information, visit www.curepharma.com.

Coeptis Pharmaceuticals, Inc. is a privately held biopharmaceutical company engaged in the acquisition, development and commercialization of innovative products that utilizes the 505(b)(2) pathways. Coeptis licensed FDA-approved Consensi (a combination of amlodipine and celecoxib), which is indicated for patients for whom treatment with amlodipine for hypertension and celecoxib for osteoarthritis are appropriate. Of the 30 million adults in the US diagnosed with osteoarthritis, 40% also suffer from hypertension. It is in the process of launching Consensi® in the US through a distribution partner with an established sales network to thousands of pharmacies nationwide. Headquartered near Pittsburgh, PA, Coeptis has put together seasoned pharmaceutical executives with demonstrated successes growing revenues and shareholder value and has a robust pipeline of 505(b)(2) products at various stages of development. For more information, visit www.coeptispharma.com.

New Study from Tufts Center for the Study of Drug Development Establishes Benchmarks

While more than 90% of all contract vendor assessments conducted by drug sponsors ultimately lead to vendors being qualified to provide services, large sponsors have significantly longer and more variable process completion-to-contract stages than other companies, according to a newly completed study from the Tufts Center for the Study of Drug Development that establishes the first industrywide benchmarks of the vendor qualification process.

The global drug development industry conducted nearly 25,000 new vendor qualifications, requalifications of existing vendors, and requests-for-information (RFIs) in 2018. Average total cycle time from an RFI to a signed contract was 19.0 weeks for single-service providers and 26.1 weeks for multi-service providers, with wide variation observed by sponsor company size and by individual assessment, Tufts CSDD found.

"Evaluating external service providers is a time-consuming process that must meet the unique demands of each R&D program and account for, among other factors, regulatory compliance, information technology expertise, operating and financial controls and oversight," said Ken Getz, Professor and Deputy Director of Tufts CSDD. "The volume and complexity of assessments needed to qualify and requalify potential vendors is increasing and the benchmarks from this new study identify opportunities for drug developers to more effectively and efficiently manage this process."

The study, conducted in collaboration with The Avoca Group, was based on an analysis of data provided by 76 small, medium, and large pharmaceutical companies engaged in global drug development.

Among other key study findings summarized in the November/December Tufts CSDD Impact Report, were the following: - Small companies using leaner operating models have more productive qualification processes, compared to medium and large companies, Vendor requalification cycle times are two to four weeks faster, on average, than new vendor qualifications, Despite longer total assessment cycle times, large drug companies have the highest rates of vendors failing to qualify (11.5%), likely due to deeper inquiry into vendor practices, For all sponsor companies, vendor requalifications are 2.4 weeks and 4.0 weeks faster on average than new single and multi-service vendor qualifications, respectively.

The Avoca Group, based in Princeton, NJ, is a life science consulting firm dedicated to improving quality and compliance in clinical trial execution. Since 2011, the Avoca Quality Consortium®, a collaborative of over 100 pharma, biotech, CRO, and clinical service provider companies, has led the industry in developing practical solutions for improving quality and execution in clinical trials.

The Tufts Center for the Study of Drug Development (http://csdd.tufts.edu) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

PromoCell Now Offers In Vitro Disease Models That Could Lead to New Therapies

PromoCell now offers cell disease models covering a wide range of diseases, including diabetes type 1 and 2, respiratory diseases, such as COPD and asthma, as well as cardiomyopathy disease. Relevant models enable experiments under physiologic conditions and are key for developing new therapies for chronic diseases. With its greater range of cell disease models, PromoCell once again underlines its role as a dedicated supporter of scientific research and innovation.

"PromoCell now offers a large selection of donor cells with known disease status that are suitable for drug discovery and research applications," says Daniel Spatz, CBO of PromoCell. These disease cell types can be cultured using PromoCell's matching growth media to ensure optimal growth performance. "Our diseased cells feature the same specifications and undergo the same rigid quality control tests as their healthy counterparts from our human primary cell portfolio," adds Dr. Irma Boercsoek, COO of PromoCell. The tests include cell factors marker characterization, growth performance and morphology.

A cell disease model is an in vitro culture of cells isolated from a tissue donor with a known disease condition. By studying cell disease models, researchers gain insights in how diseases develop and this also enables them to look for new molecular targets for specific therapies. In addition, cell disease models can be used for testing potential treatment approaches. With its comprehensive portfolio of products and services for human cell culture, PromoCell supports scientists worldwide in advancing research and developing safer drugs.

PromoCell GmbH, based in Heidelberg, Germany, is a biotech company that supplies researchers worldwide with tools and training for human primary cell culture and cell analysis. The company was founded in 1990. Today, PromoCell offers more than 7,000 human cell culture and cell biology products. As part of the human cell culture portfolio, the company offers human primary cells, stem cells and blood cells, as well as optimized products for cancer cell culture, including kits for 3D cell culture. PromoCell's cell biology products are used for in-depth analysis of cells in culture. The portfolio includes high-quality kits and reagents for cell biology, such as antibodies, ELISAs, cytokines, and growth factors.

As original manufacturer of all primary cells, stem cells and blood cells PromoCell is committed to the highest ethical and legal standards. When obtaining human tissue, the company strictly complies with European biomedical conventions, respects human rights, and protects donor privacy. Along with certified, high-quality products, PromoCell offers ISO certified professional training through its PromoCell Academy, founded in 2004. Find out more about PromoCell on the website or via its presence on Facebook, YouTube, Twitter, or LinkedIn.

Centogene Signs Collaboration Agreement With Pfizer

CENTOGENE recently announced a new data access and collaboration agreement with Pfizer Inc. The agreement grants Pfizer access to CENTOGENE's data repository, which may be used in the discovery and validation of novel genetic and biochemical targets for the potential development of new therapies for rare diseases.

"With what we believe to be the world's largest data repository of epidemiologic, phenotypic and clinical data in orphan diseases, CENTOGENE is fuelling the global knowledge base of rare disease patient populations," said Arndt Rolfs, CEO of CENTOGENE. "The potential for furthering the understanding of rare disease is extremely important for patients around the world, and we hope that today's collaboration agreement will help lead to better diagnosis and potential treatments for patients with rare diseases."

Under the terms of the agreement, CENTOGENE and Pfizer will work together to mine the data repository and jointly agree to any collaborative research projects designed to substantiate results of data mining. CENTOGENE will receive an upfront payment and will be eligible for additional research payments under any future collaborative research projects. Individual-level data from the repository will be managed, protected and shared with Pfizer in compliance with international data privacy regulations.

CENTOGENE's rare disease data repository integrates relevant structured and unstructured patient data, including clinical information; health records; and genetic, transcriptomic, proteomic, and metabolomic data. It also includes longitudinal data such as biomarker or patient recorded outcome, as well as diagnostic workflow data.

CENTOGENE is a commercial-stage company focused on rare diseases that transforms real-world clinical and genetic data into actionable information for patients, physicians, and pharmaceutical companies. The company's goal is to bring rationality to treatment decisions and to accelerate the development of new orphan drugs by using our knowledge of the global rare disease market, including epidemiological and clinical data and innovative biomarkers. Centogene has developed a global proprietary rare disease platform based on our real-world data repository with over 2 billion weighted data points from over 450,000 patients representing 115 different countries as of August 31, 2019, or an average of over 500 data points per patient.

The company's platform includes epidemiologic, phenotypic, and genetic data that reflects a global population, and also a biobank of these patients' blood samples. Centogene believes this represents the only platform that comprehensively analyzes multi-level data to improve the understanding of rare hereditary diseases, which can aid in the identification of patients and improve our pharmaceutical partners' ability to bring orphan drugs to the market. As of August 31, 2019, the company collaborated with over 35 pharmaceutical partners for over 30 different rare diseases.

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The company specializes in biodegradable sustained release dosage forms for proteins, peptides, nucleic acids and small molecules. Microspheres, liposomes, micro-nano suspensions are Integral's niche specializations, although we have developed numerous injectable and ophthalmic formulations.

Integral BioSystems invites collaborations that can be strictly on a CRO-basis to create drug products with compounds that already have IP protection, or as a co-developer with pharmaceutical companies to render repurposed drugs IP-protectable with Integral's proprietary drug delivery licensable innovations.

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Cytel Acquires MTEK Sciences, Further Expanding Advanced Real-World Analytics Capabilities

Cytel Inc. recently announced that it has acquired MTEK Sciences to further expand its advanced real-world analytics (RWA) capabilities. Cytel is showcasing its extensive range of RWA solutions for the first time at ISPOR Europe 2019 (November 2-6) at booth #C3-063. The acquisition of MTEK is the latest step in Cytel's journey to advance the field of modern data analytics.

The use of real-world data (RWD) from a variety of sources, such as information from electronic healthcare records and wearable devices, has the potential to expedite the design and implementation of clinical trials, facilitate product commercialization and better inform healthcare decision-making. As a result, many pharmaceutical companies are now looking to augment their clinical development and commercialization processes through its utilization.

"Complex RWD sets are now abundant in the healthcare sector, opening up a wealth of opportunity for pharmaceutical organizations of all sizes," said Joshua Schultz, Chief Executive Officer at Cytel. "Advanced and more sophisticated analytical methods and decision-modeling techniques are needed to harness RWD and turn it into trustworthy evidence. At Cytel, we're applying our long history of innovative statistical methods to RWD to generate cost-effective insights for our clients, and the acquisition of MTEK is another avenue where we are amplifying this approach."

Over the past 30 years, Cytel has been committed to facilitating more efficient and resourceful clinical development, including through pioneering the evolution of the adaptive clinical trial, an area MTEK has also excelled at. Cytel's team includes more than 100 specialist programmers and applied statisticians with direct experience in the area of RWA — from HEOR to the design of novel RWD-driven clinical trials. Together they are helping companies use RWD to support smarter clinical development and, through innovative approaches to comparative effectiveness research, create more efficient commercialization strategies.

MTEK Sciences specializes in using innovative methods such as machine learning models and Bayesian optimization to derive clinical insights from large and complex RWD. As such, the acquisition of the firm will allow Cytel to continue to build on its strong foundation in the RWA space.

Professor Edward Mills, Founding Partner and Director of MTEK, said, "Our experience has shown us that companies need to look beyond the confines of traditional analytical approaches if RWD is to positively transform clinical development. In working with Cytel, we're enhancing our combined ability to develop and deploy the novel solutions needed to confidently guide companies through this rapidly changing landscape."

Commenting on Cytel's attendance at ISPOR Europe 2019, Joshua Schultz added, "Three decades of rich statistical expertise and experience has guided the development of our cutting-edge RWA solutions — and we look forward to meeting with delegates to discuss how we can help them effectively leverage these to achieve their goals."

Cycle Pharmaceuticals & Catalent Partner to Develop Treatments for Rare Diseases

Cycle Pharmaceuticals Ltd. (Cycle) has recently signed an agreement with Catalent, Inc. to develop innovative formulations targeting rare disease patients. This agreement covers four products in rare metabolic and neurological disorders and each product will utilize Catalent's Zydis oral disintegrating tablet (ODT) and Zydis Ultra technologies.

Zydis technology is recognized as one of the world's best performing ODTs, and has well-established advantages over conventional oral dosage forms, including improved patient compliance, adherence and convenience. The Zydis Ultra platform is the company's next generation ODT technology and allows for increased drug load and better taste masking to be incorporated into its proven Zydis ODT dosage form.

Commenting on the agreement, Antonio Benedetti, CEO of Cycle said, "Cycle's core area of expertise is to improve rare disease medicines in order to make life easier for patients of all ages. These drug products will benefit patients with a broad range of unmet needs. Zydis technology has consistently proven its effectiveness in overcoming challenges faced by patients, such as swallowing difficulties and large pill burdens. Working in partnership with Catalent to apply the Zydis technology to Cycle's product pipeline will be life-changing for both patients and their caregivers."

Jonathan Arnold, President of Catalent's Oral Drug Delivery business, added "Catalent has proven experience and expertise in drug formulation and working with partners to bring new therapies to market quickly. The Zydis technology platform has been shown to be very versatile and effective in developing easy-to-administer dose forms for innovators, and having evaluated Cycle's molecules at our Swindon, U.K., facility, we believe them to be excellent candidates for further development."

Cycle is a pioneering pharmaceutical company, reimagining how drugs can benefit patients to make their lives easier and improve their quality of life at every stage. Specifically, Cycle focuses on three areas of pharmaceutical development: (1) Improving orphan drugs, which treat the under-served rare disease patient community, (2) Repurposing drugs – creating a new indication for an already existing drug; and (3) Generics – reinstating generic drugs previously available in the market.

With Headquarters in Cambridge, UK, and offices in Boston, MA, Cycle has developed unique partnerships with renowned universities around the world. For more information, visit www.cyclepharma.com.

Catalent is the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, gene therapies, and consumer health products. With over 85 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable clinical and commercial product supply. Catalent employs nearly 13,000 people, including approximately 2,400 scientists and technicians, at more than 35 facilities, and in fiscal year 2019 generated over $2.5 billion in annual revenue. Catalent is headquartered in Somerset (NJ), U.S. For more information, visit www.catalent.com.

Artelo Biosciences Announces Selection of Clinical Research Organization

Artelo Biosciences, Inc. recently announced it has selected Aptus Clinical Ltd. (Aptus) as its contract research organization (CRO) for the company's planned Phase 1b/2a randomized, placebo-controlled trial of ART27.13, its synthetic cannabinoid for the treatment of anorexia and weight loss associated with cancer. This latest agreement builds on earlier collaborations between Artelo and Aptus, which included feasibility studies, protocol design, and clinical site identification and selection. The ART27.13 program will continue to be under the operational stewardship of Artelo's UK subsidiary at the Alderley Park BioHub in Cheshire.

ART27.13 is a highly potent peripherally selective synthetic dual cannabinoid agonist believed to target peripheral cannabinoid receptors sending a feeding message to the brain. The combined Phase 1b/2a trial is expected to enroll up to 49 subjects at clinical sites within the UK. The study is designed to determine the most effective and well tolerated dose in cancer patients and evaluate activity using criteria such as weight gain, lean body mass, and improvement of anorexia.

Gregory D. Gorgas, President and Chief Executive Officer of Artelo Biosciences, commented "We are excited to expand our relationship with Aptus, which will allow us to leverage their broad experience as well as their understanding of local regulatory processes combined with a wide network of investigators and key opinion leaders. We look forward to providing further updates as we commence our Phase 1b/2a trial and advance our cancer anorexia program."

Steve McConchie, Chief Executive Officer of Aptus Clinical, added "We are honored to have been selected by Artelo to help oversee this important trial. Despite the fact that cancer-related anorexia affects about 60% of advanced stage cancer patients, there are no FDA approved drugs for this indication and only a few agents used off-label with limited efficacy. Clearly, patients deserve better and the profile of Artelo's product candidate is compelling."

ART27.13 is a potent, peripherally selective CB1/CB2 synthetic agonist that enables systemic metabolic effects, while minimizing central nervous system mediated side effects. ART27.13 has been previously evaluated in 205 subjects across five Phase 1 studies conducted by AstraZeneca plc. Existing clinical data with ART27.13 suggests meaningful potential for the treatment of cancer-related anorexia and weight loss as ART27.13 demonstrated a statistically significant and dose-proportional increase in body weight. In ongoing consultation with regulatory authorities, Artelo plans to advance ART27.13 as a multi-modal supportive care therapy for cancer patients suffering from anorexia or weight loss.

Artelo Biosciences, Inc. is a San Diego-based biopharmaceutical company, with fully owned subsidiaries in the UK and Ireland, dedicated to the development and commercialization of proprietary therapeutics targeting the endocannabinoid system. Artelo is rapidly advancing a portfolio of broadly applicable product candidates designed to address significant unmet needs in multiple diseases and conditions, including anorexia, cancer, pain, and inflammation.

Flexion Announces Clearance of NDA for Gene Therapy Candidate

Flexion Therapeutics, Inc. recently announced clearance of the company's Investigational New Drug (IND) application for FX201 in knee osteoarthritis (OA), a painful, chronic and progressive disease that affects more than 15 million adults living in the US. Flexion has initiated a Phase 1 multicenter, open-label, single ascending dose study and expects to treat the first patient by the end of this year.

FX201 is a helper-dependent non-integrating adenovirus containing the human interleukin-1 receptor antagonist (IL-1Ra) gene under the control of an inflammation sensitive promoter. Preclinical data show that gene expression persists for at least one year, and IL-1Ra expression increases in response to inflammation. Nonclinical safety and efficacy data submitted in the IND application demonstrated that a single administration of FX201 was well-tolerated, had no significant biodistribution outside the target tissues, and pharmacology studies with the rat, mouse, and horse orthologues showed symptomatic improvement and delay in disease progression.

The Phase 1, multicenter, open-label, dose-escalation trial will evaluate the safety and tolerability of FX201 in male and female patients, 30-80 years of age, with painful OA of the knee. The study is expected to enroll up to 24 patients across six sites in the US.

Prior to initiating the FX201 clinical program, Flexion formed a Scientific Advisory Board (SAB) of world-renowned gene therapy experts to provide on-going technical and strategic guidance as the company advances the clinical development of FX201.

As part of Flexion's ongoing commitment to expand scientific understanding of OA, Flexion co-sponsored a study to evaluate the potential of machine learning to measure and predict disease progression and its effects on bone shape. At ACR, Dr. Bodick and co-authors will present the results from the study which used machine learning to evaluate magnetic resonance imaging (MRI) data from the Osteoarthritis Initiative to develop a three-dimensional OA bone shape model of disease progression. The study looked at 47,858 knee MRIs (9,433 knees; 5,031 without OA), taken at various time points over an eight year period, with the aim of establishing a relationship between structure and clinical outcomes.

FX201 is a clinical stage, locally administered, gene therapy product candidate designed to stimulate the production of an anti-inflammatory protein, interleukin-1 receptor antagonist (IL-1Ra), whenever inflammation is present within the joint. Inflammation is a known cause of pain, and chronic inflammation is thought to play a major role in the progression of OA. By persistently suppressing inflammation, Flexion believes FX201 holds the potential to both reduce OA pain and modify the disease.

Flexion Therapeutics (Nasdaq:FLXN) is a biopharmaceutical company focused on the development and commercialization of novel, local therapies for the treatment of patients with musculoskeletal conditions, beginning with osteoarthritis, a common form of arthritis. The company's core values are focus, ingenuity, tenacity, transparency and fun.

CDMO SELECTION

Ready to Launch: Developing Your Biologic With an Eye Toward Commercial Supply

By: Stacey Treichler, PhD

INTRODUCTION

The process of successfully launching a novel biologic drug onto the market is not as simple as succeeding in clinical trials and persuading the regulators that it is safe and effective; a manufacturing process that is capable of making the product reliably, reproducibly, and in commercial quantities will also need to be developed. In comparison to a small molecule drug, which may also be challenging, the development process for a biologic is even more complex, not least because the "machinery" that makes the drug molecules involves living cells. Many companies rely on a contract development and manufacturing organization (CDMO) to assist them in developing the cells and the process, and it is vital that the CDMO they select has the right capabilities and enough experience.

The first step is to create a manufacturing cell line by inserting the DNA sequences that code for the protein into a cell line capable of being utilized for commercial production. This can be challenging, as there are multiple places where the sequences can be inserted. A clonal cell line is required – one in which every cell is genetically identical – and the clone that is selected should produce the maximum amount of protein, while still maintaining the conformation, post-translational modifications, and other properties necessary to achieve the desired pharmacokinetic and pharmacodynamic profile. In the early proof-of-concept stage of discovery, transient expression is a helpful tool, as it allows a large number of variants to be screened, and small amounts of material to be made. However, it may not be representative of the ultimate yield or manufacturability of a candidate protein in a clonal cell in which the new DNA is permanently expressed. Post-translational modifications, particularly glycosylation patterns, may also differ from those that will be produced in a more commercially viable manufacturing cell type. It is therefore important to confirm as quickly as possible that the correct protein is being expressed, and that it is of the required quality and functionality. Otherwise, there is a high likelihood that some of the early development work will have to be repeated once the final cell line has been created, potentially adding significant time and cost. The ideal cell line for scale-up has several essential features:

FIGURE 1

Catalent's state-of-the-art facility in Madison, WI, leverages single-use technology for development and manufacturing.

FIGURE 2

Catalent's GPEx® cell line development technology generates high titer, highly stable production cell lines in a wide variety of mammalian cells, including CHO and HEK293.

- it must be monoclonal and have proven stability,
- it will produce the protein in high titer (at least 4 g/L),
- traceability will be in place to ensure regulatory compliance, and
- intellectual property must be secure.

OPTIMIZATION TECHNOLOGIES

Titer and stability will be driven by the cell line development technology, and different CDMOs each have their own approaches. For the sponsor company, it must make the decision as to which technology is most appropriate for the program. The chosen technology should be able to ensure each gene is expressed in the correct ratio to form the desired drug substance. This is particularly important for bi-specific and multi-specific antibodies, which require more complex assembly, and therefore, can result in lower expression levels of drug substance with the desired composition.

In addition to cell line development, there are several other tools that can be used by a CDMO to optimize the cell lines, ensure consistent performance at scale, and reduce time spent in development. Automated technologies, such as the Berkeley Lights Beacon® platform, speed up clonal selection of cell lines that produce antibodies or Fc fusion proteins. Mini-bioreactor systems, such as the ambr® systems, enable a scalable design of experiment (DoE) approach to assist with process development and process characterization.

The nature of the host cell line will greatly impact protein functionality and glycosylation patterns. Many different cell lines can be used, such as HEK293 and PER.C6, although Chinese hamster ovary (CHO) cells are by far the most common.

It is important to remember that the combination of cell line development technology and host cell, along with cell culture conditions, will drive not only cell productivity, but also protein quality. The media and supplements used in the cell culture must be compatible with the cells and the protein and not cause the protein to aggregate. A high-performance cell line development platform is critical, as it is the key component of the Chemistry, Manufacture and Control (CMC) package and underpins all future manufacturing steps, both at a clinical scale and once it reaches commercial quantities.

Once the cell line has been created, a cell bank must be created, and so when assessing potential CDMO partners, a sponsor needs to select one that is capable of creating a cGMP compliant cell bank. The CDMO must also have the capability to apply the necessary analytical methods to evaluate both the cells and the proteins they make. It is essential that the protein remains the same, regardless of the scale at which it is being manufactured.

The next step is to ensure, through ro-

"When choosing a CDMO for commercial-scale manufacture, it is important to establish that it is cGMP compliant and has the capacity to make the biologic drug substance at the necessary scale. A company may have bioreactors that are sufficiently large for Phase 1 and Phase 2 trial supplies, but these bioreactors may not be appropriate for the larger volumes required for Phase 3 and commercial launch. Ideally, a CDMO will have flexibility in manufacturing scale, with the capability to handle batches supporting Phase 1 through to commercial-scale."

bust formulation, the biologic's stability during manufacturing, storage, and clinical administration. Ideally, the CDMO should have experience in this area too, as formulation development is typically on the critical path to successful investigational new drug (IND) filing and Biologics License Application (BLA).

It may be the case that the same CDMO is capable of handling the entire development process from cell line development through to process development, formulation development, and eventually process characterization. In this instance, it is likely that different groups will be working on different steps. A sponsor should assess the capabilities of the company in transferring a project between the various groups efficiently. This may or may not involve a transfer from one site to another, and any move offers its own challenges and risk of rework. The ability to carry out analytics on site is also recommended, as outsourcing this elsewhere – or to a third-party company – adds another layer of tech transfer complexity.

COMMERCIAL CONSIDERATIONS

When choosing a CDMO for commercial-scale manufacture, it is important to establish that it is cGMP compliant and has the capacity to make the biologic drug substance at the necessary scale. A company may have bioreactors that are sufficiently large for Phase 1 and Phase 2 trial supplies, but these bioreactors may not be appropriate for the larger volumes required for Phase 3 and commercial launch. Ideally, a CDMO will have flexibility in manufacturing scale, with the capability to handle batches supporting Phase 1 through to commercial-scale.

The cell line's productivity will have a significant impact on the cost of goods sold (COGS). If a cell line has higher productivity, it will require smaller batch sizes and/or fewer batches, which results in reduced cost. The larger the amount of protein required, the more important the COGS become. For sponsor companies that have a line of sight to commercial launch and supply, there is a benefit to investing resources upfront to develop a highly efficient manufacturing process.

However, when aiming to achieve high titers, there is a trade-off between potential COGS and development timelines, and sponsor companies ultimately must weigh the pros and cons of each approach. While a large pharma company may be willing to invest the time and money to improve manufacturing efficiency, a pre-clinical stage small or virtual biotech might need to reduce burn rate and reach the next milestone as quickly as possible so that they can secure more funding.

FIGURE 3

Scientists and engineers at the Madison, WI, and Bloomington, IN, sites have experience working with a wide variety of molecules, monoclonal antibodies, recombinant proteins, Fc-fusions, bi-/multi-specifics, and other complex biologics.

CASE STUDY IN IMPROVING MANUFACTURING EFFICIENCY TO REDUCE COGS

Catalent undertook a development project in which the Phase 1 need for a monoclonal antibody was about 3 kg. The strategy employed was to start Phase 1 work without process development to accelerate the timeline. Upstream process development, which used one round of DoE studies in the ambr mini-bioreactor system, was then carried out after Phase 1 to optimize the titer before Phase 2 trials commenced.

The difference in cost between the two batches was significant: the Phase 1 material was produced at a titer of 1.6 g/L, and three batches in a 1,000 L bioreactor were required to make sufficient biologic drug substance; whereas after process development, a titer of 4.2 g/L was achieved, and a single 1000-L batch was suitable to produce the same amount. Taking into account the cost of each batch, the Phase 2 material was less than half the cost of the Phase 1 material, and resulted in savings of over $3.5 million.

The savings can be better demonstrated at commercial-scale. For example, a drug that has an annual commercial requirement of 90 kg run in a 4,000-L bioreactor with a titer of 1.5 g/L would require 14 batches to produce enough material. By increasing the titer to 2.6 g/L, only nine batches are required, reducing the costs by nearly 40%. This shows that there is an immediate return on investment – and the potential to save tens of millions of dollars on manufacturing costs if a high-efficiency manufacturing process is developed.

TIMELINE ACCELERATION

Many CDMOs advertise extremely aggressive timelines, but a sponsor must ask whether these are truly realistic, what assumptions are being made, and what potential steps are being reduced or omitted to speed up the process? The timelines may be achievable with a "well-behaved" antibody that it is easy to produce in high titers, but this may not be the case for a difficult-to-express protein, or a non-traditional antibody.

Timelines for a simple monoclonal antibody (mAb) might be short if it is amenable to platform processes and minimal formulation development is required. Fc fusion proteins and recombinant proteins typically require longer timelines due to additional process development needs, and bi-/multi-specific antibody timelines can be longer still.

A high-performance cell line technology will reduce the amount of upstream process development that is required, and again, this can be combined with clonal selection using the Beacon platform and process development using the ambr system. A platform approach will speed up downstream process development if a mAb is purified using Protein A chromatography. Downstream processing can be initiated using stable pool material, and the toxicology batch can be manufactured using the research cell bank instead of the GMP master cell bank, which allows these tests to be carried out earlier. The drug substance batch can also be shipped under quarantine to a fill-finish provider, if it is being filled elsewhere, so the necessary tests can be carried out at the same time to reduce delays.

SUMMARY

An integrated approach is always going to make for faster timelines and more efficient development. Time is lost on the path to the clinic if multiple outsourcing providers are used, because handovers necessarily add delays. If the teams doing the cell line development, process development, drug product, and analytical work are all using the same systems and documentation, the whole process is almost certain to work more smoothly. Effective integration will increase the probability of the drug reaching patients more quickly, and for the sponsor company to achieve success, selection of the right CDMO is critical. ◆

BIOGRAPHY

Dr. Stacey Treichler joined Catalent Biologics in 2017 supporting the company's biologics drug substance and drug product business areas. Prior to joining Catalent, she worked in senior product management roles in biologics drug substance, medical devices, and diagnostics industries, and was instrumental in launching products for bioprocessing, organ transplant, and food safety testing. Dr. Treichler earned her BS in Biology from Ursinus College, and her PhD in Molecular Biology from Rutgers University, New Jersey.

PREFILLED SYRINGES

Selecting the Right Primary Container for Injectables in Acute Care

By: Alfred Harvey, MBA, MS

INTRODUCTION

Understanding hospital and care centers' unmet needs is crucial for providing them with impactful solutions. In the healthcare setting, patient safety concerns exist across the entire drug delivery spectrum. Specifically, in an acute care setting where decisions are often made quickly or under stress, error rates can be at their highest.[1] These errors result, cutting corners due to resource constraints, and/or an inherent medical product failure. Collectively, drug delivery mistakes create challenges in maintaining optimal patient safety, healthcare worker safety, and can increase clinical operating costs. The following discusses how differences in primary container options for injectable drugs can add value by offering hospitals and care centers configurations that address universal pain points.

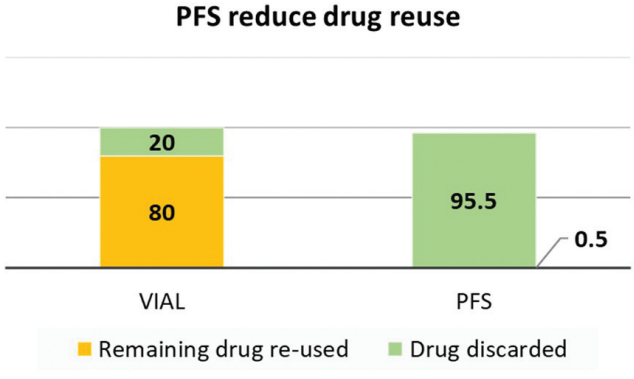
INJECTION-RELATED ADVERSE DRUG EVENTS ARE DANGEROUS & COSTLY

Reducing medical errors, such as adverse drug events (ADEs), is a goal for the entire healthcare ecosystem. Currently, nearly 5% of hospitalized patients experience a drug-related ADE.[2] Of these, injection-related ADEs alone cause between $2.7 to $5.1 billion in preventable annual costs to US healthcare payers. On average, this leads to $600,000/year in extra costs for each hospital in the US, with an additional $72,000 in medical professional liability per hospital.[3] The highest error rates have been reported in the administration of intravenous medications due to their higher complexity, which studies suggest could affect ~50% of the injections given.[1] These drug administration errors are dangerous and costly. Those that are related to administration errors could be limited in the case of injectable drugs due to primary drug containers that improve workflow, decrease contamination risk, and reduce sharps exposure.

VIAL REUSE IS A RISKY, BUT COMMON PRACTICE[4]

Syringe, vial, or ampule reuse is an existing, risky injection practice that can lead to contamination. For example, a class action lawsuit was settled in 2012 against several endoscopy clinics in Nevada because they were cross-contaminating patients with Hepatitis C. The cause of the issue was found to be linked to the reuse of vials between patients.[5] The two drug manufacturers supplying the drug involved had also been considered liable as it was argued that the large size of the vials of the drug induced a reuse, while the warnings on the vials and on packaging inserts were deemed inadequate.[4] Data from the Netherlands suggests

FIGURE 1



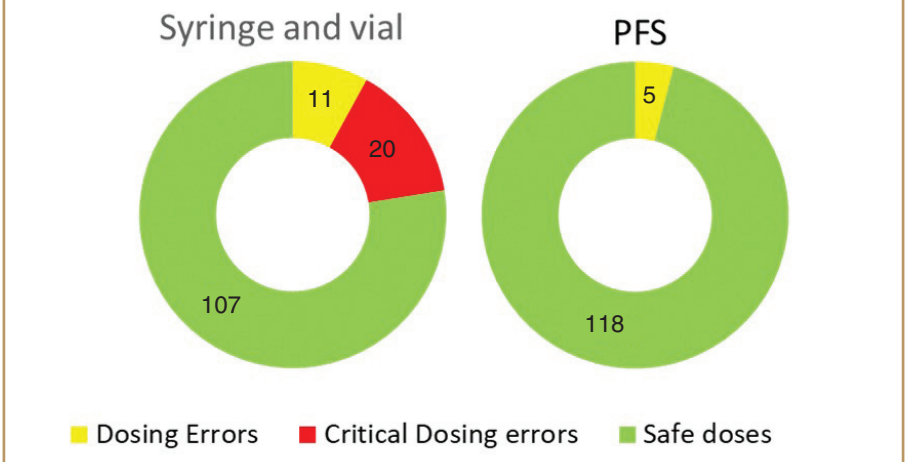
Imaging center study shows 80% imaging agent reuse in vials compared to less than 1% in Pre Fillable Syringes (PFS)[8]

that 9%-22% of their acute infusions contain some level of microbial contamination, 1% to 3% of these resulting in infections and increased hospital stays.[6] The study showed that using PFS instead of vials reduced the contamination risk from 9%-22% to 4%.[6] Despite the risks associated with reuse, a 2017 report showed that >50% of surveyed nurses admit to reusing multidose vials between patients, and almost 25% admit using the same needle to reenter the bottle for the same patient. Also reported is that in an oncology setting, about 20% of oncologists accept the practice of reusing vials, bottles, and bags between patients.[7] Similarly, a study focused on vial reuse in an anesthesia setting showed that about 80% of vials for an imaging agent were reused between patients.[8] In contrast, the same study showed that the reuse went down to less than 1% when the drug was supplied to the anesthesiologist in a PFS format (Figure 1). These are clear examples in which providing medicines in the most "ready-to-administer" form can help reduce vial/syringe use between patients, decrease cross-contamination, and improve safety.

PREFILLED SYRINGES ARE SAFER FOR PATIENTS & HEALTHCARE WORKERS

Drug dosage preparation mistakes with a syringe and vial/ampule are all too common. These can occur from preparing the wrong medicine or the wrong dose.[6] While some have minimal effects, critical dosing errors can cause severe problems and even death. A 2015 study looked at total dosing error rates in vials compared to PFS (Figure 2).[9] They found that 22% of vial-prepared doses resulted in at least one

FIGURE 2



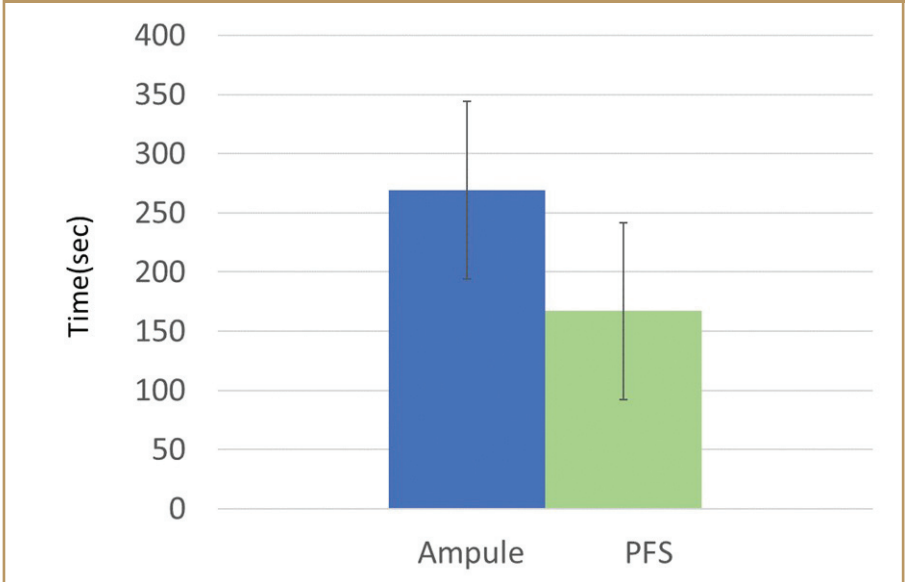
Dosing errors decrease from 31 total errors with vials to 5 with prefilled syringes in pediatric study.[9] Critical errors drop from 20 to 0.

dosing error – of the 22% error rate, two-thirds were critical errors of either severely over or underdosing the patient. In contrast, only 4% of PFS-based syringes resulted in a dosing error event, and none of those were considered critical errors. Through the use of prefilled syringes (PFS) instead of vials, the hospital was able to show a complete elimination of critical errors and significant reduction in non-critical errors. Also, on the safety side, a 2016 meta-analysis of 46 studies concluded that healthcare worker needle-stick injuries were significantly reduced when PFS were used instead of vials and ampules. PFS solutions are shown to be safer to use for both patient and healthcare workers.

PREFILLED SYRINGES SAVE LABOR & DRUG WASTE COSTS

Like all businesses, hospitals try to reduce costs as much as possible. Labor costs and product waste are two areas where the right drug delivery product can impact their bottom line. For example, patients in medical and surgical units receive an average of 10 injections daily.[10] PFS products have been shown to significantly reduce preparation and administration time (Figure 3).[11] In an average 150-bed hospital, if 10 injections daily are given to each patient using PFS instead of vials/ampules, the hospital could save 14,600 hours yearly, or $420,000 in labor costs. Similarly, a 2016 study of drug usage in an anesthesia setting showed that drug waste from discarded vial-based drugs costs institutions around $200,000 a year.[12] This cost was eliminated through the use of pre-packaged, PFS. Similarly, a French university obstetrical unit study compared drug waste between ampules and PFS. They discovered that switching to PFS for one of their common drugs resulted in a 17% decrease in drug waste, or savings of $0.55 per patient.[13] Lastly, a budget impact analysis was conducted of French hospitals comparing PFS to standard delivery methods, considering medication error and drug waste. Looking only at one drug, atropine, PFS use was modeled to yield a net one-year budget saving of $5.76 million. They concluded that even though PFS were more expensive up front, their use would result in significant budget savings in both medical errors and drugs waste.[14] As hospitals start to calculate the potential savings PFS can bring, they will look to

FIGURE 3



Ampule preparation took ~100sec more than when PFSs were used (260s versus 157s).[11]

drug companies that offer these convenient primary containers when they are ready to make a purchase.

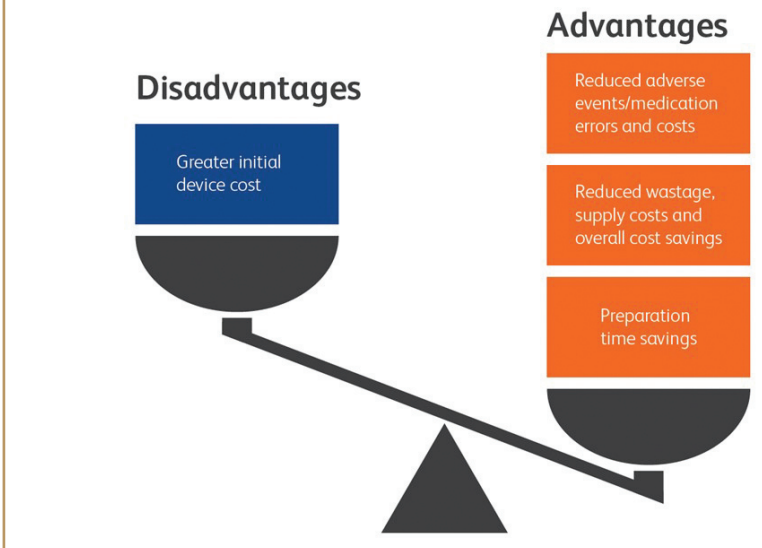
PREFILLED SYRINGES OUTPERFORM VIALS FOR DURABILITY & FILL VOLUME

Finally, there are shared pains between drug manufacturers and their customers. Several product recalls have been linked to vials in the past caused by flaws inherent in the vial manufacturing process.[15] Vial glass can delaminate and cause glass particles to appear, reducing glass durability and contaminating the drug.[16] These recalls are costly and inconvenient for both drug manufacturers and their customers. The PFS manufacturing process is different than for vials, and results in improved glass durability. In fact, PFS outperform glass vials for most test conditions and perform equivalently for others.[16] One of those additional vital tests looks at leaching chemicals. Chemicals leaching into or out of the primary container can change the makeup of the drug inside. The inner surface of PFS were found to have lower chemical leaching than glass vials.[17] Another shared cost for customers and suppliers is the need to over fill vials with drug. This is done because it is impossible to withdraw 100% of a dose from a vial. The cost to over fill is either absorbed by the drug company or passed on to their customers. Switching to PFS as a primary container not only offers a more robust package, but also eliminates the need to overfill the container.

PREFILLED SYRINGES ARE SINGLE SOLUTION FOR SEVERAL CHALLENGES

Selecting the right primary container presentation for a drug is an important decision that can directly impact customers. As the healthcare industry focuses more on safety, they will be looking for ways to reduce ADEs and needle stick injuries. When hospitals look to reduce spending, they will target workstream inefficiencies and product waste. In order to continue providing optimal care, they will seek out robust devices with low likelihood of recall. Prefilled syringes have shown the ability to address all these needs (Figure 4), and now that they are available in a variety of formats up to 50mL in both highly resistant glass or advanced plastic, drug companies have many options to meet the needs of acute care hospitals and care centers.◆

FIGURE 4



While PFS may cost more upfront, the associated costs tied to vials make them more costly in the big picture.

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BIOGRAPHY

Alfred Harvey started his career with BD in 2001 as a Research Assistant working in early stage R&D. With an initial focus on improving parenteral delivery systems, he took on greater roles, eventually managing device teams in a variety of areas, such as oncology, diabetes, rheumatoid arthritis, and IV therapies. At each stage, he brought in greater influence from his Health Economics background and drove initiatives of delivering greater customer value and improved patient outcomes. In 2017, he took on his current role as Associate Director of Health Economics and Outcomes Research for BD's Medical, Pharmaceutical Systems division, where he is helping lead the strategic focus in prefilled, self-administration, and safety systems. He earned his MBA from Stetson University and his Masters in Pharmacy-Pharmaceutical Outcomes and Policy from the University of Florida.

CONTINUOUS MANUFACTURING

Continuous Manufacturing in Pharmaceuticals: Implications for the Generics Market

By: Kamna Jhamb, PhD

Continuous manufacturing (CM) is a new trend in manufacturing. From paper to petrochemicals and automobiles, industries are embracing continuous manufacturing to enhance efficiencies and increase profits. The highly regulated nature of the pharmaceutical sector, and the low-risk-taking nature of this market, are the two main factors that have restrained the implementation of novel methods of manufacturing by pharmaceutical industries. However, the burgeoning demand for complex and innovative therapies and rising competition have led pharmaceutical manufacturers to reconsider their methods of manufacturing.

The age-old batch manufacturing process of making drugs is still the most popular method for both branded and generic drug manufacturers. The drugs are produced in single large batches step by step. A typical pharmaceutical batch manufacturing facility is built with an investment of billions of dollars and contains multiple pieces of complicated equipment. The employment of human labor and multiple transfer steps poses extreme contamination risks and introduces the possibility of errors.

Considering the commercial advantages offered by CM, the pharmaceutical industry is becoming increasingly receptive to this technology. CM technology offers a number of benefits to the pharmaceutical industry:

- A CM processing facility is at least 70% smaller than a batch production facility. The reduced size of equipment and the overall facility greatly saves operational, running, and other environmental costs.

- CM processes are highly advantageous for the production of compounds with harmful intermediates and those that may be prone to degradation.

- The growing popularity of personalized medicine and the reduction in batch sizes are proving to be burdensome for pharmaceutical manufacturers. Smaller batch production does not justify the expensive equipment and associated infrastructure costs. In contrast, it is much more economical to use smaller, single-use equipment in a continuous mode that would quicken the supply chain and boost productivity.

- From a commercial and regulatory standpoint, CM is beneficial to pharma manufacturers because the same equipment that has been used during process development can be employed for production scale. Scaling up is much easier in a continuous set-up, which eliminates any validation issues and saving costs.

- CM is also an effective solution for multi-step reactions that are commonplace in the pharmaceutical industry.

- Another advantage that CM technology offers is its amenability to automation. The integration of real-time sensors and measuring equipment with continuous manufacturing equipment enables continued monitoring and feedback control for the processes. The continued generation of process data enables manufacturers to analyze the data and use them to bring improvements to the processes. In addition to providing better quality products and improved productivity, real-time process control supports the FDA's quality-by-design (QbD) approach of manufacturing.

Throughout the years, product recalls due to poor drug production practices or inferior drug quality have increased exponentially; this comes as demand for drugs is rising sharply.

TABLE 1

Date Approved	Product	Company	Treatment
November 2018	Daurismo	Pfizer	Acute myeloid leukemia (AML)
February 2018	Symdeko	Vertex Pharmaceuticals	Cystic Fibrosis
September 2017	Verzenio	Eli Lilly & Co.	Breast cancer
April 2016	Prezista	Janssen Products, LP	Human immunodeficiency virus (HIV)
July 2015	Orkambi	Vertex Pharmaceuticals	Cystic fibrosis

FDA-Approved Continuously Manufactured Drugs. Source: BCC Research

Concerns lurk among pharmaceutical suppliers when there is an upsurge in demand for a particular drug. In both these situations, CM is the go-to strategy. Using CM technology, any response to market changes can be enacted quickly, eliminating many issues related to drug shortages.

In July 2015, the first drug produced by a CM process was Orkambi by Vertex Pharmaceuticals. Orkambi is a cystic fibrosis oral solid dosage (OSD) drug produced using a continuous manufacturing process. Since then, many pharmaceutical companies have forayed into the continuous manufacturing domain. FDA's support and the go-getter attitude of pharmaceutical companies have led to a total of four approvals for drugs produced using CM. At least 20 companies are talking to the FDA's staff about developing and implementing CM processes. The table below lists the drugs that have been produced by continuous manufacturing and received FDA approval.

The changing attitude of branded drug companies to using CM in their production processes is evident from the five drugs approved by the FDA and the fact that many more companies are actively engaged in discussions with the FDA and other suppliers to allow the implementation of CM in their processes. In contrast, generic drug manufacturers are treading the path very carefully because of the difference in the way the generics market works — it is based on a much different business model. Regulatory policies, competitive environments, manufacturing strategies, and barriers to entry and exit work in different ways for the generics sector.

In the case of branded drugs, manufacturers have extended exclusivity periods reaching up to 15 years with extensions, thereby giving them the opportunity to recover the costs of research and development with greater ease. However, for generic drug manufacturers, the market is already competitive with the brand's popularity and usage habit with its consumers. The first generic entrant though gets a limited period of exclusivity, generally 180 days, but that is soon lost, making way for more competitors to enter the market. In this scenario, the demand for a particular generic drug is always unpredictable and highly variable. In the case of uncertainty in future demand and no guarantee of return on investment, it is of no interest to generic drug manufacturers to invest heavily in new manufacturing technologies.

CM has been shown to possess a large cost-reducing potential. A study by Schaber, et al, estimated that capital expenditures would be between 20% and 76% lower in a CM facility and that overall costs would be 9% to 40% lower in a CM facility manufacturing a single blockbuster drug using dedicated equipment.1 Pfizer transitioned its Lipitor production process to a "hybrid" approach based on CM technology; however, the company's experience was not satisfactory. Pfizer's CEO later said that to realize the full benefits from investments in CM, high-volume production is needed.

In the case of generics, if manufacturers face unpredictability in demand, and return on investment is also uncertain, it is highly unlikely that they will invest in the cost-intensive transformation of the existing batch facilities to continuous production fa-

"BCC Research's new report on Continuous Manufacturing for Pharmaceuticals (PHM214A) studied the market size of the CM market. The global CM market was valued at $2.3 billion in 2018, and is expected to grow at a CAGR of 8.8% through 2024 to reach $3.8 billion in 2024."

cilities. In addition to new equipment and facility design, CM warrants the investment in novel PAT tools and technologies that will allow monitoring and control of the processes in real-time. Labor requirements are also intensified as highly skilled and trained personnel are required. Moreover, the risks and costs associated with new validations and regulatory approvals also add to the overall investment.

Another cost-related issue particularly relevant for generics is the value associated with their existing facilities and equipment. According to data released by Standard and Poor's Capital IQ Financial on the top 20 generic pharmaceutical companies, the average lifespan of depreciable assets (machinery and buildings) of these companies ranges from 4 to 12 years. As such, the abandonment of functional equipment does not make sense until the profit margins are high enough. Only when CM technology can prove its robustness and sustainability worthy of investment will it attract generic drug manufacturers.

Generics companies operate within low margins, so cost of manufacturing is an important factor when considering the competition; this is one of the main reasons why generic drug manufacturers are not changing over to CM. The costs and time associated with transformation from a well-established batch process to a new and still developing CM process may pose risks and diminish profits for generic drug manufacturers. Having received approval for a given process and location, the investment in developing new processes and waiting for new regulatory review would impose a burdensome and uneconomically wise cost. Other regulatory hurdles include: redefinition of the sampling plan, deviations that need to be handled differently, varying ways to control variability, the need for proper management, and the need to define a rationale for testing a continuous batch in comparison to traditional models.

Thus, regulators such as the US FDA and organizations like US Pharmacopoeia are focused on developing guidelines and standards for pharmaceutical CM that will give directions and help branded and generic drug manufacturers adopt CM in the best possible way. However, it is noted by many generic manufacturers that generic drug companies need to be able to produce drugs that were approved as continuously manufactured products via batch manufacturing. The paths to CM will be different for branded and generic drug companies.

BCC Research's new report on Continuous Manufacturing for Pharmaceuticals (PHM214A) studied the market size of the CM market. The global CM market was valued at $2.3 billion in 2018, and is expected to grow at a CAGR of 8.8% through 2024 to reach $3.8 billion in 2024. While the highest market share was contributed by the branded drug companies and contract manufacturing companies together, generic drug companies are currently holding 5.6% of the total market share. The generic market is highly fragmented, with a majority of companies in the mid- to small-size segment. With less investment bandwidth and lower risk-taking potential, this segment has been a slow adopter of CM technology. With increasing support from regulators and visible long-term benefits of CM technology, generic drug manufacturers will follow suit. The market is expected to be driven by new technological enhancements and increased investments from generic companies, particularly in the Asia-Pacific region, where they are carrying out facility expansions. Companies such as Dr. Reddy's Laboratories, Mylan Pharmaceuticals, and Aurobindo Pharma are developing continuous manufacturing lines in India. Some key developments in the CM market include:

- In December 2018, WuXi Biologics made an investment of $357 million in Dundalk, Ireland, to set up a new biologics manufacturing facility. The building will feature several single-use bioreactors for commercial biomanufacturing and is compatible with continu-

ous bioprocessing. Additionally, the facility will boast 48,000-liter fed-batch and 6,000-liter perfusion bioreactor capacity bioreactors.

- In November 2018, Innovate UK awarded a grant of $1.85 million to a partnership of Pall Corp., Cell and Gene Therapy Catapult (an independent research and technology organization) and Cobra Biologics (a CDMO with a focus on the development of advanced therapy medicinal products). The collaborators are working to investigate CM of adeno-associated virus for gene therapy applications.

- In January 2018, SK Biotek inaugurated its new contract manufacturing facility in Swords, Dublin, Ireland, becoming the first Korean pharmaceutical company to invest in Ireland. SK Biotek had acquired this facility from Bristol Myers Squibb earlier in June 2017. The new facility will be used to manufacture pharma products to specification for other pharmaceutical companies on a contract basis.

- In December 2017, Fette Compacting and Glatt GmbH entered into a collaboration to develop an integrated solution for the continuous manufacturing of oral solid dosage forms. The new partnership combined the tablet compression expertise of Fette Compacting and the powder processing and tablet coatings skills of Glatt GmbH, hence providing an opportunity to co-develop CM technology for pharmaceutical manufacturers of OSD forms. As part of this partnership, the companies opened a new test facility in Pune, India, that offers customer trials for continuous direct compression and continuous wet granulation.

The FDA has been a strong proponent of CM and is encouraging pharma manufacturers to adopt CM. In February 2019, the US FDA made available the draft regulatory guidance for continuous manufacturing. Titled, Quality Considerations for Continuous Manufacturing, this draft guidance provides information regarding FDA's current thinking on the quality considerations for continuous manufacturing of small molecule and solid oral drug products that are regulated by the CDER.

Despite some of the companies being early adopters, CM is still a technology that is being tested by a majority of the pharmaceutical industry. The FDA guidance and the ICH Q13 guidance are initiatives that are geared toward enhancing the adoption of CM by the pharma sector. Many proponents of CM technology, including GSK, Johnson and Johnson, Vertex Pharmaceuticals, and others are helping the agency to develop the right environment to foster the implementation of CM on a wider scale. However, organizations such as AAM and other generic pharmaceutical companies are treading with caution. They want to ensure that the entry of CM does not prove anti-competitive to the pharmaceutical market and that the technology provides the promised benefits to manufacturers as well as to patients.

This executive summary is based on the following market research report published by BCC Research: Continuous Manufacturing for Pharmaceuticals (PHM214A). For more information, visit https://www.bccresearch.com. ◆

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BIOGRAPHY

Dr. Kamna Jhamb has has more than 13 years of research experience, of which more than 4 years have been devoted to market research. Before entering the field of market research, she worked as a Research Assistant in Lawrence Berkeley National Lab, CA. With a PhD in Microbial Technology, she has vast knowledge in the areas of microbiology, protein chemistry, and molecular biology. She has several international publications in reputed journals. For BCC Research, Dr. Kamna has written reports spanning many topics, including healthcare, finance, and biotechnology.

Drug Development
EXECUTIVE

Daniel de Boer
Chief Executive Officer
ProQR

ProQR: Developing RNA Therapies for Rare Genetic Disorders

There is a great need for transformative treatments that increase life expectancy and improve the quality of life of patients and families living with rare inherited diseases. Current therapeutic approaches, including small molecules and enzyme replacement therapies, have limitations and cannot be applied to every disease. ProQR specializes in the development of RNA therapies and is expanding its toolbox of RNA approaches to develop life-changing medicines for rare genetic disorders that are currently untreatable. *Drug Development & Delivery* recently interviewed Daniel de Boer, CEO of ProQR, to discuss the use of RNA technology to directly target the underlying cause of genetic diseases.

"Several genetic diseases cannot be treated with gene therapy, due to different technical and medical reasons. Our RNA technology has the potential to treat diseases that are considered untreatable through gene therapy. One example of this is Leber's congenital amaurosis type 10 (LCA10), an inherited retinal degenerative disease."

Q: Can you explain why you started ProQR and provide an overview of the company for our readers?

A: I know first-hand how rare diseases can impact patients and their loved ones. When my newborn son was diagnosed with cystic fibrosis, my world suddenly changed. Not only did I want to do something that would help my son, but I also wanted to help other patients and families in a similar situation. This fueled my passion to develop therapies for people diagnosed with potentially treatable rare diseases. As a result of my son's diagnosis, I partnered with Dinko Valerio, Gerard Platenburg, and Henri A. Termeer, three eminent rare disease treatment pioneers, to form the company now known as ProQR.

ProQR is a clinical-stage biotech company that focuses on rare diseases that have a high unmet need for new medicines. There are more than 5,000 known rare genetic diseases with a genetic basis, yet less than 5% of diseases have approved treatment options and even fewer have options that target the underlying cause of the disorder. Our strategy is to target the underlying cause of rare diseases by making changes to the faulty RNA that is the root cause. Our RNA technology has broad applicability to a number of existing conditions that currently lack treatment options.

Q: Why does ProQR focus on RNA therapies?

A: RNA therapies enable us to correct diseases caused by defective genes and help restore protein expression without permanently modifying a patient's genetic makeup. At ProQR, we developed different RNA repairing technologies, each with the potential to address a different type of genetic defect. As the underlying cause of a genetic rare disease is discovered, we can determine which of our RNA repairing technologies are most applicable and work to make an impactful treatment for those affected by the rare disease.

Q: How do RNA therapies differ from gene therapy and gene editing?

A: Several genetic diseases cannot be treated with gene therapy, due to different technical and medical reasons. Our RNA technology has the potential to treat diseases that are considered untreatable through gene therapy. One example of this is Leber's congenital amaurosis type 10 (LCA10), an inherited retinal degenerative disease. Gene therapy is ineffective in treating LCA10 because the defective gene codes for the protein, CEP290, have to be expressed at a certain level. Too little CEP290 expression causes LCA10, and if overexposed, CEP290 can become toxic and damage the retina directly. Gene therapy-based treatments have the potential to replace the defective gene with one expressed at higher levels, potentially causing toxicity.

Another key difference is that repairing RNA does not change the basis of a person's genetic code. This means that any potential adverse side effects from the treatment are temporary in nature, minimizing any harm they may cause. This is also the key difference with DNA editing, which makes a permanent, irreversible change to a person's genes.

Additionally, RNA-based therapies are easier to deliver to therapeutic targets than gene therapies. One example of this is

in Usher syndrome, the leading cause of combined deafness and blindness. Usher cannot be treated with gene therapy because the disorder develops peripherally in the retina and progresses inward. Gene therapies for this disease would have to be delivered by sub-retinal injection, where the drug is delivered to a specific area in the retina, and is only expressed in that area. This limits the therapeutic effect of the drug to the site of injections. The RNA therapy we are developing for Usher is administered through a routine procedure called intravitreal injection, a route of administration that allows the therapy to reach the whole retina. This effectively treats a larger area than the one that can be reached with a sub-retinal injection.

Q: Can you provide an update on your development status?

A: We have several different clinical-stage research programs currently. First, we are in an ongoing Phase 2/3 clinical trial that is designed as the sole registration trial of an RNA therapy called sepofarsen (QR-110). Sepofarsen is being developed for the treatment of LCA10 in patients who suffer from the p.Cys998X mutation in the CEP290 gene, the most common mutation causing LCA10. The goal of sepofarsen is to repair the underlying defect in the CEP290 RNA and potentially reverse the vision loss associated with the disease. Interim Phase 1/2 trial results showed rapid and sustained improvement in vision in LCA10 patients treated with sepofarsen. In addition, sepofarsen was well-tolerated with a positive benefit/risk profile. As a result of the Phase 1/2 top-line data, we received PRIME Access from the European Medicines Agency, which provides an accelerated pathway for evaluation and approval.

We are also developing QR-421a as a potential therapy for patients with Usher syndrome due to mutations in exon 13 of the USH2A gene. Usher syndrome, as I mentioned briefly before, is a severe rare disease that is the leading cause of combined deafness and blindness. In March 2019 the first patient was dosed in the Phase 1/2 STELLAR clinical trial for QR-421a. This trial includes patients with Usher syndrome type 2 or non-syndromic retinitis pigmentosa (RP) and we expect interim data in Q1 2020. Additionally, QR-1123 for Autosomal Dominant Retinitis Pigmentosa received both FDA Fast Track Designation and IND clearance and will start trial enrollment soon.

Lastly, we are actively developing our Axiomer® RNA editing technology that can be used to allow the body to repair its own RNA. The Axiomer platform is positioned to target a wide range of diseases in a highly specific manner. With more than 20,000 disease-causing mutations that can potentially be treated with our Axiomer technology, we have the potential to apply Axiomer to a number of additional genetic rare diseases in the future.

In our recently announced "Vision 2023" strategy, our goal is to develop ProQR's platform of RNA medicines for patients with inherited retinal diseases. For this plan, our goal is to expand our portfolio to include at least seven new programs to complement our ongoing research as we establish ourselves as leaders for the treatment of genetic blindess diseases.

Q: Can you tell us more about Axiomer and how it works?

A: Our Axiomer technology is a proprietary RNA editing tool that is conceptually similar to CRISPR and other DNA editing technologies, but targets the RNA. Axiomer relies on specialized molecules called Editing Oligonucleotides (EONs) that make a specific targeted modification to RNA to reverse mutations that cause genetic diseases. Because Axiomer RNA editing uses enzymes present in all human cells, there are fewer concerns with off-target genetic alterations that are sometimes seen with DNA editing.

We have already demonstrated in vivo proof-of-concept for Axiomer in a mouse model of Hurler syndrome, presented at the 2017 Oligonucleotide Therapeutics Society (OTS) Meeting in Bordeaux, France.

Q: What can we expect from ProQR in the near future?

A: We expect interim data for the Phase 1/2 STELLAR clinical trial for QR-421a for Usher syndrome expected in Q1 2020.

Furthermore, we continue to pursue strategic partnerships to bolster our ability to bring meaningful treatments to patients suffering from rare disease with significant unmet need. For example, throughout the past year, we have entered into several stragetic parnterships to help us continue our research. In February, we partnered with the Foundation Fighting Blindness to develop QR-421a for the vision loss associated with Usher syndrome type 2A. This year, along with EB Research Partnership, we spun out all of our dystrophic epidermolysis bullosa activities into the newly formed Wings Therapeutics. Last year, we signed an exclusive agreement with Ionis to in-license IONIS-RHO-2.5Rx, now QR-1123, for the treatment of adRP. ◆


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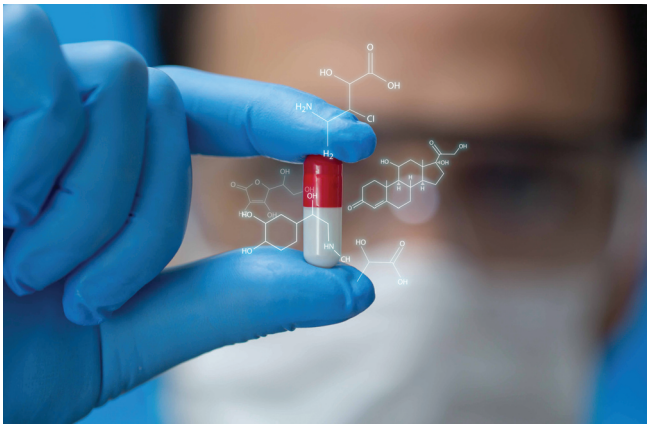

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Adare Pharmaceuticals is a global specialty CDMO providing product development through commercial manufacturing expertise focused on oral dosage forms for the Pharmaceutical, Animal Health and OTC markets. Adare's proprietary technology platforms specialize in ODT, taste masking and customized drug release.

With over 30 years of proven legacy, Adare has successfully developed and manufactured more than 40 products sold by partners in more than 100 countries globally.

FACILITIES

Adare Pharmaceuticals has four sites located in the US and Europe with over 600 employees worldwide. With our global R&D and manufacturing capabilities, in-house regulatory and clinical support, we have the expertise to take your project from formulation development through commercial scale manufacturing. Our sites are compliant with cGMP criteria and approved to handle controlled substances and solvents, and maintain excellent environmental credentials. Our in house regulatory and quality teams have a proven global track record with the FDA, AIFA in Italy, EMA in Europe and ANVISA for Brazil.

SERVICES & CAPABILITIES

Adare has recently launched a new patient centric dosage solution, the Parvulet™ Technology. The Parvulet™ Technology enables a solid powder or tablet to convert to a semi-solid in the presence of water within thirty seconds. The final dosage is easily administered, as a soft food like texture, ideal for pediatric and geriatric populations (including those with dysphagia). The Parvulet™ technology can be combined with our other proprietary technologies, providing multiple ways to provide more patient centric solutions.

OUR OTHER TECHNOLOGIES INCLUDE

Microcaps® Taste Masking Technology achieves uniform and efficient coating of drug particles by a combination of coacervation (phase separation) and spray coating to build polymeric membranes of varying porosity and thickness. The completely encapsulated particle allows for a pleasant mouthfeel without an aftertaste. The Microcaps technology can be applied to multiple dosage forms and immediate and modified release profiles.

AdvaTab® Orally Disintegrating Tablets (ODTs) incorporates coated or uncoated drug particles that are uniformly dispersed in a low-moisture, rapidly disintegrating matrix. Each ODT is formulated to achieve an acceptable taste and desired release profile. AdvaTab® technology is ideal for patients who have difficulty swallowing, pediatric, geriatric, and dysphagic patients. This technology can be combined with Microcaps® and Diffucaps® to create IR or controlled-release ODTs.

Diffucaps® Customized Release Technology has the flexibility to incorporate functional, release-controlling polymers or protective coatings onto drug-layered cores, granules, or crystals. This allows for easy adjustment of both dosage strength and dissolution profile to achieve the desired in vivo pharmacokinetic profile. Beads can have different release profiles, different active ingredients, or both — all in one product.

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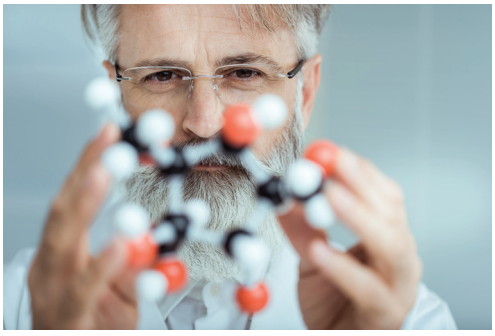

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CORPORATE DESCRIPTION

ARL Bio Pharma is a contract laboratory that provides analytical and microbiological testing to pharmaceutical companies and research scientists. Our laboratory is headquartered in Oklahoma City, Oklahoma, and serves over 3,000 clients nationwide. Since 1998, ARL has supported the industry-wide commitment to deliver high-quality therapeutic drug products by providing guidance and test services for all phases of the product lifecycle following USP, FDA, and ICH guidelines.

Whether you are an innovator or pharmaceutical manufacturer, we provide the testing needed to get your pharmaceutical products to market. ARL's dedicated team oversees the entire process from understanding your product goals to providing results and helping interpret the data.

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FACILITIES

Our state-of-the-art, award-winning facilities specialize in sterile contract manufacturing services and have primary locations in:

Bloomington, Indiana USA - The Bloomington, Indiana facility is a leader in sterile contract manufacturing and offers form/fill/finish services and solutions for injectables designed to meet complex and traditional sterile manufacturing challenges. As a full-service contract manufacturer (CMO), this facility serves client needs with clinical through commercial launch, including: manufacturing, packaging, quality systems, experience with worldwide regulatory agencies, and our Lyophilization Center of Excellence is an industry-leading resource focused on the development of high-quality freeze drying.

Halle/Westfalen, Germany - The Halle/Westfalen, Germany facility has over 60 years of experience and is recognized as a world-class manufacturer of oncology products and other sophisticated compounds. We can navigate complexity - parenteral manufacturing can be a complicated process and present many challenges that require specialized understanding and expertise. Baxter's BioPharma Solutions business brings longevity of experience in handling complex sterile manufacturing challenges. By offering a full complement of services in one location, we are able to meet clients' growing needs for oncology manufacturing in a single location, including early-to-late-stage support to fully engage and service our clients throughout the lifecycle of their products.

BAXTER BIOPHARMA SOLUTIONS
One Baxter Parkway
Deerfield, IL, 60015
US: 1 (800) 422-9837
International: 1 (847) 948-4770
E: biopharmasolutions@baxter.com
Website: www.baxterbiopharmasolutions.com

Formulation challenges. Clinical supply hurdles. Limited manufacturing capability or capacity. Market fluctuations and demand surges. Lifecycle management. Risk mitigation. Patent expiry concerns.

At BioPharma Solutions, a business unit of Baxter, we know the high-stakes challenges you face in today's complex parenteral marketplace – and how the work we do is vital to the patients you serve.

That's why we work closely with you at every step to help you achieve your molecule's full potential and your commercialization objectives – building on over 85 years of Baxter innovation, expertise and specialization in parenterals.

Learn more about us at
baxterbiopharmasolutions.com

Baxter

BioPharma Solutions

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W: http://drugdeliverysystems.bd.com/

BD Medical - Pharmaceutical Systems

A Partner of Choice for the Pharmaceutical Industry

Founded in 1897, BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics, and the delivery of care. BD helps customers enhance outcomes, lower costs, increase efficiencies, improve safety, and expand access to healthcare.

BD Medical - Pharmaceutical Systems Offers Innovative, High-Quality, Clinically Proven & Customized Pre-fillable Parenteral Drug Delivery Systems

BD's drug delivery systems are designed to protect, package, and deliver drug therapies and to maximize healthcare worker and patient safety.

- **Pre-fillable Syringes:** BD is uniquely positioned to offer pre-fillable syringe systems with expertise in drug container interactions, primary container selection, and container/device integration for a variety of drug therapies, including vaccines, chronic diseases treatment, acute care drugs, anticoagulants, and hyaluronic acid.

- **Self-Injection Systems:** BD partners with its customers to develop self-injection systems that enable drug administration across a range of volumes and viscosities, leveraging BD primary container technologies and expertise with a focus on reaching the market faster.

- **Safety & Shielding Solutions:** BD offers a wide range of safety and shielding systems that feature innovative needle shielding system technology for injectable drugs.

BD is a reliable partner that can provide expertise in highly specific fields to support your drug throughout its lifecycle, from development to launch and beyond. The company is committed to building partnerships with pharmaceutical and biotechnology companies and developing product solutions that meet their needs by leveraging our innovative technologies, extensive global manufacturing, and advanced technical, scientific, medical, and regulatory expertise.

BD is Supporting Your Drug Development With a Full Range of services

- Consultative services on drug delivery options
- Regulatory support to optimize time-to-market
- Compatibility testing to mitigate risk
- Global reach and capacity to ensure business continuity
- (Pre)Clinical and Usability assessment Data to support registrations

BD Medical - Pharmaceutical Systems at a Glance

- More than 2.5 million ready-to-administer drug delivery systems manufactured per year
- Products used by more than 500 pharmaceutical and biotechnology companies [1]
- Prefill expertise and consultation at every stage of drug development
- 7 manufacturing plants to meet global production demand
- Worldwide support and regulatory expertise
- Comprehensive cross-functional support and dedicated teams.

[1]SAP Legacy, Tracis, Nodum – January 2018

THE DIFFERENCE OF ONE DRUG DELIVERED

WITH A GLOBAL LEADER IN PREFILLABLE DELIVERY SYSTEMS. BD partners closely with leading pharmaceutical companies to support their success from drug development to launch and beyond. With a broad portfolio of innovative drug delivery systems, a global perspective and regulatory insights, a BD Medical – Pharmaceutical Systems team can partner with you to match the optimal solutions to your product. In addition to prefillable syringes, our technologies include self-injection systems, safety and shielding solutions—which we can customize and develop to meet your precise technical requirements and the demands of your business. You can also count on our depth of regulatory knowledge, product development, medical expertise and responsive support. Discover the confidence of working with the right partner. **Discover the difference of BD.**

Learn more at bd.com

BD

Advancing the world of health

COMPANY PROFILE

Capsugel® | Lonza Pharma & Biotech
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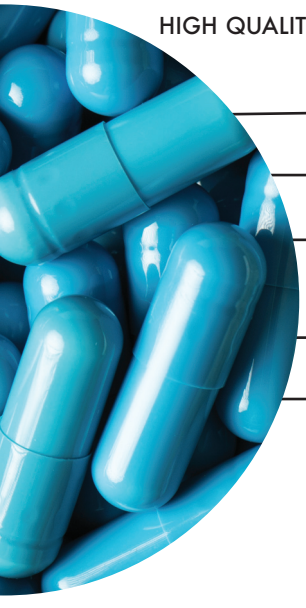
W: www.capsugel.com

Capsule Delivery Solutions, part of Lonza Pharma & Biotech, is the leader in capsule-based solutions and services, proudly offering Capsugel® products. With the largest production and supply chain footprint in the industry, Capsule Delivery Solutions provides the highest quality and deepest regulatory expertise to its 2,000 pharmaceutical customers, globally. For more information, visit www.capsugel.com and follow us on Twitter, LinkedIn and YouTube.

GROUND BREAKING CAPSULE DESIGN:

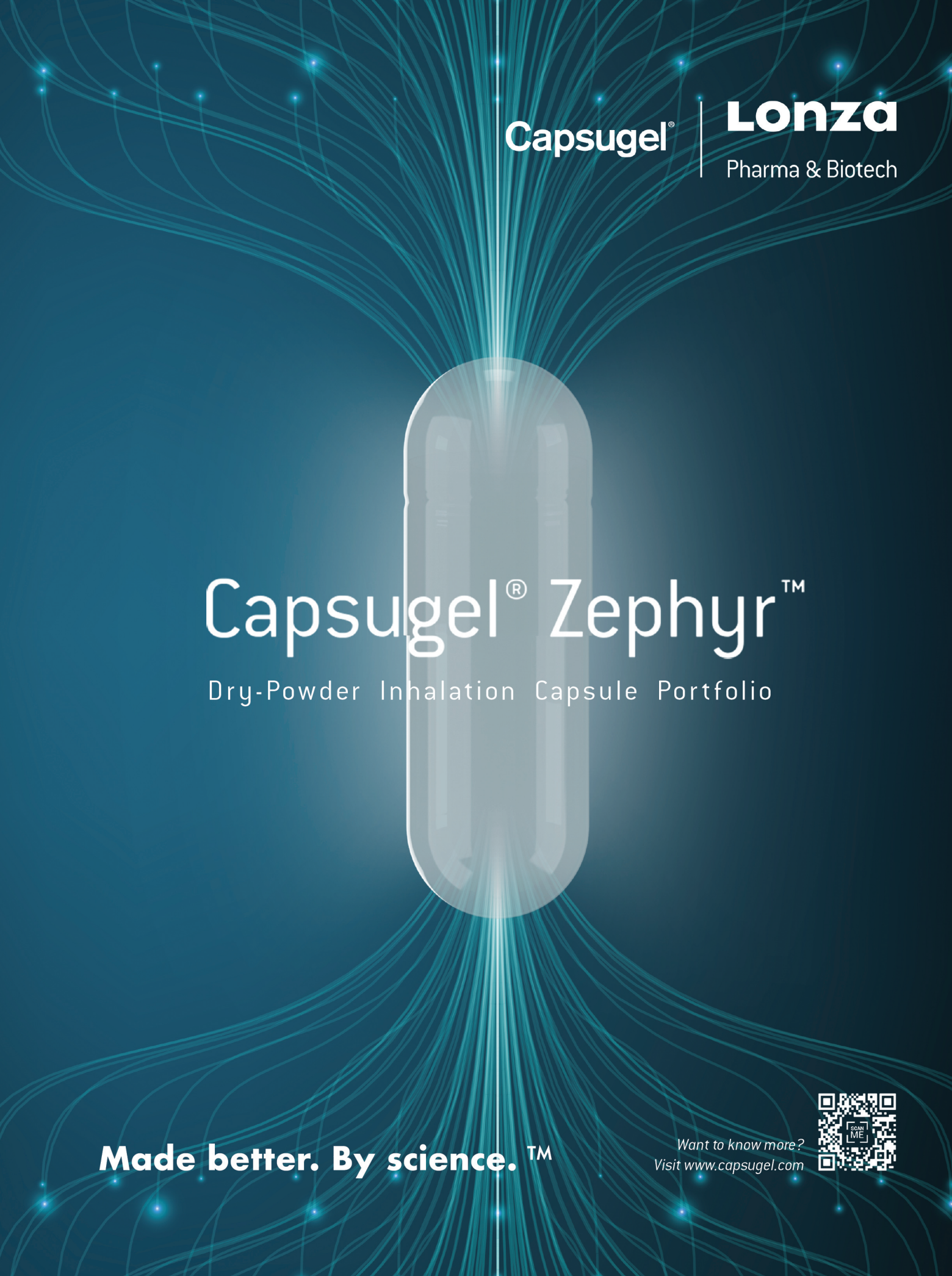
Our unique combination of science, engineering, formulation and capsule expertise enables us to optimize the bioavailability, targeted delivery and overall performance of our customer's products. We partner with them in over 100 countries to create novel, high-quality and customized solutions that meet their needs and patients' evolving preferences.

Building on our history of innovation in polymer science and capsule engineering, Capsule Delivery Solutions continues to launch ground-breaking capsule designs and equipment technologies that are improving drug development and delivery. Whether you're looking to formulate new products or enhance an existing line, we have the right capsule to help you bring improved products to market faster. With a diverse portfolio including HPMC, Dry Powder Inhalation capsules or specialized clinical capsules, we are a global leader in capsule development and manufacturing, bringing unmatched products and technical support to our worldwide customer base.



HIGH QUALITY EMPTY CAPSULES

- **Immediate release:** Coni-Snap® Gelatin, Vcaps® Plus, Plantcaps®, Vcaps® Gen C
- **Modified release:** Vcaps® Enteric, DRcaps™
- **Inhalation - Zephyr™:** *Gelatin:* Coni-Snap® Gelatin and Coni-Snap® Gelatin-PEG, *HPMC:* Vcaps® and Vcaps® Plus
- **R&D - Clinical:** PCcaps®, DBcaps®, Colorista®
- **Patient-Centric - End to End:** Coni-Snap® Sprinkle, Press-Fit®, XPress-Fit®, Licaps®, Services & Equipment - Lonza Engine™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SCAN ME

CAPTISOL®
A Ligand TECHNOLOGY

Ligand-owned, Captisol® was invented in 1990 by scientists at the University of Kansas Higuchi Biosciences Center for use in drug development and formulation.

The Captisol® technology is used to address the limitations of currently marketed drugs. Eleven FDA-approved, Captisol-enabled® medications are marketed by: Pfizer, Bristol-Myers Squibb, and Baxter International. Captisol® also has License and Supply Agreements (LSAs) in place with a number of pharmaceutical companies worldwide with Captisol-enabled® product candidates. Routes of administration investigated include parenteral, oral, ophthalmic, nasal, topical, oral, and inhalation.

The regulatory acceptance of Captisol® is supported by extensive safety studies demonstrating its excellent systemic safety profile. In 1999, a Type V Drug Master File (DMF) was filed with the FDA. This regulatory safety data package, which includes greater than 70 volumes, supports the use of Captisol® in parenteral formulations as well as support for other routes of delivery. Multiple FDA divisions and ex-US regulatory agencies have evaluated the data package and permitted the use of Captisol® in clinical trials.

Captisol® is an established enabling technology with substantial characterization, safety documentation and regulatory review. In 1999, a Drug Master File Type V, containing preclinical and clinical safety data for Captisol® was filed with the US Food and Drug Administration. Published in scientific articles and utilized in a number of ongoing clinical trials by leading pharmaceutical and biotech companies, Captisol® is recognized as a valuable and vital delivery technology whose use could mean the success or failure of a development program.

For a complimentary 20g sample, please visit www.captisol.com.

LIQUID CAPTISOL®

Now offering Aseptic-filled Liquid Captisol.

Facilitate your drug discovery and development activities with Liquid Captisol. Liquid Captisol is a 50% aqueous concentrate of Captisol® (Betadex Sulfobutyl Ether Sodium USP/NF) that has been aseptic-filled into 250 mL plastic bottles. The product will help you to move quickly into phase solubility studies, formulation development or safety studies. Now quickly dilute to your desired concentration and determine solubility or dose preclinically. Captisol has been used extensively to provide improved solubility, stability, bioavailability and dosing of challenging ingredients. Liquid Captisol is protected under our all-aqueous patented process and included within our extensive safety database. Accelerate your drug discovery and development and order non-clinical grade Liquid Captisol.

CAPTISOL.com

Catalent®

Catalent is the leading global provider of advanced delivery technologies, development, and manufacturing solutions for drugs, biologics, gene therapies, and consumer health products. With over 85 years serving the industry, Catalent has the proven expertise, superior technologies and flexible solutions at the right scale to help ensure successful product development, launch, tech transfer and reliable global supply.

Catalent has built this expertise through helping partners of all sizes, from the smallest innovators to the largest of biopharmaceutical leaders, to advance thousands of molecules through each phase of development and on to commercial supply. By arranging our expertise, capabilities, technologies and capacity, we provide services from specific, tailored program support or comprehensive, integrated solutions that are fast, flexibility, reliable and that help our partners reduce project risk. In fact, our team of nearly 13,000 at more than 35 sites develop more than 700 projects and help launch in excess of 200 products every year. We produce more than 72 billion doses of over 7,000 products for more than 1,000 customers – or 1 in 20 doses taken by patients globally. Our passion is to help unlock the full potential of your product.

More products better treatments reliably supplied™

Technology Highlights

With our wide range of expert services—including analytical, biologics, preformulation, and formulation—we drive faster, more efficient development timelines and produce better products. These include:

- Paragon Gene Therapy, part of Catalent Biologics, focuses on transformative technologies, including adeno-associated virus (AAV) gene therapies, next-generation vaccines, and oncology immunotherapies.
- GPEx® Boost technology for advanced cell expression, and advanced biopharmaceutical development, analytical and manufacturing.
- SMARTag® technology for antibody-drug conjugation, affording precision design of next-generation biologic therapies.
- OneBio℠ Suite, a single solution from cell line development through clinical supply reduces timelines, risk and complexity.
- OptiForm® Solution Suite to assist in rapid, optimized dose form development.
- Bioavailability enhancement including lipid-based systems, Pharmatek SD™ spray dry technology, particle-size engineering, and OptiMelt® hot melt extrusion.
- Unique delivery technologies: including OptiShell® gelatin-free capsule technology, the Zydis® orally disintegrating tablet platform, and controlled release dose design, as well as inhaled and injectable dose forms.
- Catalent R.P. Scherer Softgel is a global leader in innovative oral and topical softgel technologies, and nearly 90% of NCEs approved by the FDA over the last 25 years have been developed by us.

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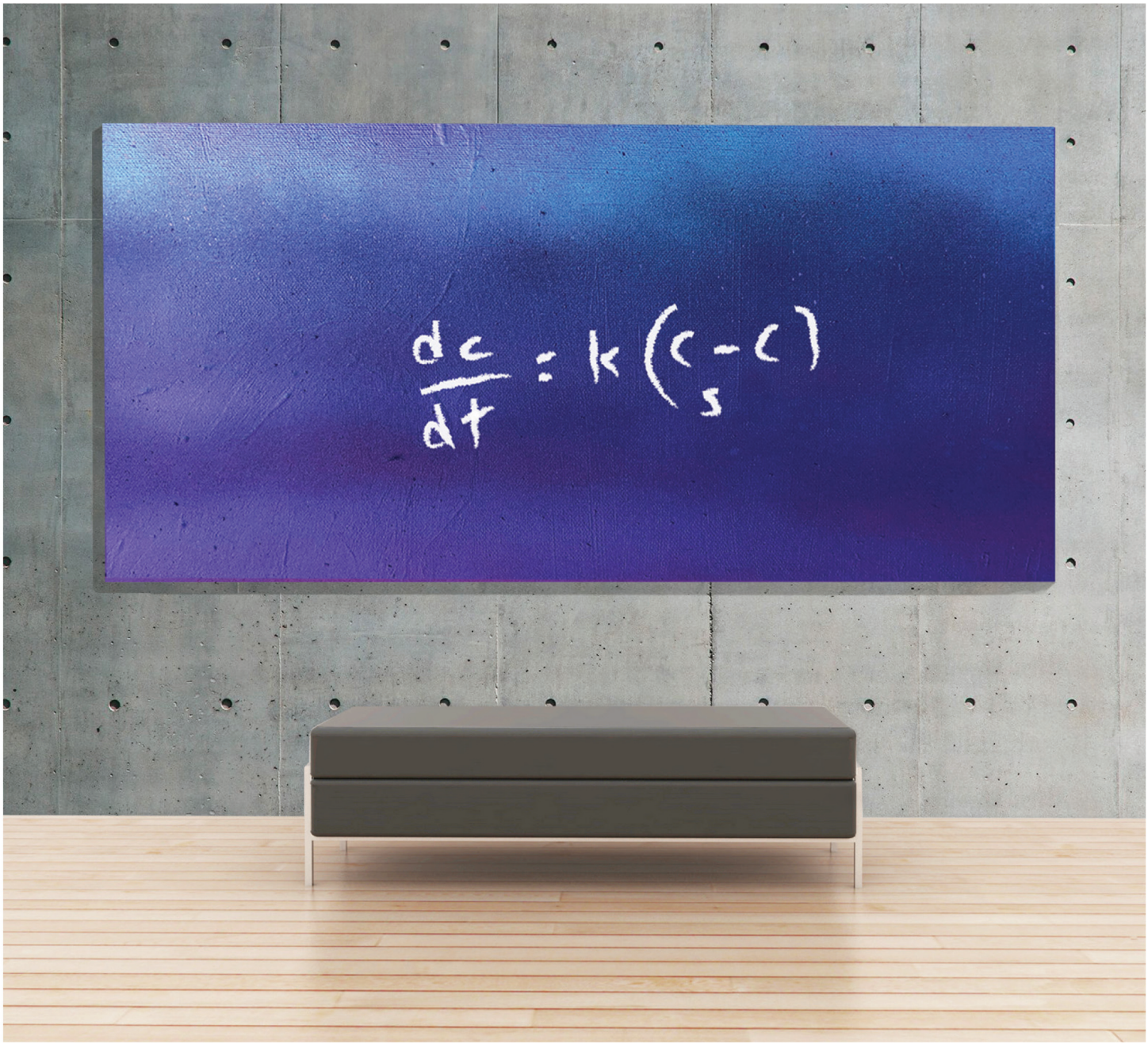

SOLVING BIOAVAILABILITY IS SCIENCE. DESIGNING TREATMENTS IS ART.

Successful formulations for better bioavailability are built on robust science, superior technologies and the art of drug design.

Catalent's expertise in solving thousands of solubility challenges with the broadest toolkit of formulation and delivery technologies, coupled with integrated screening, clinical manufacturing and supply, will help get your molecules into clinic faster, turning your science into reality. **Catalent, where science meets art.**

Catalent®

US + 1 888 SOLUTION (765-8846) **EU** 00800 8855 6178 catalent.com/solubility

CRODA

Pharmaceutical formulators continue to strive to create market leading products with maximum efficacy, quality, and performance. However, the inability to achieve a high level of API solubility and stability are common day-to-day challenges which limit product success. With the help from Croda's superior quality and high purity line of specialty excipients, formulators are able to surpass these barriers, making Croda the supplier of choice in the global pharmaceutical market. With products being manufactured at multiple sites throughout the world, we are able to provide a consistent, local supply of a vast range of high purity surfactants, lipids, and other chemical specialties.

Croda also provides a large span of products for topical dosage forms, as well as multi-compendial solvents, and surfactants suitable for parenteral, oral, ophthalmic, nasal, vaginal, and suppository formulations to help formulators maximize the value of their final drug product.

Croda has developed a proprietary process called Super Refining™ to help create products of superior quality and purity. The process helps to physically remove impurities from pharmaceutical excipients and nutritional oils without altering their fundamental structure. In addition, Croda has been actively investing in GMP API technologies and R&D to ensure the continual delivery of exceptional ingredients, including expertise in drug delivery and vaccine adjuvants. We consider future health and wellness needs when creating new specialty products.

HIGH-PERFORMANCE PRODUCTS

Croda offers a complete (and constantly growing) range of multi-compendial and high purity excipients for various dosage routes and formulations. The company's products include:

- **Super Refined™ Range of Excipients**
  - Oils: sesame, soybean, peanut, corn, olive, safflower, castor and cottonseed
  - Oleic acid: high-purity, multi-compendial excipient
  - PEGs: high-purity, multi-compendial polyethylene glycols
  - Dimethyl isosorbide: high purity solvent for hydrophilic and lipophilic APIs, enhancing skin penetration
  - Polysorbates: multi-compendial, high purity Polysorbate 20, 60, and 80
  - Propylene glycol: high purity, multi-compendial solvent
  - P35 Castor Oil: high-purity polyoxyl 35 castor oil

- **Crodamol™ Range:** a range of ester solvents and vehicles
- **Polawax™:** a complete compendial and self-emulsifying wax
- **Synperonic™ Range:** a range of monograph compliant poloxamers
- **Crodacol™ Range:** fatty alcohols
- **Crodesta™ Range:** sucrose esters for mild emulsification and sustainable release in tablet applications
- **Medilan™:** medical grade lanolin designed to surpass USP requirements for lanolin, modified

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Asia - E: hc-asia@croda.com
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W: https://sealing.datwyler.com/industry-solutions/health-care.html

Headquartered in the heart of the Swiss Alps, **Datwyler** is a leading industrial supplier and key player in global markets for system-critical components in healthcare, automotive, and general industry. The healthcare market segment provides state-of-the-art solutions for parenteral drug and medical device packaging. Datwyler is a leading manufacturer and a key player in the global healthcare world. Our state-of-the-art solutions for drug packaging and medical devices are built on over 100 years of experience. Within our healthcare offering, we provide a unique range of products and services, including the most advanced elastomer formulations, coatings, aluminum seals, and processing technologies. Partnering up with the world's top pharmaceutical and medical companies, we are a vital link and stand by our mission to ensure patients' safety and improve patients' lives.

Datwyler offers best-in-class packaging solutions for the pharmaceutical and biotech markets. The company's product portfolio, service offering, and manufacturing capabilities can meet a variety of different quality needs, ranging from early phases of drug development, through commercial-scale production of highly sensitive biologics and biosimilars. Datwyler is the preferred solution partner to global pharmaceutical companies. We offer one of the most extensive product portfolios for vials, cartridges, and prefilled syringes in the pharmaceutical and biotech markets worldwide. Datwyler's product offering includes a variety of rubber and aluminum seals, plungers, combiseals, tip caps, and needle shields.

In addition to offering a comprehensive product portfolio, Datwyler provides unique material treatment technologies, such as Omni Flex and Dura Coat, to create the highest-quality sealing solutions on the market.

Datwyler's service offering provides its customers with state-of-the-art solutions and testing strategies. In addition to supplying its customers with primary packaging, Datwyler's team of experts is prepared to assist with:

- Lab testing
- Custom product design
- Simulations: Finite Element Analysis (FEA)
- Business continuity plans

WE HELP IMPROVE PATIENTS' LIVES. BECAUSE WE CARE.

Testing experts.
Service specialists.

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P: 952-941-9226
F: 952-941-9318
E: ddlinforequests@ddltesting.com
W: https://www.ddltesting.com

DDL – West
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Irvine, CA 92618
P: 714-979-1712
F: 714-979-1721

DDL – NJ
551 Raritan Center Parkway
Edison, NJ 08837
P: 732-346-9200
F: 732-346-0295

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

Combination Product Testing
DDL specializes in testing for the following combination products:

- Pre-filled Syringes – ISO 11040
- Needle-based Injection Systems – ISO 11608
- Vials and Cartridges

Our Expertise Includes:

- Test Method Development and Validation
- Custom Fixture Development
- Protocol Development
- Injection Force Studies and other Mechanical Tests
- Shelf-Life / Stability Studies
- ISO 11607 Packaging Validation
- Complaint Handling / Field Failures / Remediation
- Regulatory and Quality Compliance
- Particulate Identification and Analysis
- Container Closure Integrity Testing (CCIT)

In preparing for regulatory submission or verifying your products conform to the required industry standards, we provide reliable test data to document the performance and safety of your combination product.

Package Testing for Medical Devices & Pharma Products
The purpose of package testing is to ensure that packages are able to withstand the typical events associated with distribution, handling and storage without defect and loss of sterility.

Our package testing services evaluate the strength and integrity characteristics of a packaging system before and after, simulating the anticipated conditions that the system may undergo. This combination of simulation and evaluation is used to validate package compliance with ASTM, ISO, ISTA and other accepted industry standards.

DDL offers full-service package testing at its Eden Prairie, MN and Irvine, CA lab locations, and select package testing capabilities in its Edison, NJ lab.

Stability Storage
DDL provides stability storage space for products requiring environmental conditions based on ICH Q1A guidelines as well as customizable storage conditions. Our facilities contain over 38,000 cubic feet of storage space that have been validated for long-term and short-term shelf life studies under various temperature and humidity requirements.

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.

EXCITE Pharma Services

EXCITE PHARMA SERVICES
324 NW. Capital Drive
Lee's Summit, MO 64086
T: (816) 572-0151 W: www.excitepharma.com
Contact: Keith Koehler, President, kkoehler@excitepharma.com

Excite Pharma Services – Why Choose Us?

Excite Pharma Services is an FDA-inspected contract research/manufacturing organization performing CMC services for pharmaceutical companies, with specialized focus on sterile manufacturing of vials and syringes with analytical chemistry services covering drug substance, drug product, and excipients. Services include small scale development, clinical manufacturing through commercial manufacturing, method development/validation, stability programs, release testing, dissolution, residual solvent and metal analysis, and extractables & leachables testing.

Excite Pharma Services values every project we receive, no matter how big or small. Each project receives the complete care and attention of our talented group of scientists and project managers. You will receive the highest level of customer service and updates regarding your project status. **Your success is our highest priority.**

Excite Pharma Services includes a world-class team with over 75 years of pharmaceutical and related laboratory experience. Excite Pharma Manufacturing Services is offering cGMP sterile fill and manufacturing services from multiple sites in addition to its headquarters in Lee's Summit, MO. Our cGMP manufacturing facilities consists of multiple clean rooms (ISO 5-8 certified) able to handle Phase I-III & small-scale commercial needs for injectable products. In addition to the fill lines Excite is equipped with multiple ISO 5 laminar flow hoods (LFH), making small hand-fill operations seamless.

Excite Pharma Analytical Services includes a wide variety of GLP, non-GLP and GMP analytical chemistry services covering the CMC (Chemistry, Manufacturing and Controls) area of drug development. We have extensive experience as a premier provider of the following analytical chemistry services for drug products and drug substances.

- Method Development, Validation & Transfer
- Bioanalytical Methods/Analysis
- Elemental Impurities/Metals Analysis
- Dissolution
- Stability Programs
- Release Testing
- Residual Solvent Analysis
- Extractables & Leachables
- Research Projects & Special Requests

We have received a number of compliments from previous projects, here are just a few examples:

"In my first project with Excite I was so impressed with their responsiveness and scientific approach to issues that I have them at the top of my list for quoting on any work in their wheelhouse."

"Excite staff are very responsive to customer needs. Additionally, they offered alternative approaches to meet the project objectives that saved time and money."

"Excite came to our rescue and allowed us to get our Phase I trial back on track after a well-known CDMO failed to release our Clinical Trial Material (CTM). We are now recruiting patients, thanks to Excite! We are very pleased with their customer focus and problem-solving expertise."

Excite Pharma Misson - Patient Safety. Both Animal and Human.

Excite Pharma Values - Treat others how you would want to be treated. Share with those that make you successful. Give back to the community.

Element Materials Technology
W: www.element.com
LinkedIn: Element Materials Technology
Twitter: @ElementTesting

Element Materials Technology is at the forefront of the world's pharmaceutical and medical device testing services. We deliver trusted contract development and quality assurance to our clients across the globe, providing certainty to physicians and patients. Our Experts specialize in Trace Metals Analysis, Analytical Method Development and Validation, Extractable and Leachable Studies, CMC and Clinical Batch Manufacturing, and more. We surpass our client's expectations through unrivaled, tailored services, solid partnerships and our proven track record of helping our customers move their products to market faster. That is why, from CMC development through finished product release testing and everything in between, the world's leading healthcare brands trust Element.

SERVICES

Preclinical

- Toxicology test design
- Toxicological evaluation
- Formulation development
- Pre-formulation analysis
- Microbiological testing

Clinical Support (Phase I & II)

- Formulation development
- Clinical Batch Manufacturing (small-large compounds, parenteral, topical & ophthalmic dosages); Vials, Pre-Filled
- Container Closure Compatibility, Evaluation and selection studies
- Materials Risk Assessments
- Microbiological and Sterility testing

Analytical Testing

- Solid-state characterization (polymorphism, XRD, DSC, microscopy)
- Medical device physical deployment testing (syringe actuation force, implant deployment, mechanical properties of biomaterials, etc.)

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- Medical device 510 K
- Raw Material Excipient and API testing following USP, NF, & EP
- Trace Metals Impurities
- Heavy Metals Testing <232> ICHQ3D
- Development and validation methods for assays and impurities/degradants
- Analytical testing to support stability
- Forced degradation
- Compendial testing (USP, NF, FCC, EP, BP, JP, ACS, etc.)
- Identification analysis for active pharmaceutical ingredient
- Microbiological testing
- Extractables from container closure systems, SUS, manufacturing bioprocessing equipment, and medical devices
- Leachables from container closure system into drug product
- Drug product release testing
- Complementary analysis of dosage forms
- Stability indicating assay development, validation
- Stability storage (ICH)
- Pharmaceutical packaging compatibility
- NMR (GMP Compliant) and Q-TOF
- CMC support documentation for IND, NDA, ANDA
- Particle sizing and characterization
- Contaminant Investigation
- Polymer testing and prototype development

element

EXTRACTABLE & LEACHABLE SOLUTIONS THAT DELIVER CERTAINTY FOR PATIENTS

Element has the expertise to support all Extractable & Leachable (E&L) programs covering materials assessments outlining testing strategies and toxicological evaluations, manufacturing equipment, final drug product packaging systems, and combination medical device products. Our Engaged Experts provide comprehensive solutions tailored for successful product approvals. We build our relationships on expertise, partnerships, and trust in establishing the safety of materials for patients.

KEY SERVICES

- Material selection for pharmaceutical container closure systems (CCS) and medical devices
- Customized E&L study designs developed according to the latest industry best practices
- Complete method development and validation programs
- Toxicological safety assessments
- Development of E&L materials risk assessments and strategy documents suitable for regulatory submission
- Comprehensive materials characterization and leachables risk evaluation according to ISO-10993 parts 18, 12, and 17
- On-site training and consulting programs

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eurofins | BioPharma Product Testing

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Experience Our Expertise

Eurofins BioPharma Product Testing offers complete CMC Testing Services for the Bio/Pharmaceutical industry, including all starting materials, process intermediates, drug substances, drug product, packaging, and manufacturing support through our broad technical expertise in Biochemistry, Molecular & Cell Biology, Virology, Chemistry and Microbiology.

In Our World, Global Is Local

With a global capacity of more than 1,600,000 square feet of facilities and 35 locations worldwide, our network of GMP laboratories and vast experience allow us to support projects of any size from conception to market.

Our local presence with four key sites in the US, including Lancaster, PA; Portage, MI; Columbia, MO; and San Diego, CA, ensures personal service backed by a unique global breadth of harmonized capabilities that supports all functional areas of bio/pharmaceutical drug development.

Collaboration Drives Cost-Effectiveness

Our fundamental philosophy is to help clients efficiently allocate their research and manufacturing expenditures by strategically engaging them to meet their unique outsourcing needs.

We offer the ability to manage your testing programs more efficiently through your choice of three unique service models, including our award-winning Professional Scientific Services® (PSS), Full Time Equivalent (FTE) or traditional fee-for-service. You can choose the best, most cost-effective service solution for your project goals.

Comprehensive Services

- Method Establishment (Development, Validation, Transfer)
- Release Testing
- Stability Testing & Storage
- Characterization
- Residuals & Impurities Testing
- Raw Materials Testing
- Extractables & Leachables Testing
- Container & Package Testing
- Shipping Studies
- Viral Clearance & Viral Safety Testing
- Bioassay & Potency Testing
- Cell Banking Services
- Critical Reagents/Reference Standards Management
- Disinfectant Efficacy/Cleaning Validation Studies
- Environmental Monitoring
- Facility and Process Validation
- Organism Identification
- Clinical Trial Material Support
- Formulation Development/Testing
- Custom Synthesis & Radiolabeling

One CTO. One comprehensive suite of services. One Project Management team eager to make outsourcing simple. Access the leader in consultative problem-solving and world-class testing capabilities.

eurofins | BioPharma Product Testing

www.eurofins.com/biopharma

From Starting Materials through Finished Product Testing, Eurofins BioPharma Product Testing's 35 facilities in 17 countries deliver the world's most comprehensive scope of harmonized GMP testing services and seamless regulatory acceptance.

As we have grown to become the world's largest network of GMP product testing labs, we continue to uphold our founding promise of personal service and impeccable quality.

When the world awaits your product, choose the lab that provides complete capabilities and rigorous quality systems you can trust.

Comprehensive GMP Testing Services

Method Development & Validation • Release Testing • Stability Testing & Storage
Cell Banking Services • Virology Services • Facility & Process Validation
Chemistry • Biochemistry • Molecular & Cell Biology • Microbiology
Raw Materials Testing • Primary & Secondary Package Testing

Flexible Service Models

Fee For Service (FFS)
Full-Time-Equivalent (FTE)
Professional Scientific Services® (PSS)

Global Facilities

Australia	Denmark	India	Japan	Spain	UK
Belgium	France	Ireland	Netherlands	Sweden	US
Canada	Germany	Italy	New Zealand	Switzerland	

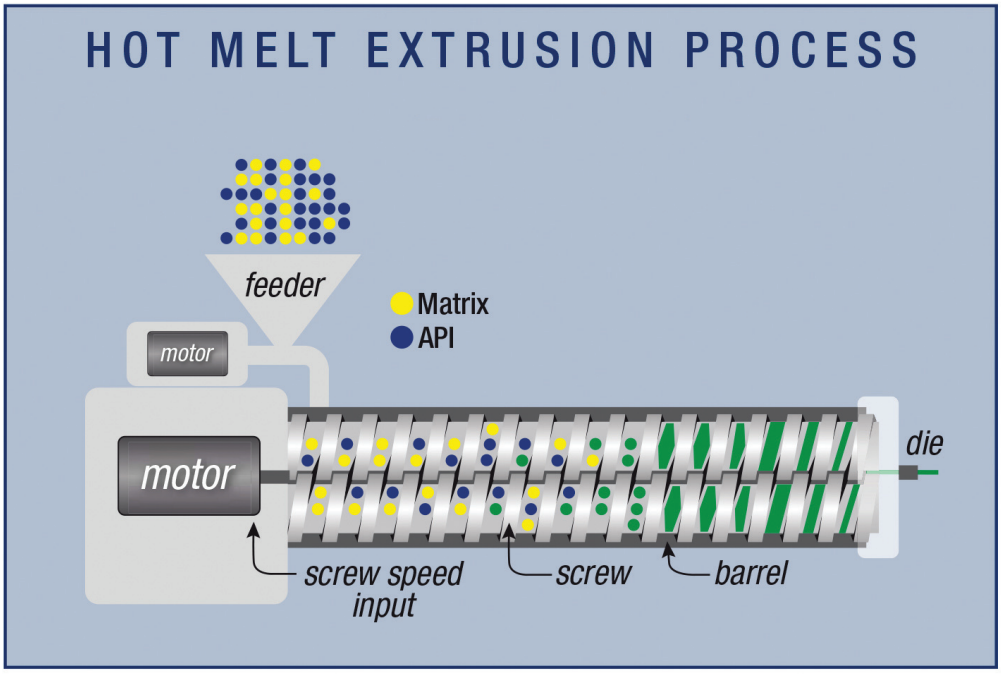
FOSTER DELIVERY SCIENCE
36 Ridge Road
Putnam, CT 06260
T: 860-630-4515
E: rsterling@deliveryscience.com W: www.deliveryscience.com

Foster Delivery Science focuses on GMP and Formulation development Hot Melt Extrusion, applying our expertise using twin screw extruders not only for traditional solubility enhancement techniques, but to create local and long term Drug Delivery Implant and film solutions. As extrusion is a continuous process by nature, melt granulation programs are an obvious interest for lifecycle management and new drug development.

Using the industry range of FDA acceptable polymers, we can create permanent and bio-absorbable implants to deliver drugs immediately or over a desired time period. These implants can be micro implants like ophthalmic applications or macro such as intravaginal rings.

We can also deliver effective APIs in a localized manner using transdermal and mucosal films and other polymer shapes, depending on drug need and client interest.

We work with our clients from our facility located just 75 minutes west of Boston in Putnam, CT.



MELT EXTRUSION

OF DRUG/POLYMER BLENDS

Now Offering GMP Milling of Polymers and Extrudates

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860.630.4515 DeliveryScience.com

36 RIDGE ROAD, PUTNAM, CT 06260

FRONTAGE
YOUR DRUG DEVELOPMENT PARTNER

Frontage Laboratories, Inc. - Your Drug Development Partner

Frontage Laboratories, Inc. is a CRO that provides integrated, science-driven, product development services throughout the drug discovery and development process to enable pharmaceutical and biotechnology companies to achieve their development goals. Comprehensive services include drug metabolism and pharmacokinetics, analytical testing and formulation development, preclinical and clinical trial material manufacturing, bioanalysis, preclinical safety and toxicology assessment and early phase clinical studies. Frontage has enabled many biotechnology companies and leading pharmaceutical companies of varying sizes to advance a myriad of molecules through development and file regulatory submissions in the United States, China and other countries.

Integrated:
Capability and Expertise to Solve Complex Problems

Expertise:
Deep Pool of Talented & Highly-Qualified Scientists

Quality:
Strong Track Record of Regulatory Inspections

Chemistry, Manufacturing, and Control (CMC) Services

Frontage Laboratories, Inc. is a CRO providing integrated, scientifically-driven research, analytical and product development services throughout the drug discovery and development process. With an outstanding compliance history, the CMC (Chemistry, Manufacturing and Control) team operates under strict adherence to ICH and US FDA GMP guidelines. Our broad portfolio of services includes formulation development, and clinical trial material development and production, spanning from preclinical stages through Phase II clinical trials. We have experience with a range of dosage forms, including oral solids/liquids, semi-solids, injectables, and ophthalmics.

We have extensive expertise in analytical method development and validation of both small and large molecules, method transfer, as well as commercial product release and stability testing for global markets.

FRONTAGE LABORATORIES, INC
HEADQUARTERS, BIOANALYTICAL & DMPK SERVICES
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FRONTAGE LABORATORIES, INC
CMC SERVICES & GMP MANUFACTURING
75 East Uwchlan Avenue, Suite 100
Exton, PA 19341
T: (484) 362-0424 Website: www.Frontagelab.com

LinkedIn: https://www.linkedin.com/company/frontage-laboratories-inc/

With an outstanding compliance history, the CMC team at Frontage operates under strict adherence to ICH and US FDA GMP guidelines.

Our broad portfolio of CMC services spans drug product development, analysis, and clinical trial materials' delivery and supply, from preclinical stages through Phase II clinical trials.

To learn more, visit our website at **frontagelab.com/service/cmc/**

FRONTAGE
YOUR DRUG DEVELOPMENT PARTNER

CONTACT US TODAY: *sales@frontagelab.com*
OR VISIT US AT: *frontagelab.com*

About Gattefossé

Gattefossé provides functional excipients and innovative drug delivery solutions to the health and beauty industries worldwide. Our service and distribution network spans over 60 countries, ensuring responsiveness to the pharmaceutical industry's needs from both regional and global perspectives.

Products and Applications

At Gattefossé, each excipient is designed to meet a unique set of formulation and functionality objectives while conforming to the highest safety, quality, and regulatory standards.

Product applications include solubility and bioavailability enhancers; sustained/controlled release matrix formers; protective coatings or taste masking agents for actives; emulsifying bases for topical dosage forms; skin penetration and permeation enhancers; and carriers for suppository and vaginal pessaries.

Among our renown products are Compritol®, Labrafil®, Gelucire®, Labrasol®, Capryol®, Lauroglycol™, Precirol®, Tefose®, and Suppocire® series. Globally established for safety and pharmaceutical qualifications, many of these excipients are also found in pediatric dosage forms.

Technical Support

In addition to safety and characterization data, formulation guidelines, and regulatory filing support, we offer formulation assistance. Working closely with drug manufacturers, our Technical Centers of Excellence work in Asia, Europe, and North America are hard at work resolving solubility, dissolution, drug release rate, and or dosing options.

Typical customer projects include solubility and compatibility screening, formulation characterization and ultimately development of prototype formulations for oral, topical, transdermal, and other routes of administration.

Our aim is to advance drug pipelines, speed up drug delivery projects, and essentially shorten drug development time.

Gattefossé Corporate Headquarters
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Email: infopharma@gattefosse.com

Gattefossé USA Regional Office
Tel: +201-265-4800
Email: info@gattefossecorp.com

GATTEFOSSÉ

Lipid systems bring formulation solutions that others don't...

Capryol®, Compritol®, Gelucire®, Labrafil®, Labrasol®, Lauroglycol™, Maisine®, Transcutol®

People make our name

HASELMEIER
Reliability and success in therapy

HASELMEIER, INC.
126 John Street, Suite 11
Lowell MA 01852
T: +1 978 252 3700
E: Terry O'Hagan, T.Ohagan@Haselmeier.com
W: www.Haselmeier.com

Experts in subcutaneous drug delivery systems for self-administration, Haselmeier provides innovative and award-winning individual system solutions to support patients for a successful therapy. This family-owned business covers all steps – from design to planning to industrialization – in the creation of high-quality self-injection systems. In 2020, this well-established company will be able to look back on a 100-year-old success story.

As a leading solutions provider in customized smart drug injection systems, we support reliable, successful therapies. As a leading solution provider for subcutaneous self-injection devices, Haselmeier constantly drives innovation. We develop advanced technology that improves therapy and examine the requirements of therapy efficiency to evolve technology even further. We place patient comfort and the needs of our customers at the heart of our approach.

We believe that while technology can enhance therapy efficiency, the needs of therapy inspire even better solutions. As a proactive partner, we offer high-tech products and bespoke services, and adapt quickly to evolving engineering opportunities or market changes. Our approach is built on a century of experience – and an open, curious mind.

Haselmeier works with pharmaceutical and biotechnology companies to improve the lives of patients by manufacturing pens and auto-injectors that are convenient, reliable and that can be dosed with precision.

Spread across seven global locations on three different continents, the Haselmeier Group employs a workforce of more than 240 people. Our development and operations facility is located in Stuttgart, Germany with global manufacturing facilities in Germany, Czech Republic and India. Our manufacturing capabilities include high volume injection molding, precision machining, manual and fully automated pen assembly.

As a full-service provider, Haselmeier can support you with a lot more than just R&D, product development and pen assembly. We also provide certified pharmaceutical manufacturing services, and so are able to offer pharmaceutical and biotechnological companies a comprehensive assembly, labeling and packaging service. As a result, we are able to support these companies with their drug manufacturing challenges.

Our innovative reusable and disposable product platforms, connected devices, data management and related service portfolios assist you every step of the way – leading to an advanced combination of drug and device that is as time-saving and economical for your company as it is safe and convenient in therapy. We support you at every stage – from technology to therapy.

Rapid drug development, smooth conduct of clinical trials and fast time-to-market are high priorities for pharmaceuticals companies. For drugs designed for subcutaneous application, self-injection pens from Haselmeier can help reduce risk and shorten time-to-market.

HASELMEIER
Reliability and success in therapy

D-Flex – a new generation of manual injection pens

CUSTOMIZED DRUG DELIVERY – FROM TECHNOLOGY TO THERAPY

As a reliable partner, we develop customized solutions for small batch to high-volume production, from clinical trials to long-term commercial use, and from manual applications to connected devices.

Wide customizable pen portfolio

For more information, visit
www.haselmeier.com

Haselmeier Inc.
126 John Street, Suite 11
Lowell, MA 01852 USA
Phone +1 978 2523700
customer-care@haselmeier.com

HERMES PHARMA

Get the dose right®

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A division of Hermes Arzneimittel GmbH
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82049 Pullach, Germany
T: +49 – 89 79102 261
W: www.hermes-pharma.com

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

ABOUT US

HERMES PHARMA has been working with healthcare companies around the globe for over 40 years to expand their product lines and grow their brands. From new product design and formulation development to manufacturing and regulatory support, HERMES PHARMA offers expert advice and customized solutions at every point along the pharmaceutical value chain. We are the experts in the development and manufacture of user-friendly oral dosage forms, offering a 'one-stop-shop' to meet our customers' needs. Whether they are looking to co-develop a new product, in-license one our products or concepts, or simply outsource manufacturing to our specialists, we can do it.

HERMES PHARMA is a division of Hermes Arzneimittel, a leading German pharmaceutical company that manages a rich portfolio of over-the-counter (OTC) brands.

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.

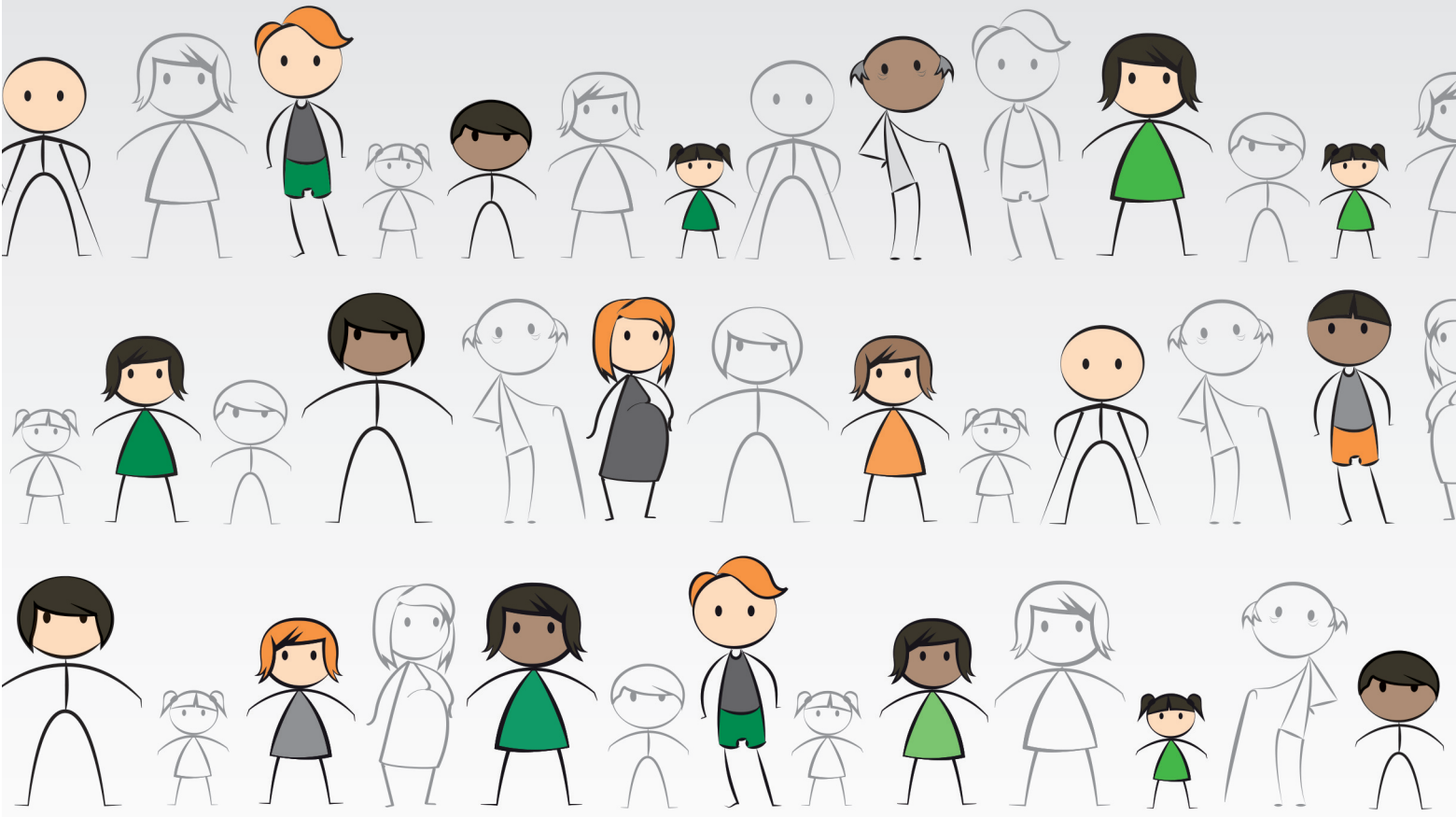
HERMES PHARMA is the leading expert for effervescent and chewable tablets, lozenges, instant drinks, orally disintegrating granules and HERMES NutriCaps. These user-friendly dosage forms:

- 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®

INTEGRAL BIOSYSTEMS LLC
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Bedford, MA 01730
T: (781) 258-4039 (direct line) T: (781) 275-8059 (general)
E: sbarman@integralbiosystems.com
W: www.integralbiosystems.com

Integral BioSystems is a Bedford, MA-based CRO specializing in formulation development, analytical methods, scale-up, and technology transfer of ophthalmics, dermals, injectables, otics, pulmonary, sublinguals, etc. With state-of-the-art formulation and analytical equipment and expert staff, the company excels at sustained-release drug products, including injectable microspheres, liposomes, hydrogels, nano-complexes, and micro/nanocrystals.

With greater than 75+ years of combined pharmaceutical drug development expertise, Integral BioSystems has built a significant track record since the beginning of its operations in 2011. To date, Integral has developed complex formulations and dosage forms for small molecules, proteins, peptides, nucleic acids, and small molecules. As a CRO, Integral BioSystems offers pharmaceutical companies formulation development services, process engineering, scale-up, technical transfer, and CMC writing services for FDA submissions. Integral BioSystems, LLC is based in the Boston area, with offices and fully equipped laboratories at Bedford, MA.

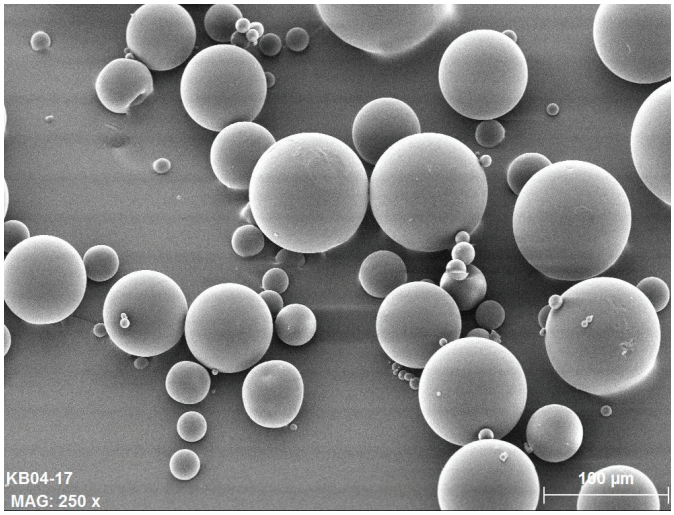
Operating on a hybrid business model of both fee-for-service (CRO) and innovation (offering patent-protected licensable technologies for 505b2), Integral has focused on the most complex of delivery challenges in ophthalmic and injectable dose formats. As fee-for-service, Integral offers both R&D and GLP services in to the pharmaceutical industry, and is nimble in its delivery timelines. Additionally, Integral offers R&D bioanalytical services for early stage pharmacokinetics studies and GLP services when formulations for toxicology are needed.

Integral BioSystems invites collaborations that can be strictly on a CRO-basis to create drug products with compounds that already have IP protection, or as a co-developer with pharmaceutical companies to render repurposed drugs IP-protectable with Integral's proprietary drug delivery innovations.

As an innovation company, Integral scientists have developed and patented two delivery systems: OcuSurf™ and NanoM™.

OcuSurf™ is a proprietary nanostructured, bioavailability-enhancing eyedrop-based platform delivery system, designed to deliver drugs to the ocular surface, enhancing permeation into ocular tissues.

NanoM™ is wafer-based ocular insert, releasing precise, predictable concentrations of drug over time. The composition of the NanoM delivery system can be modulated for a drug regimen that lasts a week, to one that can be designed to last multiple weeks. The company is in active collaborations with multiple drug companies to co-develop ophthalmic products utilizing these delivery modalities. Integral invites questions for future collaborations and opportunities.



JRS PHARMA FAMILY

The Global Excipient Maker

A Member of the JRS Group

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Customer Service: +49 79 67 152-34
W: www.jrspharma.com

USA
T: 845-878-8300 F: 845-878-3484
Customer Service: 1-800-431-2457

COMPANY DESCRIPTION

JRS Pharma is a leading manufacturer of excipients, offering a complete portfolio of excipient solutions for the pharmaceutical and nutraceutical industries. Our excipients portfolio includes: high functionality excipients, binders, disintegrants, lubricants, functional fillers, thickeners, stabilizers, carriers, and coatings. In addition to our wide range of excipients, we offer excellent technical and formulation support to address the needs of our customers.

Our innovative excipients and coatings, along with our formulation expertise, provide our customers with a complete portfolio of solutions for the development and manufacture of solid and liquid dosage forms.

COMPANY BACKGROUND

Founded in 1878, the JRS Group has over 140 years of experience. With twelve business units, including Pharma, Food, and Road Construction, the global JRS network has grown to more than 90 Production Sites and Sales Organizations worldwide.

MARKETS SERVED

Pharmaceutical

To best serve the pharmaceutical industry, we offer the most complete portfolio of excipients for solid and liquid dosage forms

Nutraceutical

We are committed to sourcing our raw materials from sustainable sources. Thus, our wood-based products are derived from sustainable forests and our fiber-based products are developed out of responsible agriculture.

Contract Pharma

We are dedicated to offering products that increase speed to market, provide ease of scale-up, improve content uniformity, and optimize formulations.

Animal Health

To meet the needs of the growing global animal health industry, we provide solutions for custom delivery systems and dosage forms. Our animal health product portfolio includes stabilizers, as well as nutritional and functional fibers, for veterinary medicine and animal health supplements.

SERVICES & CAPABILITIES

We offer technical support worldwide through our Technical Competence Centers (TCCs) located in Germany and the U.S, as well as application labs in Mexico, Brazil, China and India. Our highly qualified team of experts provides product/process-specific solutions, as well as formulation and application support.

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

WHO WE ARE

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

Clients leverage on our abilities for bringing new products to the clinic and implementing improvements for current products. Capitalize on over 25 years of excellence and our unparalleled capabilities in product development, process engineering, clinical manufacturing, and technical support.

MAJOR MARKETS

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

SERVICES OFFERED

Capabilities

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

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

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

Development Sciences

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

- Product Design
- Formulation Development
- Thermal Analysis
- Cycle Design/Refinement
- Product Characterization
- Pilot Plant Scale-up
- Isolation/Containment
- Cartridges

Clinical Manufacturing

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

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

Technical Services

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

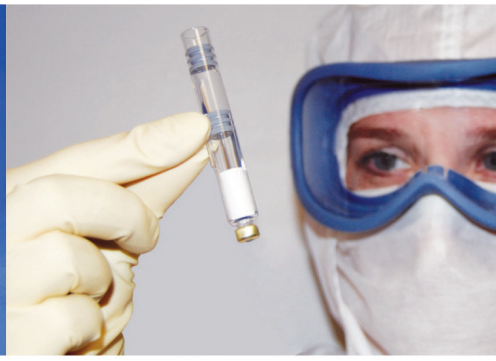
- Customized Training
- Consulting on equipment specifications
- Process requirements
- Guidance on CMC submission
- Support on IQ/OQ and process validation
- Technology transfer
- Process excursions
- Product and process troubleshooting
- Batch record review
- Compliance auditing

Lyophilization TECHNOLOGY Inc.

Integrating Science and Technology

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





DEVELOPMENT SCIENCES • CLINICAL MANUFACTURING

CONSULTING AND TRAINING

Product Design • Formulation Development • Thermal Analysis • Boundary Studies

Process Engineering • Dual Chamber Processing • Clinical Material Preparation

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

LYOTECHNOLOGY.COM

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

metrics contract services

Company Overview

Metrics Contract Services is a full-service pharmaceutical development and manufacturing organization serving clients worldwide. Offering clients a complete concept-to-commercialization solution, we've recently expanded our capacity, and added equipment and people to deliver excellence and flexibility for solid oral dosage forms. With an invigorated focus on our dynamic industry, we invite you to learn why we're stronger by any metric.

Pharmaceutical Development and Clinical Trial Materials Manufacturing

We offer comprehensive formulation development services from preclinical through Phase III CTM including: tableting, immediate release, modified release (including controlled/matrix and sustained release), capsule filling, milling, micronizing, enteric coating, spray drying, extrusion, and spheronization. Our facilities and processes are designed to handle potent products, cytotoxic compounds, and controlled substances.

Analytical Services

With more than 125 chemists on staff, Metrics Contract Services analyzes the physical and chemical characteristics of drug substances and drug products through development and validation of methods, release and stability testing. We perform this work in compliance with industry standards and international regulatory guidelines.

Potent Products

Our potent facilities provide total engineered containment through customized, hardwall isolation technologies. Containment is achieved at 30 nanograms per cubic meter of room air; equipment and change parts are dedicated exclusively to potent use. The facility features independent entry, exit and equipment double airlocks, decontamination showers, dedicated washroom, dedicated equipment storage and pass through for product/waste.

Fast Track First Time In Man (FTIM) Studies

Metrics Contract Services has successfully delivered materials for over 150 FTIM studies. Our process ensures speed and quality, with a 16-24 week timeline from receipt of well-characterized NCE to shipment to the clinic. Services include stability studies, analytical methods development and validation. Choose simple formulation, blended powder in capsule, or neat API in a bottle.

Concept-to-Commercialization

The parent company of Metrics Contract Services, Mayne Pharma, recently invested $80 million to significantly expand facilities and equipment at its site in Greenville, NC. The new 126,000 sq. ft. oral dose commercial manufacturing facility quadruples the company's US manufacturing capacity, and the repurposing of existing space creates 10+ new analytical laboratories and formulation development suites.

Metrics Contract Services can now offer a complete concept-to-commercialization solution in one contiguous location for clients, providing larger scale and increased capabilities for seamless scale-up, eliminating the need for site transfers.

METRICS CONTRACT SERVICES
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Stronger By Any Metric.

Increased capacity. Expanded formulation and analytical teams. Enhanced flexibility. At Metrics Contract Services, we're better prepared than ever to take on your project… and see it through from concept to commercialization and everything in between.

Our new, globally compliant facilities and equipment are commissioned and ready for use. We've added talented new team members. And we've designed new flex suites that can be configured for different processes and your unique project needs.

We're investing in people, equipment, systems and facilities across our site because we're invested in our dynamic industry.

Visit metricscontractservices.com to learn more about why we're stronger by any metric.

Formulation Development
Analytical Testing
Commercial Manufacturing
Greenville, NC, 252-752-3800
www.metricscontractservices.com

metrics contract services

An Industry-Leading Portfolio of Formulation Products

Our portfolio of formulation products includes excipients for solid, semi-solid and liquid dosage forms for small and large molecules, allowing you to formulate APIs to your exact specifications and requirements. We offer both customized manufacturing and a standard portfolio of synthetic lipids and functionalized PEGs, biodegradable polymers for sustained release of small and large molecules and functional excipients for excellent performance in tableting processes, solubility enhancement and controlled release. EMDMillipore.com/formulationapp

Parteck® Products for Solid Dosage Forms

With formulation challenges in mind, we have used particle engineering technologies to develop functional excipients specifically for solid oral dosage forms. The products in our Parteck® portfolio feature unique particle properties tailored for excellent performance in tableting processes, for specific drug delivery technologies, or for solubility enhancement. EMDMillipore.com/Parteck

Polymers for Modified-Release Formulations of Biologics

Create long-acting sustained release formulations of proteins and large peptides in injectable formulations with our biodegradable polymer platform. Polymers are suitable for subcutaneous, intramuscular and site-specific injectable formulations in the form of microparticles and implants with high API doses of up to 100 mg/mL. Key benefits include:

- Robust and scalable production process
- Excellent lot-to-lot robustness
- High production yields
- Suitable for continuous mode operation

EMDMillipore.com/polymericplatform

PLA & PLGA Polymers for Modified Release Formulations of Small Molecules & Selected Peptides

PLA and PLGA biodegradable polymers optimize and provide better control of the release kinetics of final drug products. Additionally, nano- and microsphere formulations based on PLGA polymers can be used for the injectable delivery of peptides, therapeutic proteins, hormones and antibiotics, increasing patient comfort and compliance.

The portfolio includes poly (D,L-lactic acid) (PLA) and poly (D,L-lactic-co-glycolic acid)(PLGA) polymers with varying polymer content and characteristics applicable for fine-tuning of sustained release of small molecule and selected peptide injectables. We also offer custom manufacturing capabilities for your unique polymer. EMDMillipore.com/pla-plga

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W: www.emdmillipore.com
Twitter: @MilliporeSigma Facebook: @MilliporeSigma LinkedIn: www.linkedin.com/company/milliporesigma/

MilliporeSigma

Parteck® Functional Excipients

EXPLORE VERSATILITY

Parteck® excipients offer unique particle properties and functionalities that enhance API release kinetics and solubility in your solid dosage formulations. By fine-tuning your formulation's characteristics, Parteck® excipients allow you to optimize — or completely innovate — your product as you advance toward approval and commercialization. We make intelligent formulation design easy.

Let's Explore What's Next at
EMDMillipore.com/Explore

MS_AD2255EN

The life science business of Merck KGaA, Darmstadt, Germany operates as MilliporeSigma in the U.S. and Canada.

Pharma & Biopharma Raw Material Solutions

MITSUBISHI GAS CHEMICAL

Mitsubishi Gas Chemical (MGC) is a leading company in the field of functional chemicals, such as oxygen barrier and absorbing polymers. MGC established the Advanced Business Development Division in 2015 for tackling a variety of today's problems, and the division created OXYCAPT™ Multilayer Plastic Vial & Syringe to solve some issues of existing primary packaging for injectable drugs.

Products

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 example, although about 70% of 300 nm of UV light transmits through glass and COP, only 1.7% transmits through OXYCAPT™. These excellent barrier qualities contribute to the stability of biologics. According to internal studies, OXYCAPT™ surpassed glass and COP in terms of preventing oxidation of antibody.

Furthermore, the characteristics of COP used to the drug contact layer bring more advantages to OXYCAPT™. Some studies have shown OXYCAPT™ generates extremely low levels of extractables. Especially, the level from OXYCAPT™ is much less than type 1 glass with regard to inorganic extractables.

OXYCAPT™ Vial & Syringe are produced by co-injection molding technology. Although the technology has been applied to beverage bottles for many years, MGC is the first company that succeeded in coming up with multilayer plastic syringes. MGC has also developed inspection machinery for the multilayer vial & syringe. All of the containers are 100% inspected by the machinery.

There are 2-mL, 6-mL, and 10-mL for vials, and 1-mL long and 2.25-mL long for syringes. Regarding the ready to use (RTU) vials and syringes, these are sterilized by gamma and provided with ISO-based nest & tub formats. As customizability is one of the features for plastic, MGC is able to consider developing customized OXYCAPT™ containers if requested.

Biologics is a target application for OXYCAPT™ because it is basically sensitive to oxygen, UV, and metals. In addition, OXYCAPT can be applied to epinephrine, which is well-known as an oxygen-sensitive drug. MGC believes that OXYCAPT™ contributes to stability of oxygen and UV-sensitive drugs.

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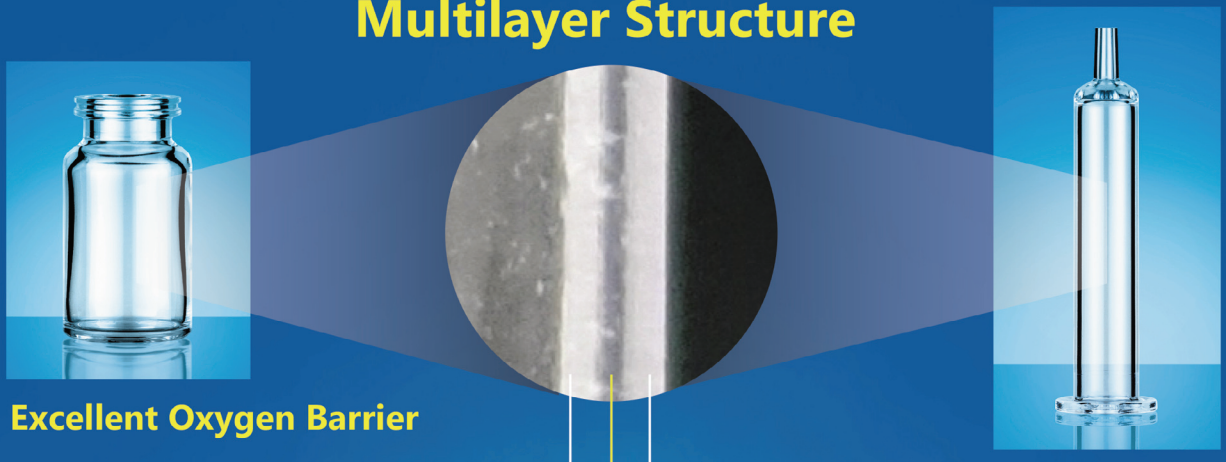
T: +81 3 3283 4913
E: nb3.pharmapackage@mgc.co.jp W: https://www.mgc.co.jp/eng/products/abd/oxycapt.html

OXYCAPT™ Plastic Vial & Syringe

Multilayer Structure



Water Vapor Barrier Layer (COP)

Oxygen Barrier Layer (New Polymer)

Drug Contact Layer (COP)

Excellent Oxygen Barrier

High Water Vapor Barrier

Very Low Extractables

Low Protein Adsorption

Excellent Ultraviolet Barrier

High Break Resistance

High pH Stability

Silicone Oil Free Barrel

Pre-sterilized Vial & Syringe

Customizable

Suitable for Biologics

MITSUBISHI GAS CHEMICAL

Mitsubishi Gas Chemical Company,Inc.

https://www.mgc.co.jp/eng/products/abd/oxycapt.html

Mitsubishi Gas Chemical America, Inc.

http://www.mgc-a.com

E-mail: nb3.pharmapackage@mgc.co.jp

CREDENCE MEDSYSTEMS

INNOVATION WITHOUT CHANGE

Credence MedSystems, Inc.

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

IMPRESS. PRESERVE. PROTECT.

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

Simple, safe, and intuitive usability creates a better, safer experience for patients and healthcare professionals. Innovative designs provide safety activation clicks, end-of-dose feedback cues, and automatic needle retraction—without changes to familiar injection procedures.

Preserve. Differentiate without disruption.

Our unique product innovations coexist with your existing processes, avoiding disruption to your filling lines and simplifying your secondary packaging operations. Use the primary container and components of your choice. Maintain your preferred sourcing strategy and manufacturing processes.

Protect. Safeguard healthcare professionals and patients.

Protect your end users from needlestick and prevent reuse—the needle retracts into the plunger rod after use and is secured inside the barrel. Eliminate glue from your combination products, maintaining your drug integrity and enhancing patient safety.

Stand Out Among the Competition

Differentiating through drug delivery has never been safer, more achievable, and less disruptive. Change the value you provide without changing your processes.

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Note: This product has not been evaluated by FDA.

Nemera

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NEMERA is a world leader in the design, development, and manufacturing of drug delivery devices for the pharmaceutical, biotechnology & generics industries. Nemera always puts patients first, providing high-quality solutions that have a demonstrable impact on patients' health.

NOW WITH END-TO-END DEVELOPMENT OFFERINGS

Nemera's newly branded Insight iInnovation Center, with offices in North America and Europe, can help customers navigate their device strategy for both novel and platform solutions. It provides user research, Human Factors, User Experience design, and Design for manufacturing. Users are at the center of everything Nemera does in its effort to always put Patients First.

Nemera offers a comprehensive portfolio of products and services covering several key delivery routes:

OPHTHALMIC: 0% PRESERVATIVES IN THE DRUG, 100% EYE PROTECTION

TThe use of preservatives can cause side effects to the eye, thus jeopardizing adherence to treatments and damaging patients' eyes. Nemera offers a multi-dose closing tip system, **Novelia®, which avoids the need for preservatives in the drug and prevents bacterial contamination over the duration of treatment.**

EAR, NOSE, THROAT: EASY USE, EASY BREATHE

The number of drugs delivered through ear, nose and throat is expanding. Nemera offers various technologies with **a full range of metered pumps and valves platforms, for regulated and unregulated markets: Advancia®, SP270+ and SP370+, SP27, and SP37.** Nemera now also offers **Child Resistant spray system for oral and nasal sprays**, in collaboration with Roy LeClair.

DERMAL & TRANSDERMAL: CONVENIENT DEVICES FOR DERMAL DELIVERY

Some dermal or transdermal drugs can be very sensitive and need to be delivered at a consistent and precise dosage. Nemera offers **high-performance atmospheric or airless delivery devices for Prescription and OTC applications: Sof'bag®, Sof'Airless**, and a wide range of pumps.

PARENTERAL: COMPLEX DEVICES, SIMPLE PATIENT CARE

Parenteral drug administration exposes patients and healthcare professionals to many hazards. To provide a complete set of services, Nemera has integrated pharmaceutical **drug handling capabilities** (ability to assemble a filled primary container with a device). Nemera's experience in drug delivery devices includes: **Insulin Pens, Autoinjectors and Implanters, and Safety devices for prefilled syringes.**

INHALATION: NEMERA, A PARTNER OF CHOICE

Over 10 million patients use devices manufactured by Nemera every day. **From concept generation to large scale manufacturing, Nemera is the key partner for your inhalation device.**

ELECTRONIC: KNOW-HOW & CAPABILITIES TO ANSWER PATIENTS' NEEDS

Nemera also developed **electronic know-how and capabilities** to answer patients' needs. Nemera brings a wealth of knowledge in development, manufacturing and innovation to electronic devices: **e-Novelia®, e-Advancia®, wearable systems and a cloud platform.**

NOBLE
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Website: www.GoNoble.com

Founded in 1994, Noble® is the global leader in medical device training solutions, patient onboarding strategies, and multisensory product development for the world's top pharmaceutical brands and biotechnology companies. Focused on driving innovation, Noble works closely with brand, device, and commercialization teams to develop turnkey solutions that improve onboarding and adherence, bringing value to clients and patients alike.

We have the expertise to make a difference for patients and brands

As a fully integrated product development company, Noble's in-house design, development, and manufacturing expertise enables the seamless transition of concepts from design/engineering to manufacturing. Noble's experience and platforms in these disciplines are supported by an award-winning cross-functional team of industrial, mechanical, material, manufacturing, and quality engineers who consistently develop novel solutions related to mechanical demonstration device requirements. Such solutions result in unparalleled demonstration devices that accurately mimic the behavior of key device features, all while having the ability to be reset and function reliably over the lifetime of the product.

Our exclusive industry-leading collaborations uniquely position us to serve our clients and deliver unrivaled value and quality. Through cooperative agreements with prominent device manufacturers, Noble is provided key product specification information and insights, thereby ensuring that all training and demonstration devices not only simulate commercial drug delivery device functionality, but also provide patients a hyper-realistic simulation experience.

Beyond Noble's device manufacturer partnerships, our device agnostic technologies allow us the versatility to accommodate a wide variety of autoinjector, prefilled syringe, on-body, and respiratory device form factors – all while being a low-cost reusable solution to safely and effectively onboard users.

We're more than a product development company – we're your go-to resource

In addition to developing innovative training platforms and holistic-based solutions, Noble also offers a variety of services designed to provide clients with comprehensive support through pre-and post-launch. We provide clients with in-depth market research, ranging from device usability and preferences, competitive analysis to training and onboarding benchmarking. We also prepare you to get the most out your launch with customized utilization and commercialization strategies, including forecasting, best practices for training devices and patient support, lifecycle management, a revolutionary Train the Trainer program, and more. Plus, Noble's reach spans the globe – with major facilities located in Orlando, FL, and Ningbo, China – so when you're ready to ship, we are well equipped to handle your global logistics management and help you navigate the nuances of shipping your patient training resources worldwide.

Experience the Noble difference

Noble is changing the future of adherence and onboarding through research-driven insights, innovative technologies and patient-focused solutions. Our products drive innovation to make a true impact, and our advanced strategies – from development to commercialization to utilization – are purpose-built to help transform your bottom line. Find out how Noble can make a world of difference for your patients and your brand

PUTTING PRACTICE INTO BEST PRACTICES

DEVICE REPLICATION
Provides a hyper-realistic training experience for patients.

VARIABLE PLUNGER SPEEDS
Allows patients to gain familiarity with the amount of time it takes to successfully inject.

REPEATABLE & RELIABLE
Enables patients to train over and over again.

AGITATOR NEEDLE SIMULATION
Helps diminish wet injections by safely preparing patients for the pressure sensation of a needle.

AGITATOR TIP

noble®

Find out how Noble's training solutions can help improve patients' injection technique and set your brand apart from the competition.

To request a sample, contact us today at **855.400.0833,** go to **GoNoble.com/Solutions** or scan this code ›

Pace Analytical®
LIFE SCIENCES

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T: (651) 738-2728

CDO PRODUCT DEVELOPMENT SERVICES
CRO GMP LABORATORY TESTING

SUPPORTING MEDICAL INNOVATION WORLDWIDE

Pace Analytical Life Sciences (PLS) provides services to help improve human health. Every day our technical teams work together to ensure the safety and efficacy of treatments and therapies created by local and global manufacturers of drugs and medical devices. We share a common goal to bring real value to people, healthcare professionals, and health businesses around the world. Driven by our commitment to improve our health, we deliver services that offer hope — and a better, safer, and healthier life for everyone.

Our CMC Development laboratory in Boston, MA, develops robust, stage-appropriate drug products with concomitant process understanding by leveraging analytical methods, physicochemical, biophysical, and/or biopharmaceutical characterization. This rational approach to pharmaceutical development ensures that our clients' programs are sufficiently de-risked for their stage of development.

Technology transfer to Pace Life Sciences' state-of-the art GMP testing facilities enables our clients to seamlessly and confidently advance their programs to preclinical and clinical studies in a manner compliant with regulations and industry standards.

Our laboratories offer clients access to expertise in testing a full range of dosage forms. As a contract laboratory services provider, we help to ensure the quality of marketed pharmaceutical products by providing:

- Microbiology Testing Services
- Raw Materials Clearance Testing
- Finished Product Testing
- Method Development and Validation
- Stability Storage & Testing
- Extractable / Leachable Studies
- Complete Laboratory Programs

Strategic partnering with Pace Analytical 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 CMC Development through marketed product support.

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 PLS, 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: We integrate all critical path components to ensure that programs advance while meeting rigorous scientific demands with flexibility to address dynamic challenges and aggressive timelines.

Drug Development & Delivery

print + digital + events

Drug Development & Delivery is a print, digital and event provider committed to advancing the applied science, technology, and related business practices of pharmaceutical and biological drug development.

Drug Development & Delivery provides readers with an editorial environment that fosters innovation and collaboration resulting in a shorter time to market.

We report on formulation development, bioavailability and solubility enhancement, drug devices, drug delivery technologies, combination products, contract services, API manufacturing, life cycle management, business development, partnerships and collaborations.

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Exclusive Online Content | Resource Directory
Webinar Production & Marketing
Custom Publishing (print & eBooks)
Custom eNewsletters | Supplier Microsites

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Pfizer CentreOne® is a global CDMO embedded within Pfizer and a leading supplier of specialty APIs. Our global manufacturing network includes more than 35 sites across six continents. Backed by Pfizer resources, we deliver technical expertise, global regulatory support and long-term supply. Working together with our customers, we combine our knowledge with open dialogue to solve challenges.

OUR SERVICES

We concentrate on segments and specialties where we excel. Currently, we focus on:

- Custom small-molecule API synthesis
- Oral solid dose manufacturing
- Small-molecule steroid and hormone intermediates and APIs
- Sterile injectables fill-finish

A CDMO EMBEDDED WITHIN PFIZER

At Pfizer CentreOne we are focused on providing specialty outsourced services to overcome complex manufacturing challenges and meet specific market demand.

Our custom API and oral solid dose offerings are in high demand and we expect these to go from strength-to-strength over the next five years.

Of course, we will continue to leverage Pfizer's facilities and capabilities so that we can offer our partners reliable services.
We are constantly evaluating the Pfizer network to see where there are opportunities for us to serve the market. Ultimately, we aim to address the development and manufacturing challenges faced by pharmaceutical companies today, as these challenges create the demand for outsourced capabilities and skills. Identifying these key areas and ensuring our offering is in line with market demand is our focus. In short, we must focus on delivering services that are of real value to pharmaceutical companies.

Pfizer CentreOne

Wait a minute. What? Pfizer offers API supply and CDMO services?

Yes, we do. Collaborate with Pfizer CentreOne. And access our manufacturing network for your API and finished dosage form needs.

Welcome to Pfizer CentreOne®. We're a global CDMO embedded within Pfizer and a leading supplier of specialty APIs.

Backed by Pfizer resources, we deliver technical expertise, global regulatory support and long-term supply. For more than 40 years, we've been guiding complex compounds securely and efficiently from development through commercial manufacture.

Listening. Solving. Guiding.

Working together with our customers, we combine our knowledge with open dialogue to solve challenges.

Intelligent collaboration with Pfizer CentreOne.

APIs & Intermediates

Pfizer CentreOne has been a leading provider of specialty APIs. You can count on us to deliver you a high-quality molecule over the long term.

Custom API

Pfizer CentreOne specializes in small-molecule API synthesis. We can perform almost any kind of chemistry you need.

Oral Solids

Pfizer CentreOne excels in the manufacture of oral solid dosage forms.

Sterile Injectables

Pfizer CentreOne is a global leader in sterile injectables fill-finish.

Let's collaborate

www.pfizercentreone.com

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

Pfanstiehl's tried and true, platform-enabling protein and cell membrane stabilizers include Trehalose, Sucrose, Arginine, and Maltose. Parenteral-grade, multi-compendial Mannitol and Sodium Succinate are also offered as key tools for formulation optimization. We are continuing to expand this portfolio to include other key excipients based on feedback from our clients who want real cGMP manufacturing from a company that understands and supports their requirements. Many clients are not simply looking for a high-quality source of consistent ingredients, but seek a partner who can adapt to the ever-evolving regulatory landscape and address emerging formulation challenges collaboratively.

For upstream applications, Pfanstiehl manufactures high purity, low endotoxin, low metal galactose for reduction of lactate and ammonia production. Overall cell culture performance improvements can be achieved with optimized titration of galactose in lieu of other carbon sources. Pfanstiehl offers multiple types of galactose, including a non-animal- derived product. Mannose is also offered as a high purity cell culture supplement to improve native glycosylation and improve consistency in product quality attributes, particularly in high titer processes. Trehalose can be utilized in upstream bioprocessing and cell therapy applications to reduce protein aggregation and improve cell robustness.

Pfanstiehl was founded in 1919 and is celebrating its 100-year anniversary as a leader in carbohydrate and process chemistry. Pfanstiehl's customers include most of the world's leading biopharmaceutical and pharmaceutical companies. Our products are utilized in market-leading drugs that treat life-threatening and debilitating diseases, including cancer, rheumatoid arthritis, STDs, and diabetes. Increasing regulatory and quality requirements are benefiting high integrity biopharmaceutical and pharmaceutical suppliers like Pfanstiehl with high purity, strong cGMP controls and a strong reputation with FDA and other regulatory agencies. In everything we do, Pfanstiehl is motivated by a concern for both product quality and environmental/worker safety. We design and equip our plant, write our procedures and train our people to meet or exceed US FDA, cGMP, OSHA and international regulatory and multi-compendial standards.

Delivering on the Promise of Purity

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.

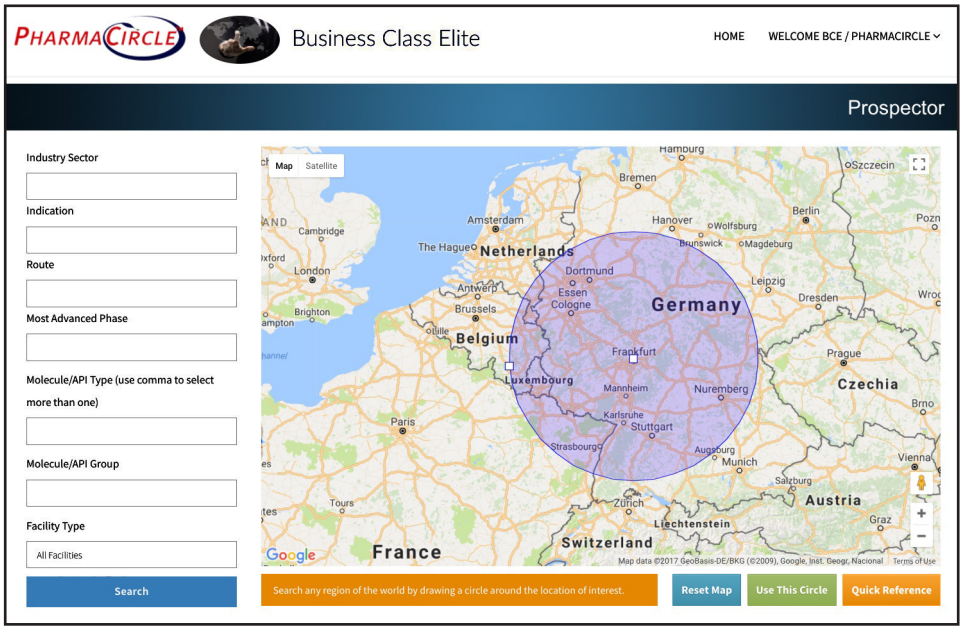
PharmaCircle's premier database tracks drugs, biologics and combination products in all stages of development, connecting pipeline and product information with formulation and component details. The database delivers seamless integration of scientific, clinical, safety, regulatory, manufacturing and commercial information, and detailed analyses on over 7,000 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
- Global Regulatory Compendium
- Physical Chemical & Pharmacokinetic Data
- Venture Capital Investment Tracking
- Service Provider Comparisons
- Patent Exclusivity Tracking
- Drug Label Comparisons
- Key Product Sales & Forecasts
- Veterinary Market Data

To learn more about how PharmaCircle can help your company, please see our ad on pages 7 & 102 and visit our website www.pharmacircle.com.



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Twitter: @portalcambridge

Portal Instruments aims to replace all needles and syringes with a safe, fast, and connected device and to become the standard for modern drug delivery. Portal's needle-free injector is easy to use, and its digital health features empower the patient to holistically manage their chronic condition.

Patient Preferred

Studies have shown that patients perceive less pain and prefer Portal's Needle-free injector versus needle and syringe injections.[1] A recent survey by Portal Instruments found the majority of patients were highly interested in Portal's needle-free injector and that 60% were likely to switch medications in order to use a needle-free drug delivery device.[2]

Next Generation-Needle-Free Technology

Portal Instrument's approach to needle-free drug delivery is quite different from earlier generations of mechanically-based injectors. The Portal Instrument injector administers the drug into the subcutaneous space through a highly pressurized, computer-controlled jet stream. One of the advantages of Portal's needle-free injector is that the jet-stream has a diameter of 200 µm while commonly used needles have a diameter of 400 µm (27 gauge).

In Portal's closed loop system, the device's computer-controlled motor and internal feedback control system work together to sense the pressure and adjust the velocity of the jet-stream accordingly.

A Platform Solution for a Wide Variety of Drug Products

The drug is delivered from a one-time use, ready-to-fill cartridge that is provided to the fill/finish manufacturer in a standard 16 x 10 nest and tub. The design of the cartridge and nest and tub format enables easy and seamless product fill at leading global fill/finish CMOs.

The Prime device has been successfully tested with a wide array of 1-mL drugs, from small molecules to peptides and mAbs over 400 cP. Regardless of the viscosity, the subcutaneous injection is able to be administered in less than 0.5 seconds.

Connectivity for Adherence Insights

The Prime needle-free device can be automatically connected to a secure cloud server, allowing patients the ability to automatically track their injections. Portal's vision is for this data to provide real-time adherence insights which can ultimately be used by the healthcare team to drive better outcomes.

Portal is looking to develop strong partnerships with biopharma manufacturers seeking to differentiate their drugs via a patient-centric delivery system.

References

1. Kojic, N., et al. (2017). An innovative Needle-free Injection System: Comparison to 1 ml Standard Subcutaneous Injection. AAPS PharmSciTech. Doi: 10.1208/s12249-017-0779-0.
2. Research Partnership patient survey. Quantifying Patient Interest in a Needle-Free Drug Injector. February 2019. Available upon request.

Differentiate your drug delivery

Connected, Needle-free Drug Delivery

Available today for your feasibility Studies & Testing

Portal Instruments

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Quotient Sciences
Assess. Adapt. Accelerate.

Quotient Sciences: Your Innovative Drug Development and Manufacturing Partner

Quotient Sciences is dedicated to accelerating the development of new drugs for patients around the world. As a global drug development and manufacturing organization, we support our clients across the full development cycle from candidate selection through to commercial supply.

With over 30 years of experience, our formulation and biopharmaceutics teams are focused on providing innovative, customized solutions for pharmaceutical and biotech customers. As experts in small molecule development, we work with both simple and complex drug products, for oral and inhaled medicines.

Core Services

- Formulation Development
- Clinical Trial Manufacturing
- Commercial Manufacturing
- Clinical Pharmacology
- Translational Pharmaceutics®

When it comes to working with challenging molecules, we use a data-driven approach to formulation design and select the best technology for the molecule. Our global facilities are outfitted with a broad suite of solubility enhancement and modified release technologies and are built with high-potency handling capabilities.

At Quotient Sciences, we believe drug development shouldn't be costly, lengthy, and risky with high rates of molecule attrition. Our unique Translational Pharmaceutics® platform accelerates drug development by integrating formulation development, real-time manufacturing and clinical testing. Translational Pharmaceutics is proven to be significantly faster than the traditional drug development approach, getting life-changing medicines to market and patients sooner and generating multi-million dollar R&D cost savings.

Key Applications Include

- Transitioning molecules from first-in-human (FIH) to proof-of-concept (POC)
- Development and optimization of clinical formulations
  - Enhanced Solubility
  - Modified Release
  - Pediatric Dosage Forms
- Lifecycle management of late-stage and marketed products
- Evaluation of novel drug delivery technologies for all routes of administration

A recent study conducted by the Tufts Center for the Study of Drug Development (CSDD) compared Translational Pharmaceutics® to traditional development programs and concluded that Translational Pharmaceutics® reduced development timelines by more than 12 months and lowered R&D costs by more than $100 million per approved new drug, compared to traditional multi-vendor development paradigms. And given that decision-making is driven by human data, reduced the probability that a drug would fail in later stage clinical testing due to sub-optimal formulation performance.

Whether you're looking for a fully integrated development plan or standalone development and manufacturing services, connect with Quotient Sciences today to discover how we can accelerate the development of your molecule at www.quotientsciences.com/contact-us.

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Quotient Sciences
Assess. Adapt. Accelerate.

Your Innovative Drug Development and Manufacturing Partner

Experts in Accelerating Drug Development

Quotient Sciences has over 30 years of experience in small molecule drug development, supporting clients from candidate selection to commercial supply. We specialize in formulating simple and complex oral and inhaled drug products, and possess a broad range of solubility enhancement and modified release technologies along with high-potency handling capabilities.

Key Services Include:

- **Formulation Development**
- **Clinical Trial Manufacturing**
- **Clinical Pharmacology**
- **Commercial Manufacturing**
- **Translational Pharmaceutics®**

Our unique Translational Pharmaceutics® platform which integrates formulation develoment, real-time adaptive manufacturing and clinical testing has been proven to reduce development timelines by more than 12 months and generate multi-million dollar R&D cost savings.

Whether you're looking for fully integrated or standalone development and manufacturing services, connect with us today to discover how we can accelerate the development of your molecule at www.QuotientSciences.com.

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Locations

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Markham, Ontario
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SGS gives you convenient access to five North American locations that offer a wide range of life science capabilities and proven processes.

COMPANY OVERVIEW

SGS Life Sciences is a leading contract service organization offering high quality analytical development, biologics characterization, utilities qualification, and quality control testing for over 40 years. Backed by a global network of testing facilities, we can help you to reduce risks, shorten time to market and demonstrate the quality and safety of your products. Our facilities utilize cutting-edge techniques and technologies and are staffed by knowledgeable and experienced personnel who stay abreast on the most recent developments in the field. Our aim is to provide a comprehensive package to support clients from molecule to market, through research, clinical trials product development, quality control testing, manufacture and supply. Whether you need a partner to handle all your testing needs or just an extra hand when your in-house capabilities are restricted, SGS is flexible to meet your needs.

SERVICES OFFERED

cGMP Analytical Testing

- Quality control testing of raw materials, APIs, and finished products
- Method development and validation
- Container testing
- Extractable and leachable testing
- Stability testing according to ICH guidelines or customer specifications
- Microbiological testing
- Utilities qualification (air, gas, water and surface)
- Medical device testing
- In vitro toxicology

Biologics Analysis

- Protein/peptide analysis and quantification
- Glycosylation analysis
- Cell line characterization
- Host-cell impurity testing (residual DNA)
- Antibody product analysis
- Higher Order Structures analysis

LIFE SCIENCES

LABORATORY SERVICES

LIFE INSPIRED, QUALITY DRIVEN

GET TO MARKET QUICKLY, SAFELY & EFFICIENTLY

SGS Life Sciences enables the medical and health innovators of the world to deliver life-changing solutions in the quickest, safest and most efficient way, helping improve the lives of many.

SERVICES INCLUDE:

- Biologics Characterization
- Extractables & Leachables
- Stability
- In Vitro Toxicology
- Microbiology
- Analytical Chemistry

CONTACT

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www.sgsgroup.us.com/lifescience

WHEN YOU NEED TO BE SURE

SGS

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Singota Solutions is a contract development and manufacturing organization (CDMO) focused on getting products to patients faster by being agile, accountable, and transparent. Founded in 2006, and headquartered in Bloomington, Indiana, Singota provides responsive, quality driven outsourcing services.

Aseptic Manufacturing - Singota can fill parenterals into ready-to-use vials, syringes, or cartridges utilizing our gloveless, robotic, aseptic filling workcell for pre-clinical, clinical, and small commercial therapies. Our manufacturing process ensures freedom from in-process human intervention by not only removing the impact of operators from the initial aseptic environment but also by removing operator variability from the filling process. Some features include:

- Precise, automated, robotic filling allowing repeatability and reduced line loss
- Small volume runs for vials, syringes, or cartridges
- Use of pre-sterilized, nested containers, and pre-sterilized, single use product contact materials
- Customized finishing services, specializing in small-volume clinical batches

Quality Control & Development Laboratory - Our laboratory services include formulation development, process development, and analytical testing. We work with clients in the early phases of development to post-manufacturing support. Our on-site lab saves valuable time on client projects by working seamlessly with our comprehensive services to ensure client milestones are met. Services include:

- Technology/method transfer
- Method qualification
- Thermal characterization
- Particle size reduction
- Lyophilization
- Raw material testing—compendial and other QC release test methods for identity and CoAs
- Release and stability testing (ICH)
- Transport simulation testing, thermal cycling, and thermal excursion studies
- Material compatibility
- Degradation studies

Supply Chain Management & Warehousing - Singota manages a diversified group of materials from APIs and excipients to finished products in our secure cGMP warehouse. We have the capability to handle toxic, potent, flammable, and hazardous materials. Service features include:

- Controlled room temperature (15°C-25°C), cool (2°C-8°C), and frozen (-20°C, and -80°C) storage conditions available
- Clinical trial support and material distribution
- Expertise in temperature-controlled materials management and distribution practices
- Sampling and dispensing capabilities for bulk material forms (liquids, powders, tablets)
- Client accessible material management software
- International supply chain assistance including importer of record services and European storage

Contact us today to schedule a visit or have a conversation with our Business Development team.

singota®
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- **Powerful Analysis Tools**
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Since 2003, PharmaCircle has been supporting Pharmaceutical Development & Innovation, providing clients with the integrated data, powerful analysis tools, and industry knowledge needed to solve complex, real world challenges in drug delivery and formulation.

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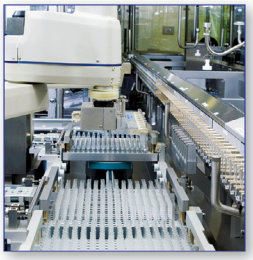

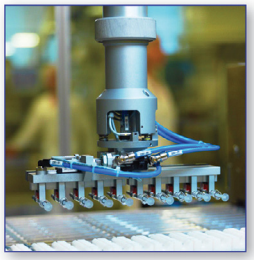

YOUR PARTNER IN ASEPTIC FILLING

Vetter is a leading contract development and manufacturing organization (CDMO) that specializes in the aseptic filling of syringes, cartridges and vials. Vetter holds numerous patents and has extensive experience with biologics and other complex compounds, including monoclonal antibodies, peptides, interferons, and vaccines. More than 80% of Vetter's active projects are biologics.

Collaborating with biotechnology and pharmaceutical companies both large and small, Vetter supports products from preclinical development through global market supply. Through its US and European facilities, Vetter Development Service provides state-of-the-art support for early stage products, with seamless transfer at Phase III to Vetter Commercial Manufacturing for large-scale production. We offer state-of-the-art technology and innovative processes to promote product quality and maximize API yield.

VETTER AT A GLANCE

- Headquarters in Ravensburg, Germany
- Additional clinical development facility in Chicago, US
- A Representative offi ce for Asia Pacific in Singapore and a subsidiary in Japan and South Korea
- Approximately 4,600 employees
- Worldwide specialist in the aseptic production of prefilled drug delivery systems
- Global experience and expertise with regulatory authorities including FDA, EMA, PMDA (Japan), and RP (Germany)
- Lyophilization (freeze-drying) and siliconization specialist

CONTACT US

Visit www.vetter-pharma.com or contact us at info@vetter-pharma.com for more information.

YOURWAY
THE BIOPHARMA SERVICES COMPANY

YOURWAY
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Allentown, PA 18106
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T: +1 610 395 9198
E: info@yourway.com
W: http://www.yourway.com

ABOUT US

The Only Truly Integrated Premium Courier & Clinical Packager

Yourway is The Biopharma Services Company changing the landscape of clinical supply chain solutions by pioneering a unique, single-source model. We are the only truly integrated provider of clinical packaging, temperature-controlled storage, and premium courier services, supported by a global GMP depot network. We have the resources, experience, and commitment to make your management of clinical trials easier and more efficient, delivering competitive advantage.

- Clinical Trials Premium Courier Services
- Clinical Packaging
- Warehousing & Inventory Management
- Global GMP Depot Network
- Comparator Drug Sourcing & Ancillary Materials
- Direct-to-Patient Services
- Cell & Gene Therapy Logistics
- Integrated Project Management

PRODUCTS & SERVICES

Premium Courier Services

With 2 decades of experience and a robust global footprint, Yourway delivers faster turnaround times, flexibility to your protocols, and all the requisite quality and regulatory compliance.

- Biopharmaceutical Drug Product Shipments
- Biological Sample Shipments
- Temperature Control Solutions
- Direct-to-Patient Services
- Cell & Gene Therapy Logistics

Clinical Packaging

We have built and continue to invest in state-of-the-art facilities to integrate packaging services with our storage and distribution and premium courier services.

- Packaging Design & Planning
- Label Design, Translation & In-House Printing
- Primary Packaging
- Secondary Packaging

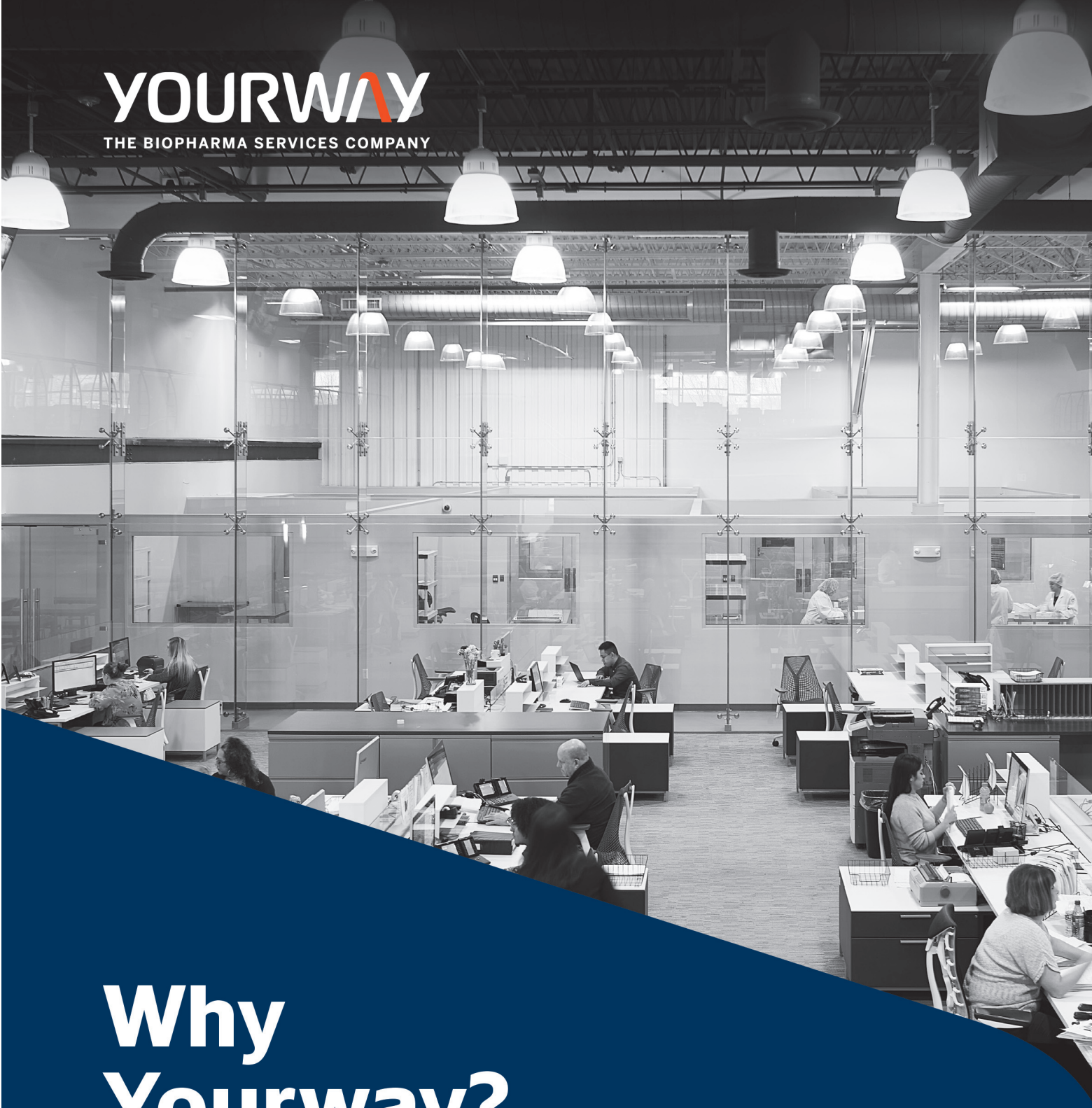
Warehousing & Inventory Control

We enable you to outsource the full scope of your biopharmaceutical storage and distribution needs to a single provider, which optimizes your supply chain efficiency and minimizes risk.

- Controlled Ambient Storage (15°C -25°C)
- Refrigerated Storage (2°C -8°C)
- Frozen Storage (-20°C, -30°C, -80°C, -180°C)
- PCM/Gel Packs
- Liquid Nitrogen
- Hazardous Materials (HAZMAT)
- Active & Passive Solutions

GMP Depot Network

We are headquartered in Allentown, Pennsylvania, close to three major international airports. With 21 fully managed GMP depots worldwide, we are one of few companies that can guarantee to efficiently get your clinical materials around the world in hours, not days.



YOURWAY

THE BIOPHARMA SERVICES COMPANY

Why Yourway?

The Only Truly Integrated Premium Courier & Clinical Packager.

Yourway is The Biopharma Services Company changing the landscape of clinical supply chain solutions with a unique, integrated model. With 20+ years of clinical supply experience and 21 depot locations worldwide, We are the only truly integrated provider of clinical packaging, storage & distribution, and premium courier services.

Discover more at www.yourway.com

Contract Manufacturing

By choosing **AbbVie Contract Manufacturing**, your team gets so much more than the typical CMO engagement. AbbVie's partners gain access to integrated scientific expertise and processes that have successfully guided many small molecule and biologic medicines through commercialization. AbbVie's Contract Manufacturing has been serving our partners for over 35 years. Our contract/toll development and manufacturing capabilities span Fermentation, Drug Product, Potent, Hot Melt Extrusion, Prefilled Syringes, Biologics, and Bulk Active Pharmaceutical Ingredients (APIs) across 10 production facilities in North America and Europe. You can rest easy knowing we have done this before as your compound enters our cGMP contact manufacturing facilities. For more information, visit AbbVie Contract Manufacturing at www.abbviecontractmfg.com or email us directly at **abbviecontractmfg@abbvie.com**.

Lipid-Based Excipients

ABITEC Corporation is dedicated to the advancement of essential bioavailability enhancement and formulation development technology. ABITEC develops and manufactures lipid-based excipients to enhance the bioavailability of poorly water-soluble and poorly permeable Active Pharmaceutical Ingredients (APIs) for the pharmaceutical industry. ABITEC has an expansive portfolio of CAPMUL® bioavailability enhancers, which are medium-chain mono- and di-glycerides and propylene glycol esters. These functional lipid excipients act as solubilizers and emulsifiers in oral, topical, transdermal, and parenteral drug delivery systems. For more information, visit ABITEC at **www.abiteccorp.com**.

Specialty CDMO

Adare Pharmaceuticals is a global specialty CDMO providing product development through commercial manufacturing expertise focused on oral dosage forms for the Pharmaceutical, Animal Health and OTC markets. Adare's proprietary technology platforms specialize in ODT, taste masking and customized drug release. With over 30 years of proven legacy, Adare has successfully developed and manufactured more than 40 products sold by partners in more than 100 countries globally. For more information, visit Adare Pharmaceuticals at **www.Adarepharma.com**.

CDMO Services

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

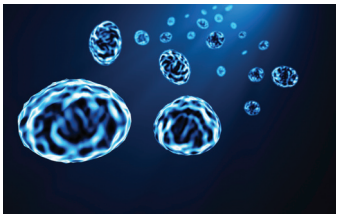
CDMO Services

Alcami is a world-class fully integrated end-to-end contract development and manufacturing organization (CDMO) headquartered in North Carolina, with executive offices in Durham and Wilmington. With approximately 900 employees at nine locations worldwide, Alcami helps biologics and pharmaceutical companies of all sizes navigate the complex road of delivering breakthrough therapies to patients faster, from concept to commercialization. Alcami connects its global clients with customizable and innovative solutions for API development and manufacturing, solid state chemistry, formulation development, analytical development and testing services, clinical and commercial finished dosage form manufacturing (oral solid dose and parenteral), packaging, and stability services. For more information, visit Alcami at **www.alcaminow.com.**

Contract Laboratory Testing Services

ARL Bio Pharma is a contract laboratory that provides analytical and microbiological testing to pharmaceutical companies and research scientists. Since 1998, ARL has supported the industry-wide commitment to deliver high-quality therapeutic drug products by providing guidance and test services for all phases of the product lifecycle following USP, FDA, and ICH guidelines. Whether you are an innovator or pharmaceutical manufacturer, we provide the testing needed to get your pharmaceutical products to market. Services: USP <61> Microbial Enumeration, USP <62> Specified Organisms, USP <51> Antimicrobial Effectiveness, USP <71> Sterility, USP <85> Endotoxin, Stability Studies, Method Development /Validation, USP Monograph Testing, Y-Site Compatibility Studies, and Dissolution. For more information, contact ARL at (800) 393-1595 or visit **www.arlok.com**.

Nanoparticle Formulations



Ascendia Pharmaceuticals is a contract development and manufacturing (CDMO) company offering services for formulation development of poorly soluble drugs and other challenging development programs. Our formulation options include nanoemulsions, amorphous solid dispersions, nanoparticles, liposomes, and oral controlled release. These technologies are suitable for oral, topical, or injectable dosage forms. NanoSol is our technology for production of nanoparticle formulations. Ascendia has the capability to make nanoparticles from native drug crystals using ball milling, or lipid-based nanoparticle composites for lipophilic drugs. When the nanoparticle is delivered to the body there is greater surface area for dissolution, and by using enhancers in the formulation higher bioavailability can be more readily achieved. Ascendia can optimize nanoparticle formulations and produce clinical trial materials for first-in- man studies. For more information, contact Ascendia at (732) 640-0058 or visit **www.ascendiapharma.com.**

Specialized Sterile Injectables

Baxter

Backed by over 85 years of experience in parenterals, **Baxter's BioPharma Solutions (BPS)** business collaborates with pharmaceutical companies to support commercialization objectives for their molecules. BPS is a premier CMO with a focus on injectable pharmaceutical manufacturing designed to meet complex and traditional sterile manufacturing challenges with confidence of delivery, service, and integrity. BPS can support your pharmaceutical needs with a broad portfolio of sterile fill/finish production capabilities, and our reputation is built on the high-quality products we manufacture for our clients in a cGMP environment. Our delivery systems include: prefilled syringes, liquid/lyophilized vials, diluents for reconstitution, cartridges, powder-filled vials, and sterile crystallization. For more information, visit Baxter BioPharma Solutions at **www.baxterbiopharmasolutions.com.**

Parenteral Delivery Devices

BD

FOR BETTER TREATMENT OF CHRONIC DISEASES. Across the healthcare continuum, BD is the industry leader in parenteral delivery devices that help health systems treat chronic diseases. We not only continually advance clinically proven, prefillable drug delivery systems, we do so with a vision to help healthcare providers gain better understanding of how patients self-inject their chronic disease therapies outside the healthcare setting. This is why we partner with leading pharmaceutical and biotech companies worldwide to develop digitally-connected self-injection devices — including wearable injectors and autoinjectors — to capture valuable data that can be shared with caregivers. Discover how BD brings new ideas and solutions to customers, and new ways to help patients be healthy and safe. For more information, visit BD Medical – Pharmaceutical Systems at **bd.com/Discover-BD1.**

Platform Technology

CAPTISOL®

Captisol is a patent-protected, chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Captisol was invented and initially developed by scientists in the laboratories of Dr. Valentino Stella at the University of Kansas' Higuchi Biosciences Center for specific use in drug development and formulation. This unique technology has enabled 11 FDA-approved products, including Onyx Pharmaceuticals' Kyprolis®, Baxter International's Nexterone®, and Merck's NOXAFIL IV. There are more than 30 Captisol-enabled products currently in clinical development. For more information, visit Captisol at **www.captisol.com.**

Oral Dose Design & Development

Catalent offers its partners end-to-end solutions, from early drug product development, formulation, and drug delivery technologies, to manufacturing and clinical supply services. From its global network of facilities, Catalent supports the development and launch of over 100 new products annually. Catalent has a wide range of tools and technologies available to profile each molecule's unique characteristics and challenges and create dose forms that benefit patients. The award-winning OptiForm® Solution Suite platform is fast, flexible, and fact-based, combining the broadest selection of enabling technologies to ensure the right decisions are made at each stage of development to create oral dose forms that can improve a drug's clinical efficacy and commercial success. For more information, contact Catalent Pharma Solutions at (888) SOLUTION or visit **www.catalent.com**.

Super Refined™ Excipients

CRODA

Croda manufactures a complete range of high purity excipients and delivery aids, offering superior quality for the global pharmaceutical market. These excipients are ideal for multiple dosage forms, including topical, parenteral, oral, and ophthalmic formulations as well as advanced delivery systems. Croda's Super Refined™ excipients go through a proprietary process to remove the polar and oxidative impurities that can cause performance and stability issues. These excipients are ideal for use when working with sensitive drug actives, helping to maximize the stability and overall performance of the drug product. Excipients in the Super Refined range include PEGs, polysorbates, oils, and triglycerides, propylene glycol, castor oil, and a range of topical penetration enhancers, such as oleic acid and dimethyl isosorbide. For more information, contact Croda at (732) 417-0800 or visit **www.crodahealthcare.com.**

Datwyler Healthcare

Datwyler Sealing Solutions is a leading industrial supplier and key player in the healthcare industry. The Swiss-based company provides state-of-the-art solutions for parenteral drug and medical device packaging which are built on over 100 years of experience. Datwyler's product portfolio, service offering, and manufacturing capabilities can meet a variety of different needs, ranging from early phases of drug development through commercial scale production. Datwyler is the preferred solution partner to pharmaceutical companies and offers one of the most extensive product portfolios for vials, cartridges, and prefilled syringes in the pharmaceutical and biotech markets worldwide. The offering includes a variety of rubber and aluminum seals, plungers, combiseals, tip caps, and needle shields. Our mission: to ensure patients' safety and improve patients' lives. BECAUSE WE CARE. For more information, visit Datwyler Sealing Solutions at **www.sealing.datwyler.com**.

Testing Services

DDL®

Testing experts.
Service specialists.

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

Testing Services

element

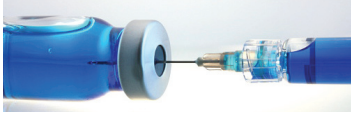
Element Materials Technology is at the forefront of the world's pharmaceutical and medical device testing services. We deliver trusted contract development and quality assurance to our clients across the globe, providing certainty to physicians and patients. Our Experts specialize in Trace Metals Analysis, Analytical Method Development and Validation, Extractable and Leachable Studies, CMC and Clinical Batch Manufacturing, and more. We surpass our client's expectations through unrivaled, tailored services, solid partnerships and our proven track record of helping our customers move their products to market faster. For more information, visit Element Materials Technology at **www.element.com.**

CMC Testing Services

eurofins | BioPharma Product Testing

Eurofins BioPharma Product Testing offers complete CMC Testing Services for the Bio/Pharmaceutical industry, including all starting materials, process intermediates, drug substances, drug product, packaging, and manufacturing support through our broad technical expertise in Biochemistry, Molecular & Cell Biology, Virology, Chemistry and Microbiology. With a global capacity of more than 1,600,000 square feet of facilities and 35 locations worldwide, our network of GMP laboratories and vast experience allow us to support projects of any size from conception to market. For more information, visit Eurofins BioPharma Product Testing at **www.EurofinsUS.com/BPT.**

Contract Research/Manufacturing



Excite Pharma Services is an FDA-inspected manufacturing/contract research organization performing GMP manufacturing with specialized focus on aseptic manufacturing and CMC services for pharmaceutical companies both animal and human. Sterile fill/manufacturing capabilities are for small-scale development through small-scale commercial products. The current manufacturing facility consists of several cleanrooms (ISO 5-8 certified) able to handle Phase I, II, III, IV, and small-scale commercial & hand fill needs. Excite just recently added another facility to its arsenal that consists of another set manufacturing suites in KS that can be used for traditional or sterile manufacturing. Chemistry services include analytical chemistry covering drug substance (APIs), drug product, and excipients. Specific services include method development/validation, stability programs, release testing, dissolution, residual solvent and metal analysis, and extractables & leachables testing. Excite can meet all of your CMC needs. For more information, visit Excite Pharma Services at **www.excitepharma.com.**

CMC Services

FRONTAGE
YOUR DRUG DEVELOPMENT PARTNER

Ensure comprehensive product analysis with Frontage's team of experienced analytical scientists. We specialize in analytical method development, validation and transfer for product development and clinical trial materials (CTM) manufacturing support, as well as commercial product release and stability testing. Our services are designed to help sponsors throughout the drug development process in their effort to fully characterize drug substances, developmental formulations and commercial drug products. Our facilities house a wide range of the latest analytical instrumentation for a comprehensive array of methods. And, we continually keep pace with technology to ensure compliance with evolving regulatory and market requirements. Our development team can solve your analytical challenges efficiently. For more information, contact Frontage at (610) 232-0100 or visit **www.frontagelab.com.**

GMP & Formulation Development

Foster Delivery Science focuses on GMP and Formulation development Hot Melt Extrusion, applying our expertise using twin screw extruders not only for traditional solubility enhancement techniques, but to create local and long-term Drug Delivery Implant and film solutions. As extrusion is a continuous process by nature, melt granulation programs are an obvious interest for lifecycle management and new drug development. Using the industry range of FDA acceptable polymers, we can create permanent and bio-absorbable implants to deliver drugs immediately or over a desired time period. These implants can be micro implants like ophthalmic applications or macro such as intravaginal rings. For more information, visit Foster Delivery Science at **www.deliveryscience.com**.

Formulation Support, Lipid-Based Technologies

With application and R&D Centers in the United States, France, India, and China, the **Gattefossé** group is providing formulation support for oral, topical, transdermal, and other routes of administration. Equipped with state-of-the-art analytical and processing instruments, we are able to support your development efforts and stay at the forefront of research both in basic and applied sciences pertaining to lipids and related drug delivery technologies. Our support covers all stages of development, from solubility screening and preclinical to late-stage formulation and "proof-of-concept" studies. Moreover, we provide extensive regulatory support, sharing toxicological and safety data, and analytical/characterization methods. For more information, visit Gattefossé at **www.gattefosse.com.**

High-Quality Self-Injection Systems

Experts in subcutaneous drug delivery systems for self-administration, Haselmeier provides innovative and award-winning individual system solutions to support patients for a successful therapy. This family-owned business covers all steps – from design to planning to industrialization – in the creation of high-quality self-injection systems. In 2020, this well-established company will be able to look back on a 100-year-old success story. As a leading solutions provider in customized smart drug injection systems, we support reliable, successful therapies. For more information, visit Haselmeier at **www.Haselmeier.com.**

User-Friendly Dosage Forms

HERMES PHARMA is the expert in developing and manufacturing user-friendly oral dosage forms, including effervescent and chewable tablets, instant drinks, lozenges, orally disintegrating granules, and HERMES NutriCaps. The company offers customized solutions at every point along the value chain, from new product development and formulation to manufacturing and regulatory support. For more than 40 years, leading healthcare companies around the globe have been working with HERMES PHARMA to expand their product lines and grow their brands. User-friendly dosage forms are not only a smart solution for people who cannot swallow tablets. Whilst creating an enjoyable experience for the patient, they support healthcare companies to revitalize ageing products and differentiate products from the competition. HERMES PHARMA is a division of Hermes Arzneimittel, a leading German provider of high-quality medicines and supplements marketed under its proprietary, well-established brands. For more information, visit HERMES PHARMA at **www.hermes-pharma.com**.

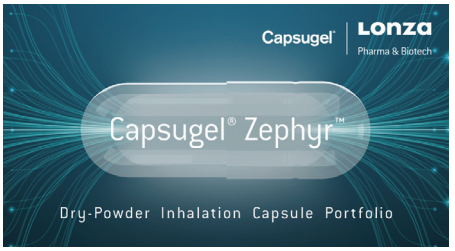
Formulation Development

Integral BioSystems specializes in formulation development, analytical method development, scale-up /technology transfer of ophthalmics, dermals, injectables, otics, pulmonary, intranasal and rectal dose forms. The company offers sustained release drug development including injectable microspheres, liposomes, hydrogels, nano-complexes and micro/nanocrystals. Additional services include GLP formulations for toxicology supplies and non-GLP bioanalytical analyses. Additionally, the company offers licensable, patent-protected delivery systems (OcuSurf™ and NanoM™) for 505b2 products. Integral BioSystems has built a significant track record since the beginning of its operations in 2011, and has established credibility in the pharmaceutical industry. To date, Integral has developed complex formulations and dosage forms for small molecules, proteins, peptides, nucleic acids and small molecules. Integral BioSystems, LLC is housed in 10,000 square feet in laboratory and office space in Bedford, MA. For more information, visit Integral Biosystems at **www.integralbiosystems.com**.

Excipients

JRS Pharma is a leading manufacturer of excipients, offering a complete portfolio of excipient solutions for the pharmaceutical and nutraceutical industries. Our excipients portfolio includes: high functionality excipients, binders, disintegrants, lubricants, functional fillers, thickeners, stabilizers, carriers, and coatings. In addition to our wide range of excipients, we offer excellent technical and formulation support to address the needs of our customers. Our innovative excipients and coatings, along with our formulation expertise, provide our customers with a complete portfolio of solutions for the development and manufacture of solid and liquid dosage forms. For more information, visit JRS Pharma at **www.jrspharma.com/pharma_en/.**

DPI Portfolio



Dry-powder inhalation (DPI) technology offers a favorable drug development opportunity for respiratory or systemic drug delivery. Delivering a uniform dose in a portable, easy-to-use system, capsule-based DPI device is a simple and cost-effective way to deliver inhalable medication. Capsugel® Zephyr™ is Lonza's customizable dry-powder inhalation capsule portfolio that is optimized to provide superior performance and compatibility between the capsule/device and capsule/formulation. Please visit our page for more information or contact our experts to request samples at **https://www.capsugel.com/biopharmaceutical-products/dpi-capsules.**

Lyophilization Services & Solutions

Lyophilization TECHNOLOGY Inc.

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.

The Right Equipment for Your Project

metrics contract services

With our new high-shear mixer, the QUEST HSM III granulator, **Metrics Contract Services** can transition formulations from initial development to the process validation stage and, ultimately, to commercial production. Developed jointly by ACG and Xertecs, the flexible QUEST HSM-III granulator can use three different size bowls to accommodate granulation batch sizes from 3 kg to approximately 25 kg. Moreover, its slip ring technology affords us the ability to measure the force acting on the rotating impeller shaft. It provides a sensitive measure of granulation endpoint and, just as important, provides scale-up data during tech transfer. The new granulator further expands our portfolio of manufacturing and service capabilities including pharmaceutical formulation development, preclinical and Phases I-III clinical trial materials manufacturing & comprehensive analytical testing. For more information, visit Metrics Contract Services at **www.metricscontractservices.com.**

Life-Saving Therapies

MilliporeSigma

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

Functional Chemicals

MITSUBISHI GAS CHEMICAL

Mitsubishi Gas Chemical (MGC) is a leading company in the field of functional chemicals, such as oxygen barrier and absorbing polymers. MGC established the Advanced Business Development Division in 2015 for tackling a variety of today's problems, and the division created OXYCAPT™ Multilayer Plastic Vial & Syringe to solve some issues of existing primary packaging for injectable drugs. OXYCAPT Vial & Syringe consists of three layers. The inner and outer layers are made of cyclo-olefin polymer (COP), the most reliable polymer in the pharmaceutical industry. The middle layer is made of state-of-the-art polyester developed by MGC. The oxygen-barrier property is almost equivalent to glass and much better than COP. OXYCAPT also provides an ultra violet (UV) barrier. For more information, visit Mitsubishi Gas Chemical at **www.mgc.co.jp/eng/products/abd/oxycapt.html.**

Patient-Focused Delivery Devices

Nemera

With over 1,600 people and four plants across two continents, **Nemera** is a world leader in the design, development, and manufacturing of drug delivery devices for the pharmaceutical, biotechnology, generics industries. Nemera's services and products cover several key delivery routes: Ophthalmic (multidose eye droppers for preservative-free formulations), Nasal, Buccal, Auricular (pumps, valves, and actuators for sprays), Dermal & Transdermal (airless and atmospheric dispensers), Parenteral (autoinjectors, pens, safety devices, and implanters), and Inhalation (pMDIs, DPIs). Nemera always puts patients first, providing the most comprehensive range of devices in the industry, including off-the-shelf innovative systems, customized design development, and contract manufacturing. For more information, contact Nemera at information@nemera.net or visit **www.nemera.net.**

Device Training Platforms

Noble works with drug delivery device manufacturers and biopharmaceutical companies to develop self-injection training devices, including autoinjectors, prefilled standard and safety syringes, wearables, and respiratory platforms to provide biopharmaceutical companies improvements in launch strategies and patient adherence. Noble's training and onboarding platforms are built true to form and function to device specifications and are available as off-the-shelf and customized solutions, with the optional inclusion of proprietary technologies for products ranging from mechanical training devices to smart error-correcting training platforms. These devices are designed to emulate a device's form factor and functionality, including tactile feedback, operational forces, and administration steps to provide patients with accurate simulation of actual delivery devices while being a low-cost reusable solution to safely and effectively onboard users. Companies providing reusable, device-comparable training products will be well positioned for competitive differentiation through improved patient satisfaction, adherence, and outcomes. For more information, contact Noble at (888) 933-5646 or visit **www.gonoble.com.**

Specialized Products & Services

Pfanstiehl is a leading cGMP manufacturer of parenteral grade excipients and highly potent APIs. Pfanstiehl develops and manufactures high-purity, low-endotoxin (HPLE) carbohydrates such as trehalose, sucrose, mannitol, galactose, and mannose utilized as injectable excipients for the stabilization of proteins, mAbs, and vaccines. These HPLEs are also used as supplements for industrial cell culture, cell therapy, and cryopreservation media. Pfanstiehl also works closely with some of world's largest multinational pharmaceutical and biopharmaceutical firms, as well as with virtual pharmaceutical companies, to synthesize proprietary and commercial compounds in quantities ranging from grams to MT quantities. Manufacturing and development occur at Pfanstiehl's a 13-building campus located near Chicago, IL. For more information, visit us at **www.pfanstiehl.com.**

Global Contract Manufacturer

Pfizer CentreOne® is a global CDMO embedded within Pfizer and a leading supplier of specialty APIs. Our global manufacturing network includes more than 35 sites across six continents. Backed by Pfizer resources, we deliver technical expertise, global regulatory support, and long-term supply. Working together with our customers, we combine our knowledge with open dialogue to solve challenges. For more information, visit Pfizer CentreOne at **www.pfizercentreone.com.**

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