Advancing Development & Manufacturing
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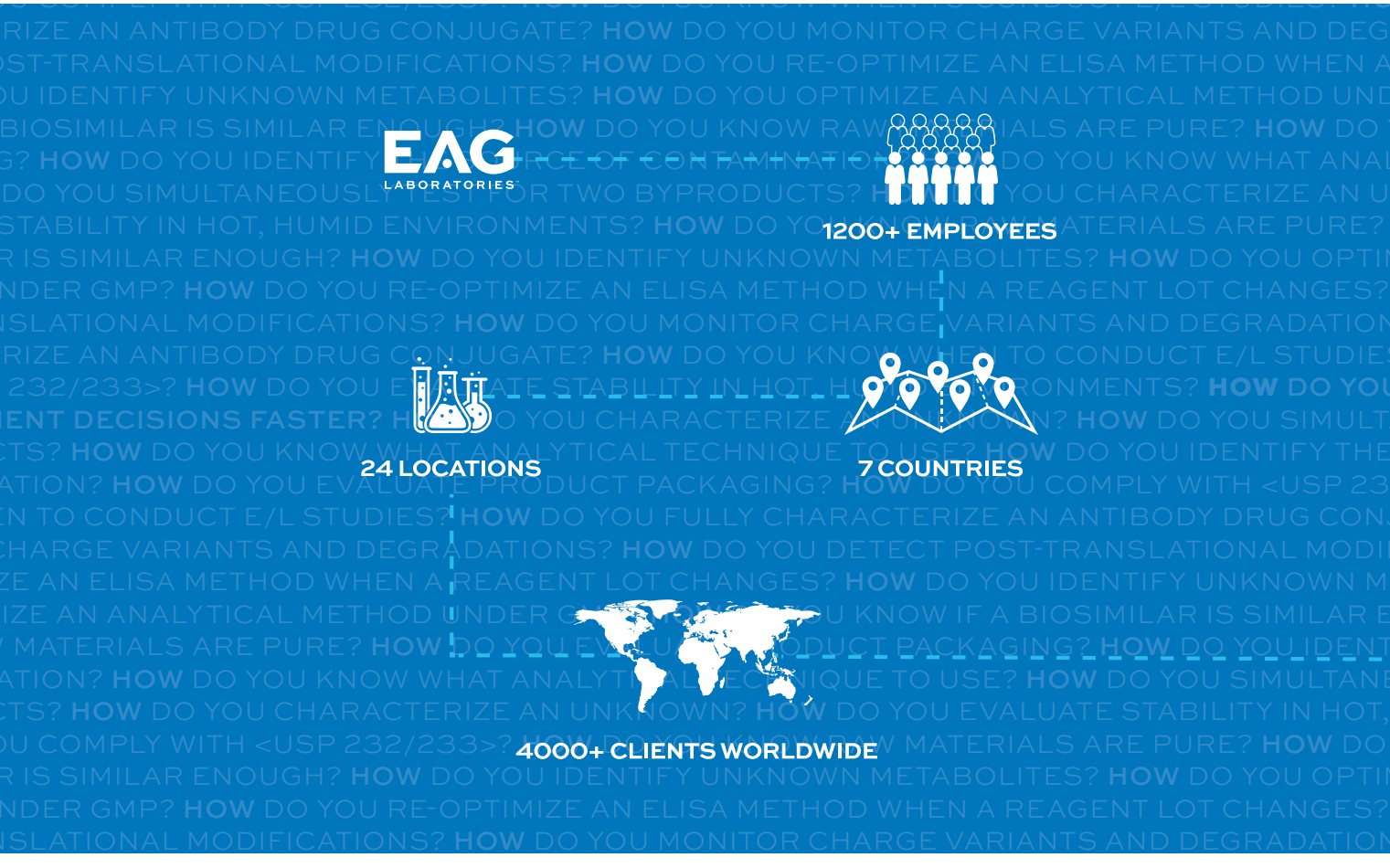
2016



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EAG Laboratories is a global scientific services company serving clients across a vast array of technology-related industries. Through multi-disciplinary expertise in the materials, engineering and life sciences, EAG helps companies innovate and improve products, ensure quality and safety, strengthen supply chains, protect intellectual property and comply with evolving global regulations.

Advancing Development & Manufacturing

Pharmaceutical Technology®

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2016

CORPORATE CAPABILITIES 2016

LEADING PHARMACEUTICAL INDUSTRY SUPPLIERS

UBM

PHARMACEUTICAL TECHNOLOGY CORPORATE CAPABILITIES
2016
pharmtech.com

Mike Tracey is publisher of *Pharmaceutical Technology*, mike.tracey@ubm.com.

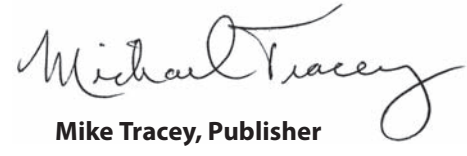
Supplier Connections

Choosing the right supplier can make all the difference in bio/pharmaceutical manufacturing, and *Pharmaceutical Technology's Corporate Capabilities* issue can help make choosing the right partners easier. This special issue offers up-to-date information on suppliers in manufacturing, ingredients, cleanroom, packaging, laboratory, information technology, and outsourcing.

To make connecting to these suppliers even easier, *PharmTech* is proud to present our online Pharma Marketplace. This online directory provides bio/pharma companies with contact and services information on a wide variety of bio/pharmaceutical companies that provide equipment and supplies in ingredients, facility design, laboratory equipment, manufacturing, and packaging, as well as a variety of outsourcing services. Be sure to visit www.PharmTech.com/marketplace to make your next connection.

While you are visiting *PharmTech.com*, be sure to check out the latest articles, news reports, blog posts, podcasts, and webinars that are available. A wide variety of topics including outsourcing, manufacturing, regulations, and more are covered.

We hope that this special *Corporate Capabilities* issue, along with our online Pharma Marketplace, provides you with all the market options and contacts you need to have a successful and productive 2017!



Mike Tracey, Publisher

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PharmTech.com

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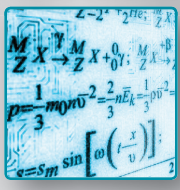

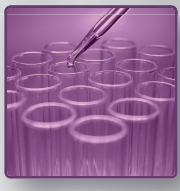


Corporate Capabilities 2016

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CLEANROOM Equipment and Supplies

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wipers@contecinc.com

WEBSITE
www.contecinc.com

DATE FOUNDED
1988

CORPORATE CAPABILITIES

Contec, Inc.

Company Description
Contec is a leading manufacturer of contamination control products for critical cleaning in manufacturing environments worldwide. With more than 25 years of experience behind us, we understand the unique cleaning requirements of these highly regulated markets. Our sales and technical support teams are fully trained to assist customers in finding or creating a Contec product that best meets their needs.

Markets Served
Contec's cleanroom wipes, mops, and disinfectants are used in various industries across the globe including biotechnology, pharmaceutical, medical device, and other critical life science applications. Contec has local distribution throughout North America, Europe and Asia.

Major Products/Services
Contec's extensive product line for cleanrooms and critical environments includes:
- Sterile and filtered 70% alcohols
- Sterile and filtered disinfectants
- Mopping systems and cleaning tools
- Presaturated wipes
- Knitted and nonwoven dry wipes
- Spill control products, sponges, and swabs

Contec Alcohols
70% IPA is available sterile and filtered in either 16oz trigger sprays, 32oz, or 128oz capped containers. Blended with purified water, the sterile version has a less than 0.25 EU/mL endotoxin level guaranteed.

Contec Disinfectants
Contec's disinfectant range includes a unique fast-acting sporicide, Peridox RTU, and Concentrate; and AHP (Accelerated Hydrogen Peroxide)- based PREempt RTU solutions and wipes. This range is being expanded all the time.

PROSAT® and SATWIPES®
Contec introduced the first presaturated wipes in 1993 and the range has expanded to include sterile and non-sterile, knitted and non-woven presaturated wipes in many sizes, formats, and substrates.

Dry Wipes
Dry wipes have been Contec's core business for the past 25 years. Contec offers one of the widest ranges of sterile and non-sterile, knitted and non-woven dry wipes available for cleanroom use.

Mopping Systems and Cleaning Tools
A variety of mopping systems and cleaning tools are available for all sizes and grades of cleanroom. From triple bucket systems, bucketless systems, and isolator cleaning tools, Contec has a mop for every facility. Sterile and non-sterile, reusable and single-use mops heads are available, in a wide variety of substrates.

Facilities
Contec owns and operates manufacturing facilities in South Carolina, USA and Suzhou, China. Contec has established a cleanroom manufacturing facility and distribution center in Europe that allows us to locally support our European customers. Contec has a team of technical specialists and sales representatives in Europe, North and South America, and Asia. These facilities and dedicated team members give Contec the ability to provide product and technical support to multi-national customers with global needs.

More than meets the eye

With one of the widest ranges of cleanroom wipes and mops available, plus a newly completed range of alcohols, disinfectants and detergents, there is definitely more to Contec than meets the eye. From patented Anticon wipes with particle attraction technology, or market leading presaturated wipes in a variety of substrates, Contec has a cleanroom wipe to suit every budget, application and facility. Contec has launched three new innovative mopping products, adding a curtain cleaner and sealed edge mops to their extensive mopping range. Visit our web site to view our newly launched Low Endotoxin wipes, mops and solutions.

For more information contact Contec at wipers@contecinc.com or by calling 1-866-855-4682

CONTEC®

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NUMBER OF EMPLOYEES
150

DATE FOUNDED
1981

CORPORATE CAPABILITIES

Veltek Associates, Inc.

General Description

Veltek Associates, Inc. (VAI), with more than 35 years of experience, has developed an extensive line of products and services that offer solutions to the challenge of contamination control within aseptic manufacturing and controlled environments. With our manufacturing operations that mirror current GMP and GLP standards, VAI is equipped to produce a broad line of sterile chemicals, process cleaners, wipers, cleanroom documentation, a cleanroom printer, synthetic paper, sterile disposable garments, cleaning equipment, and viable air monitoring equipment. All of which constitute an innovative answer to these challenges faced associated with the ingress of contamination.

Technical Services

- Consulting services
- Cleaning and disinfection systems evaluation
- Disinfectant validation studies
- Anti-microbial effectiveness testing
- Personnel gowning training
- Aseptic processing systems
- Viable air monitoring evaluation

Facilities

VAI is headquartered in Malvern, PA USA with satellite sales offices located worldwide. Our manufacturing operations are located in a state-of-the-art facility that mirrors current GMP and GLP standards. The Malvern facility houses all of our divisions: The Environmental Control Monitoring Division, VAI Labs, The Disposable Products Manufacturing Division, and our Sterile Chemical Manufacturing Division. VAI, in addition, is able to serve the pharmaceutical and biotechnology industries in an even greater capacity through our 120 distribution partners.

Major Products

VAI is the leader in innovation. Our innovative products include a complete line of disinfectants, sporicidies, process cleaning detergents, quality water, cleaners, lubricants, buffers, and clean-in-place detergents for use in numerous applications. A variety of VAI's sterile chemicals, in addition, are available in saturated wipers including sterile sodium hypochlorite and hydrogen peroxide wipes. VAI further innovates the cleaning and disinfection process by developing a completely sterilizable, all in one, spray, mop and fog cleaning system that allows operations to effectively, efficiently, and correctly apply cleaning agents. Furthermore, VAI provides sterile disposable garments that are comfortable, breathable, have strong particulate performance, and offer personal protection. Also, Cleanroom Documentation with low particulation including synthetic paper, CleanPrint10, custom logbooks, forms, tags, and labels, Core2Write, and a HEPA filtered printer, the Core2Print. Furthermore, VAI offers our new Cart2Core®, for correct aseptic cart transference by allowing the cart top to detach from the base. Finally, VAI offers viable monitoring equipment that conducts continuous monitoring of air quality to capture and evaluate the ingress of viable contamination. VAI manufactures completely computerized, facility wide, portable, or compressed air sampler systems.

Markets Served

VAI continually innovates, develops, and specializes in contamination control products for classified, cleanroom areas in the pharmaceutical and biotechnology industry. Many of our developments have been landmarks in the industry's history that have allowed our customers to overcome regulatory, manufacturing challenges and reach their business goals.

COVERALL YOUR NEEDS.

STERILE GARMENTS FOR ALL ENVIRONMENTS

Veltek Associates, Inc. offers two garment product lines, which are both pre-folded in our EASY 2 GOWN system. Comfortably styled and fitted with elastic thumb loops to reduce shifting, as well as tunnelized elastic wrists and ankles.

1600 Garments

- Breathable
- Comfortable
- High bacterial efficiency

1700 Garments

- High filtration efficiency
- Low particulate and shedding performance
- Excellent water repellency

Face Masks

- Breathable
- Reduces goggle fogging due to absorption efficiency
- Soft and comfortable

vai

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WWW.STERILE.COM

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The latest business, scientific, and regulatory news, plus feature articles, delivered to your inbox every Thursday.

PHARMTECH FIRST LOOK | *MONTHLY*
Preview the latest issue of *Pharmaceutical Technology* with quick links to online content, expanded coverage, and the digital edition of the magazine.

SOURCING & MANAGEMENT | *MONTHLY*
Reports, analysis, and updates on innovations, regulations, and technology advancements to guide bio/pharmaceutical experts in navigating the contract services and supplier marketplace.

EQUIPMENT AND PROCESSING REPORT (ePR) | *MONTHLY*
Focus on pharmaceutical manufacturing processes and technology, providing analysis of manufacturing news, regulatory issues, and current trends. Each issue features a showcase of processing equipment.

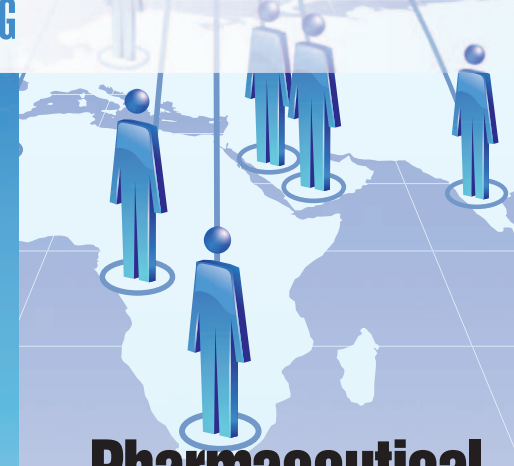
PHARMTECH WHITEPAPER ALERT | *MONTHLY*
Receive free technical whitepapers and application notes submitted by leading pharmaceutical manufacturing product and solution providers.

SUBSCRIBE TO *PHARMACEUTICAL TECHNOLOGY'S* FREE eNewsletters

YOUR GLOBAL RESOURCE

ON EQUIPMENT, SUPPLIES, AND SERVICES FOR BIO/PHARMACEUTICAL DRUG DEVELOPMENT AND MANUFACTURING

Pharmaceutical Technology's print issues and online portfolio address key trends in drug development, including equipment and manufacturing trends. Read expert editorial coverage on emerging trends, strategies, and best practices in these key areas!



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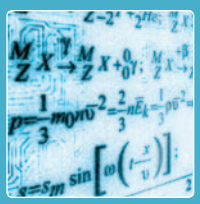

INFORMATION Technology

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NUMBER OF EMPLOYEES
120

DATE FOUNDED
1992

CORPORATE CAPABILITIES

EtQ, Inc.

Corporate Description
Founded on March 4, 1992 by former lead auditors of Underwriters Laboratories, EtQ has always had a unique knowledge of compliance processes related to GMP, Quality, Safety, and Environmental Health and Safety Management. EtQ uses best in class integrated modules and enterprise application integration to manage and measure compliance processes and execute organizational change. EtQ's solution, Reliance, is an enterprise suite of modules designed to foster operational excellence in businesses with modules and utilities such as eMDR, Complaint Handling, Risk Management, CAPA, Document Control, Employee Training, Supplier Rating, Audits, and many more. EtQ has been providing software solutions to a variety of markets for over 20 years.

Major Products
EtQ's FDA Compliance Management Software is an integrated Quality and Compliance Management system that has been pre-configured to specifically address the needs of the Pharmaceutical industry. EtQ's unique modular approach provides unparalleled flexibility and automation, delivering a best-in-class solution.

Corrective and Preventive Action
EtQ's FDA Compliance software can generate a Corrective and Preventive Action request that routes through review, root cause, corrective action taken, and verification stages. Multiple reports are generated automatically providing an effective mechanism for tracking the source and costs of problems.

EtQ Risk Register
EtQ's Risk Register calculates risk using a variety of techniques, updates risk at multiple points in the process, and displays risk mitigation history by event. Users can identify risk scores and related actions, view risk charts, build risk histories, and use configurable views to determine top risks in the quality system.

Audits
EtQ's Audits module automates the process of auditing and surveying, including internal audits and customer satisfaction surveys. Some key user definable features include: checklists, question library, evaluation method (numerical scoring or counting), and more.

Change Management
EtQ's Change Management module is designed to manage all aspects of the Change Management process. Change Management integrates with other key modules such as Risk Register to analyze the impact of change, and Complaint Handling to identify adverse events, analyze change feedback, and collect customer requirements for future changes.

EtQ's Electronic Signature and Record
EtQ's FDA Compliance Management Software automatically and securely binds the authenticated user's electronic signature. EtQ ensures that the user has signed onto the system and exposed their signature via the forced authentication process, as required by 21 CFR Part 11. Authentication is required each time a document is processed.

EtQ
Excellence Through Quality

Robust Simplicity.

EtQ features the most comprehensive Compliance Solution that is completely configurable to your business needs

- Automated processes such as Corrective Action, Audits, Risk Management, Complaint Handling, Document Control, and more
- Flexible to adapt to unique business processes, without programming
- Scalable solution that integrates with other business systems
- Make any application mobile and access your data from anywhere, anytime

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http://www.etq.com/fda

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WEBSITE
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International Centre for Diffraction Data

Company Description

ICDD is a non-profit scientific organization dedicated to collecting, editing, publishing, and distributing powder diffraction data for the identification of crystalline materials. Our mission is to continue to be the world center for quality diffraction and related data to meet the needs of the technical community. We promote the application of materials characterization methods in science and technology by providing forums for the exchange of ideas and information. We sponsor the Pharmaceutical Powder X-ray Diffraction Symposium (PPXRD); Denver X-ray Conference, its proceedings; Advances in X-ray Analysis; and the journal, *Powder Diffraction*.

Technical Services

- Powder Diffraction File databases: PDF-4+, PDF-4/Organics
- Pharmaceutical Powder X-ray Diffraction Symposium (PPXRD)
- Denver X-ray Conference
- ICDD XRD Clinics and Workshops
- *Powder Diffraction* journal

Markets Served

ICDD's PDF-4/Organics 2017 database is designed for a multitude of applications in the pharmaceutical, regulatory, specialty chemical, biomaterials, and forensic fields. Its design allows for easy interface with diffractometers and data analysis systems of leading software developers and manufacturers of X-ray equipment. The database is useful for scientists working in consumer products, catalysis, forensic science, analytical labs, drug discovery, and production.

Products and/or Services

- Material Identification Databases
- PDF-4/Organics 2017—The PDF-4/Organics database is a highly targeted collection, with special focus on materials used in commercial and regulatory fields. It is designed to solve difficult problems that are analyzed by powder diffraction analysis for a multitude of applications in the pharmaceutical, regulatory, specialty chemical, biomaterials, and forensic fields. The PDF-4/Organics provides the best of both worlds by including single crystal and powder diffraction data together in a single, edited, and standardized database. We not only extract from the public literature like other databases, we add unique content by extracting patent data, combining single crystal and powder references, adding common inorganics and polymers, and continuously adding targeted materials through grants and research proposals.

Technical Symposium

ICDD will sponsor PPXRD, the 15th Pharmaceutical Powder X-ray Diffraction Symposium. It will be a satellite meeting to the 24th Congress & General Assembly of the International Union of Crystallography - IUCr 2017 from 18–20 August 2017 in Hyderabad, India. This annual symposium is designed to create a forum for the exchange of knowledge and cutting-edge ideas among those interested in the combined fields of XRD and pharmaceutical sciences.

INGREDIENTS and Materials

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WEBSITE
www.cordenpharma.com

NUMBER OF EMPLOYEES
1500

DATE FOUNDED
2006

CORPORATE CAPABILITIES

CordenPharma

Company Description
CordenPharma is your full-service partner in the Contract Development & Manufacturing (CDMO) of **APIs, Drug Products,** and associated **Packaging Services**. Through a network of fully-inspected cGMP facilities across Europe and the US organized under five technology platforms—**Peptides, Lipids, Carbohydrates & Oligonucleotides, Injectables, Highly Potent & Oncology, Small Molecules, and Antibiotics**—CordenPharma experts translate complex ideas at any stage of development into high-value products.

Technical Services
Peptides, Lipids, Carbohydrates & Oligonucleotides
- Synthetic Peptide API Production
  - Solid/Liquid-phase, Hybrid Synthesis
  - cGMP & non-cGMP
- Synthetic Lipids
- Carbohydrates
- Oligonucleotides
  - New Development & Manufacturing Services

Sterile Injectables
- New Development Suite for Aseptic Filling > 1-100 L Batch Sizes (Pre-filled Syringes, Liquid or Lyophilized Vials)
- Sterile Drug Products
- Packaging & Labeling
- Sterile Emulsion Technology
- Parenterals
- Large Pre-Filled Syringes
- Clinical Trial Services

Highly Potent & Oncology
- API Development & Commercial Manufacturing (SafeBridge Category 4, OEL ≤1 ng/m^3)
  - New Development & Scale-up Capacity for Phase I/II Supply
- Drug Product Development & Manufacturing
  - New Development Suite (CTD2) for Mid-scale (up to 20 kg) Oral Dosage Forms
  - Sterile Liquid & Lyofilistion
  - Coated & Uncoated Tablets
  - Hard Gelatine Capsules

- Primary & Secondary Packaging
  - Blister & Bottle Packaging
  - Serialisation & 2D Data Matrix Coding

Small Molecules
- APIs & Excipients
  - Proprietary & Generic Advanced Intermediates & APIs
- Drug Products
  - Solid Oral
  - Terminally Sterilized Injectables
  - Aseptic Filled Injectables
  - Packaging & Labeling
  - Sterile Emulsion Technology
  - Clinical Supply from Phase I–III

Antibiotics
- Non-segregated
  - Oral APIs & Drug Products
  - Sterile Drug Products
  - Primary & Secondary Packaging
- Segregated
  - Cephalosporins & Penicillins
  - Monobactams
  - Primary & Secondary Packaging

Facilities
CordenPharma Bergamo - Italy
CordenPharma Brussels - Belgium
CordenPharma Caponago - Italy
CordenPharma Chenôve - France
CordenPharma Colorado - USA
CordenPharma Latina - Italy
CordenPharma Plankstadt - Germany
CordenPharma Switzerland - Switzerland

CORDENPHARMA

EXPERTS TAKING CARE

FULL–SERVICE, FULLY COMMITTED

CordenPharma is your full-service CDMO for a global market. Through our network of technology platforms and cGMP facilities for the manufacture of APIs, Drug Products and pharmaceutical Packaging, CordenPharma experts translate your complex ideas at any stage of development into high-value products.

www.cordenpharma.com

TECHNOLOGY PLATFORMS

- PEPTIDES, LIPIDS & CARBOHYDRATES
- HIGHLY POTENT & ONCOLOGY
- INJECTABLES
- SMALL MOLECULES
- ANTIBIOTICS

VISIT US AT

DCAT Week '17
March 20–24, 2017
New York, NY USA

Inquiries
www.cordenpharma.com/contact–us/

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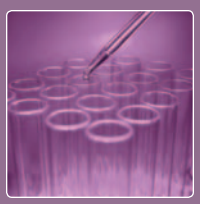

LABORATORY Equipment and Supplies

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NUMBER OF EMPLOYEES
2850

DATE FOUNDED
1945

CORPORATE CAPABILITIES

Eppendorf

Company Description

Eppendorf is a leading life-science company that develops and sells instruments, consumables, and services for liquid-, sample-, and cell handling in laboratories worldwide. Its product range includes pipettes and automated pipetting systems, dispensers, centrifuges, mixers, spectrometers, and DNA amplification equipment as well as ultra-low temperature freezers, fermentors, bioreactors, CO2 incubators, shakers, and cell manipulation systems. Consumables such as pipette tips, test tubes, plates, and disposable bioreactors complement the range of premium products.

Eppendorf products are most broadly used in academic and commercial research laboratories (e.g., in companies from the pharmaceutical and biotechnological as well as the chemical and food industries). They are also aimed at clinical and environmental analysis laboratories, forensics, and at industrial laboratories performing process analysis, production, and quality assurance.

Quality, reliability, experience, innovation—these are words that people worldwide associate with Eppendorf.

We believe this highly regarded reputation is the result of our 65-year history and commitment to deliver the best solutions for handling your most precious samples.

Whether inventing a new technology or enhancing an existing product, every detail is designed with the user in mind. We stay in close touch with customers, so we understand their everyday challenges. Customer insights combined with expert engineering and high-tech manufacturing has enabled Eppendorf to continuously deliver quality products that have helped scientists achieve their goals.

Products and Services

Eppendorf quality products: Backed by expert, reliable support. Eppendorf is not just about products; we're equally committed to providing quality support. Knowledgeable and experienced Eppendorf professionals will assist

you every step of the way—from your product purchase to application support to instrument service. And, we will help you integrate your Eppendorf products to ensure maximum accuracy and reliability of your results.

Preventive maintenance ensures system reliability by early detection and solving of problems. Our certification packages provide calibration, verification, installation qualification/operational qualification (IQ/OQ) services for your instruments ensuring precision and accuracy according to manufacturer or customer requirements. Complete documentation is provided in compliance with legal guidelines and standards.

With the new global service programs for our ultra-low temperature freezers, CO_2 incubators, and biological shaker instruments, a comprehensive range of service programs build the basis for the premium support from Eppendorf worldwide.

Facilities

Eppendorf was founded in Hamburg, Germany in 1945 and has more than 2850 employees worldwide.

The company has subsidiaries in 25 countries and is represented in all other markets by distributors.

eppendorf

We Know Bioprocessing

Eppendorf bioprocess solutions—for all your bioprocess needs

The Eppendorf bioprocess portfolio combines the DASGIP and New Brunswick product lines to offer a complete portfolio of scalable hardware and software solutions for R&D, process development, pilot and production.

> 35 mL to 2,400 L working volumes
> Parallel Benchtop Bioreactor Systems
> Autoclavable and SIP fermentors
> Rigid wall single-use vessels with 65 mL to 40 L working volume
> Precise and intuitive process control
> Comprehensive information management

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NUMBER OF EMPLOYEES
420 (U.S.)
11,050 (Worldwide)

DATE FOUNDED
1975 (U.S.)
1875 (Shimadzu Corporation)

CORPORATE CAPABILITIES

Shimadzu Scientific Instruments

Company Description

Shimadzu Scientific Instruments (SSI) is the North American subsidiary of Shimadzu Corp., headquartered in Kyoto, Japan, a leading provider of analytical measurement and testing instrumentation for a broad range of applications. Shimadzu's extensive portfolio of innovative high-quality system platforms provides customers with unparalleled solutions-based offerings and we encourage results-driven collaborations that meet growing customer demands. With a vast installed base and preferred vendor status at many institutions, SSI's instruments are used for quality control and research across the globe by customers who can count on the long-term stability, experience, and support only Shimadzu offers.

Technologies

- Chromatography (HPLC/UHPLC, GC)
- SFE/SFC
- Mass Spectrometry (LC-MS/MS, GC-MS/MS, MALDI-TOF)
- Molecular Spectroscopy (UV-Vis, FTIR, Fluorescence)
- Atomic/Elemental Spectrometers (AA, ICP-MS, EDXRF)
- Thermal Analyzers
- Particle Size Analyzers
- Total Organic Carbon Analyzers
- Data Management
- Balances
- Materials Testers

Facilities

Shimadzu's US headquarters includes a customer service and training center, a solution center to showcase technologies, and a new innovation center that will house a team of engineers and scientists whose goal will be to develop close collaborations with universities, government agencies and industry centers. Shimadzu's regional facilities, strategically located around the US, provide customers with local sales, service, and technical support.

Major Products/Services

Shimadzu's instruments are used throughout the pharmaceutical pipeline, from life science research and drug discovery and development to manufacturing and QA/QC. Key instruments include:

- Nexera X2 UHPLC
- i-Series Integrated HPLC/UHPLC
- Nexera UC SFE-SFC
- Triple Quad LCMS-8040/8050/8060
- AXIMA Performance TOF/TOF
- MALDI-7090
- PPSQ Protein Sequencers
- Triple Quad GCMS-TQ8040
- RF-6000 Spectrofluorometer
- ICPE-9800 Spectrometer

In addition to a wide array of instruments, Shimadzu actively pursues collaborative research projects with customers and partners. Its new solution center and innovation center enable SSI to more quickly develop new software applications and focus-based solutions to better serve growing customer demands.

Markets Served

With a diverse portfolio of instruments, Shimadzu's products are used in a wide range of industries, academia, and government. These include pharmaceuticals, biopharma, life sciences, clinical, environmental, chemicals, forensics, electronics, automotive, food and beverages, and material sciences.

SHIMADZU
Excellence in Science

SHIMADZU
Excellence in Science

Nexera UC
Unified Chromatography

Unifying SFE/SFC Workflows

Sample Prep to Analysis in One Click

Nexera UC on-line SFE-SFC is the first system to break the technology barrier between automated sample pre-treatment and chromatographic analysis using supercritical mobile phase.

Learn more about Shimadzu's Nexera UC.
Call (800) 477-1227 or visit us online at
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Shimadzu Scientific Instruments Inc., 7102 Riverwood Dr., Columbia, MD 21046, USA

Automatic extraction of up to 48 samples with seamless transfer to SFC/MS provides:

- Rapid separation harnessing the unique characteristics of supercritical mobile phase
- Efficient separation of isomers and enantiomers
- High-sensitivity detection using a variety of separation modes
- Split-less introduction to MS for enhanced trace analysis
- Reduced environmental impact and mobile phase cost compared to typical organic solvents

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SOURCING & MANAGEMENT | *MONTHLY*
Reports, analysis, and updates on innovations, regulations, and technology advancements to guide bio/pharmaceutical experts in navigating the contract services and supplier marketplace.

EQUIPMENT AND PROCESSING REPORT *(ePR)* | *MONTHLY*
Focus on pharmaceutical manufacturing processes and technology, providing analysis of manufacturing news, regulatory issues, and current trends. Each issue features a showcase of processing equipment.

PHARMA KNOWLEDGE RESOURCES | *MONTHLY*
Receive free technical whitepapers and application notes submitted by leading pharmaceutical manufacturing product and solution providers.

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CORPORATE CAPABILITIES

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Sales@eliz.com

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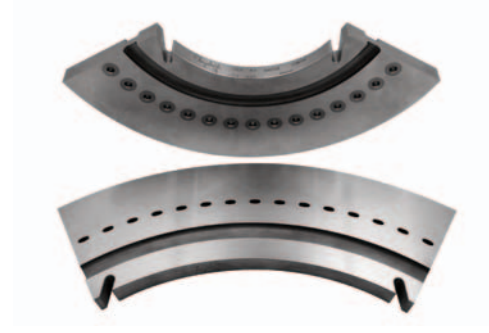
www.eliz.com

Elizabeth



About Us

Since our inception in 1954, Elizabeth has grown to be the premier global supplier of compression tooling, rotary tablet presses, spare parts, and services to rotary tableting industries. Elizabeth is your global partner for precision compression tooling and tablet press spare parts. With modern manufacturing centers in America, Europe and Asia, and our network of experienced customer service and sales staff, you can count on Elizabeth to support your needs before, during and after your purchase.

While worldwide capabilities have grown steadily; the Elizabeth philosophy of Complete Customer Satisfaction continues to thrive from its founding principles. Elizabeth is dedicated to providing the best possible products and services through an unequaled level of satisfaction, trust, communication and customer service.

Markets Served

Elizabeth's customers are world leaders in the pharmaceutical, nutritional, battery, powdered metal, ceramic, electronics, automotive airbag, nuclear fuel, and confectionery industries.

Products and Services

Our range of powder compression technologies include:

- Elizabeth Carbide Die compression tooling.
- Elizabeth Scheu & Kniss replacement parts, turrets, and press services.
- Elizabeth-Europe blister feeding solutions.
- Elizabeth-Hata tablet presses.
- The new Eliza-Press series of manual and automated tableting presses.

Elizabeth's customers include tablet manufacturers of branded and generic pharmaceuticals, over-the-counter medications, nutritional and vitamin supplements, as well as confectionary and veterinary products.

Areas of Excellence

Elizabeth is passionate about our customer relationships, our customers' success, and our own integrity. Our staff works tirelessly with our customers to improve their production yields, production rates, and extend the useful life of their compression tooling. By leveraging the collective experience of our multi-disciplined organization, Elizabeth provides Total Tableting Solutions to our customer's problems.

GLOBAL FOOTPRINT

WITH MANUFACTURING CAPABILITIES ON 3 CONTINENTS; ELIZABETH ASSURES COMPLETE SATISFACTION ANYWHERE IN THE WORLD.

412-751-3000
ELIZ.COM

Elizabeth

Your Global Source for Tableting Solutions

World Class: Tablet Presses - Turrets - Parts - Compression Tooling - Blister Packaging Tooling - Service



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NUMBER OF EMPLOYEES
1400

DATE FOUNDED
1998

CORPORATE CAPABILITIES

Emergent BioSolutions, Inc.

Who We Are

Emergent is a fully integrated specialty pharmaceutical company seeking to protect and enhance life. It is also a recognized leader in the production of sterile biopharmaceuticals. Emergent develops, manufactures, and delivers a portfolio of medical countermeasures for biological and chemical threats, as well as emerging infectious diseases. For over 15 years, Emergent has been dedicated to the quality of services and safety of our products for our customers in effort to create a healthier world. Through our work, we envision protecting and enhancing 50 million lives with our products by the year 2025. We operate with integrity; Emergent is committed to the safety of our products and the service of our customers!

Major Markets

Emergent BioSolutions provides contract development and manufacturing services for bulk drug substances and sterile injectable drug products, while providing commercial production for clients. Our state-of-the-art, single-use facility enables turnkey upstream and downstream support for microbial, mammalian, and viral cell lines. Our fill/finish service offerings include vials and syringes, for both liquid and lyophilized products. Our manufacturing facilities (located in Baltimore, MD) currently produce 20 commercial products that support a host of clinical stage programs (Phase 1–3) approved for distribution in more than 50 countries, including the United States, Canada, Japan, Brazil, and most of Europe. With our strong regulatory history, proven flexibility, commitment to quality, and continuous improvement, we are an excellent choice for pharmaceutical or biotechnology companies looking for value and reliability through outsourcing.

Services

Drug Substance Manufacture

- Clinical & commercial scale
- Single-use platform (up to 2000L)
- Cell culture
- Microbial
- Viral
- Mammalian
- Avian
- Insect
- Process development
- Upstream & downstream

Drug Product Manufacture

- Clinical & commercial scale
- Vials & Syringes
- 3cc–100cc (2 vial filling lines)
- 2cc–50cc (2 syringe filling lines)
- Aseptic processing
- Terminal sterilization
- Lyophilization
- Lyo cycle development
- Optimization of critical lyo cycle parameters
- Material characterization
- Microbiology
- ICH stability

emergent
biosolutions®

Emergent's Mission is Simple:
To Protect & Enhance Life

BDS Manufacture | **Single-use Platform** | **Aseptic Fill/Finish** | **Vials & Syringes** | **Clinical & Commercial**

Emergent BioSolutions is a global specialty pharmaceutical company with fully integrated Contract Development & Manufacturing services, supporting both bulk drug substances and sterile injectable drug products at clinical and commercial scale.

EBS LISTED NYSE

emergentcontractmanufacturing.com
800-441-4225 | CMO@ebsi.com

50
PROTECTING & ENHANCING
50 MILLION LIVES BY 2025

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Rockaway, NJ 07866

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FAX
973.586.0450

E-MAIL
sales@fetteamerica.com

WEBSITE
www.fette-compacting-america.com

NUMBER OF EMPLOYEES
36 corporate employees
15 full-time technicians

DATE FOUNDED
1991

CORPORATE CAPABILITIES

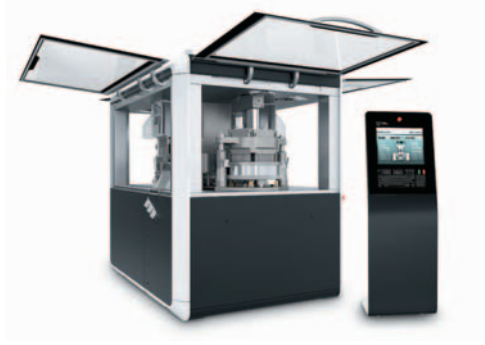
Fette Compacting America

Fette Compacting America, Inc., the leading supplier of tablet press equipment for pharmaceutical and nutritional applications, is located in Rockaway, New Jersey. A direct extension of Fette Compacting GmbH of Schwarzenbek, Germany, it was one of the first companies to develop and perfect the high-speed, rotary tablet press. Fette Compacting America offers complete services to clients in the United States, Canada, and Puerto Rico, including new and used machine sales, technical assistance, and machine installations. Other products and services include training classes and seminars, laboratory trials, validation, maintenance, trouble-shooting and repairs, spare parts, and tooling.

FEC40 Capsule Filler—World's Fastest Capsule Filling Machine

This year, Fette entered a new pharma manufacturing sector when it introduced its first—and the world's fastest—capsule filling machine: the FEC40 Capsule Filler. The FEC40 has an output volume of up to 400,000 capsules per hour—nearly twice the production capacity of any other capsule filler on the market. The FEC40 accomplishes this elevated production bar in a remarkably small footprint, making machine reconfiguration due to floor space issues unnecessary.

The extraordinarily high ratio of performance-to-footprint is made possible by Fette Compacting's patented Duplex Concept, which enables the FEC40 to feature a dual capsule filling process. The result is significant production savings—up to 30% per 1000 capsules.



Innovative Tablet Presses

Fette's premium family of tablet presses are headlined by its three-member FE Series: smallest to largest, the FE35, FE55, and FE75. The FE75 Tablet Press is a double-sided rotary press that can be equipped with up to 115 punch stations to produce more than 1.6 million tablets/hr. Ideal for producing large batches, the FE75's four compression rollers feature a special control system for direct compression, enabling the machine to operate with two intermediate pressures.

The FE35 and FE55 tablet presses share several technologies with the FE75, including a new, patent-pending conical filling unit, a highly accurate manually adjustable filling table, innovative compression rollers, trouble-free tablet discharging through the column, a revamped operating terminal, and the connection of process equipment through a standardized plug-and-play interface.

TRI.EASY Design Concept

Fette machines embody the company's TRI. EASY design concept, based on the notion that technology's efficiency runs parallel to its ease of use during production, changeover, and maintenance. The Tri.Easy design focuses on the user and ensures trouble-free production irrespective of an operator's experience and qualifications.

FETTE COMPACTING

NON-OEM PARTS HAVE EARNED A VERY SPECIAL PLACE IN THE TABLET PRESS MARKET.

TRUE STORIES…

Buying a non-OEM emergency stop switch saved a customer a couple of dollars up front, but ended up sparking thousands of dollars in damage, downtime and repair costs when it shorted out.

A warped, non-OEM baseplate caused metal contamination in the product, risking consumer safety and regulatory action.

A non-OEM turret had an improper weld on the lower punch retaining band, causing erratic product weights and expensive material loss.

We could go on and on, but you get the ugly picture. Why risk everything to save nothing? Put your trust in the superior precision and guaranteed performance of Genuine FETTE parts.

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Call 973.586.8722

FETTE COMPACTING

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www.fluidairinc.com

NUMBER OF EMPLOYEES
60

DATE FOUNDED
1983

CORPORATE CAPABILITIES

Fluid Air

Fluid Air®, a Division of Spraying Systems Co®, is a manufacturer of solid-dosage processing equipment and controls for the pharmaceutical, nutraceutical, food, cosmetics, and fine chemical industries. From small research and development applications to full production scale, we offer custom-designed solutions to your solid-dosage processing challenges, which include: Fluid Bed Systems, High-Shear Granulators, Size Reduction Mills, Tablet Coating Systems, and our new PolarDry™ Spray Dryers.

Keeping strong in its 34 years of experience, Fluid Air® specializes in solid-dosage technology. Fluid Air® has always excelled in its ability to develop quality and robust products tailored to its customers' needs.

Working together with Spraying Systems Co.®, Fluid Air® has a strong international presence with best-in-class global service. With an aggressive will to develop new and innovative technology, Fluid Air® continues to push the boundaries of what is possible and always aims to exceed their customer's expectations.

The Future, Low Temperature Spray Dry/Perfect Microencapsulation

This fall, Fluid Air released its revolutionary new patent-pending PolarDry™ Electrostatic Spray Dry Technology. This new technology based on the use of electrostatic, leads to outstanding benefits never before achieved in Spray Drying such as low processing temperature spray drying, near perfect encapsulation, and selective agglomeration in the creation of particles. Specifically, after years of development and testing, the PolarDry™ Technology is proven to bring multiple advantages to the pharmaceutical industry that include superior morphology, higher bulk density, longer shelf life, non-reactive processing, minimal emissions, and low energy consumption compared to traditional spray drying processes.

PolarDry's promising technology will open up the realm of applications as it relates to Active Pharmaceutical Ingredients that often times could not be produced in a powder form due to the required high temperatures of traditional spray drying. Using the PolarDry™ technology, particles can be produced at ambient to 80 °C inlet conditions. This is possible since the electrostatic effect drives highly polarizable water/solvent to the outer shell of the particle making it easy to dry the particle. Among other attributes, low temperatures eliminate ingredient loss, degradation, or denaturalization.

At the same time, less polarizable active and excipients are driven to the core. A very telling application example is microencapsulation; due to the electrostatic effect, the active is driven to the core of the particulates, resulting in stunning encapsulation efficiency. Perfect encapsulation promises more efficient, effective products and new avenues for drug delivery. Furthermore, the PolarDry™ Technology can also be leveraged to accomplish agglomeration in a single step process, eliminating the need for secondary operations, reducing operating costs and simplifying regulatory requirements.

FLUID AIR PolarDry™ The Cooler Technology

KEEP UP WITH CURRENT TRENDS IN *Pharmaceutical Technology's Equipment and Processing Report* E-Newsletter

Each monthly issue focuses on pharmaceutical manufacturing, processes and technology, providing analysis of manufacturing news, related regulatory issues, and current trends. Each issue features a showcase of processing equipment and reviews, as well as upcoming events.

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404.344.9350

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www.gemu.com

NUMBER OF EMPLOYEES
Atlanta 90+
Worldwide 1500+

DATE FOUNDED
1988

CORPORATE CAPABILITIES

Gemü Valves

Company Description:
GEMÜ Valves, an ISO9001-certified company, is a leading worldwide manufacturer of high-quality valves, measurement, and control systems. The GEMÜ Group has been manufacturing innovative products and customized solutions in and around the field of process media control since 1964, with the Atlanta facility opening in 1988. Over the years, the GEMÜ Group has continued to develop and grow with a large number of production and manufacturing facilities throughout the world. GEMÜ's ground-breaking design and leading edge manufacturing technology provides engineered solutions to complex process challenges. GEMÜ's overriding philosophy is to ensure that each and every customer contact is a quality experience.

Technical Services
GEMÜ offers comprehensive technical services including web-based part number configuration and 3D drawing download capabilities. GEMÜ's services also feature process-based testing of components to simulate the conditions experienced in the field ensuring the best application of components to the process application. Engineering, drafting, and custom design capabilities provide excellent technical support as part of GEMÜ's overall customer service offering.

Facilities
Located in Atlanta, Georgia, this 52,000-square-foot facility processes all orders from start to finish for the United States, Canada, Caribbean, Puerto Rico, and Mexico. With sales subsidiaries and production plants worldwide, the GEMÜ Group employs more than 1600 people and continues to grow. GEMÜ is committed to the pursuit of excellence in the development, production, and manufacturing of every product and that of quality service to the customer.

Major Products/Services

The GEMÜ product line includes Diaphragm, Globe, Angle Seat, PFA and PVDF, and Polypropylene valves, as well as Measurement and control systems. GEMÜ provides the optimal solution from a single source. As a system supplier of isolation, actuator, and control technology, GEMÜ responds to your individual needs and your project-specific needs. As a project partner, GEMÜ's Project Management team gives you a dedicated single point of contact to coordinate with all project partners and manage resources to achieve project success.

Markets Served
With an unparalleled vision of excellent customer service, GEMÜ serves the pharmaceutical, microelectronics and semiconductor, and food and beverage industries as well as the chemical, mining, and metal extraction, and water/waste water treatment industries.

GEMÜ®

VALVES, MEASUREMENT AND CONTROL SYSTEMS

GEMÜ Quality Products... GEMÜ Quality Service

4212 & 4242 Automation features:

- *Class 1 DIV 2, UL & CSA*
- *Multiple control options: 24 VDC, AS-I, DeviceNet*
- *Super bright LEDs indicate valve position*

Multiport Diaphragm Valve features:

- *Thousands of block designs to solve process challenges*
- *Minimize dead leg and hold up volume for optimal process efficiency*

Globe Valve features:

- *High cycle life*
- *Variety of end connections, materials of construction and actuation*

550 Globe valve with 1434 positioner

Multiport

4212 Switch

650 Diaphragm valve with 4242 switch

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www.gemu.com

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WEBSITE
www.meissner.com

DATE FOUNDED
1984

CORPORATE CAPABILITIES



Meissner Filtration Products

Corporate Description
The key characteristics that define Meissner can be categorized into core **commitments** and **focus**, and they drive what we deliver on daily for our clients.

Meissner Commitments

Risk Reduction
Our primary commitment is a reduction in risk for our client's processes, and ultimately, the patients who use their products. We understand that the products and services we provide have an immediately tangible impact on the human condition.

Vertical Integration
Vertical integration allows us to provide an exceedingly robust supply chain and augmented quality control, while at the same time facilitating enhanced material traceability and transparency.

Automation
Automation encompasses all of our processes, not just production equipment. We use automation to reduce risk for our clients, while also increasing their operational efficiency. Automated systems provide error proofing and are refined until all sources of variability are removed. We employ sophisticated IT technology to facilitate increased transparency, promote efficiency via electronic order processing, establish customer access portals, and integrate with our client's operating systems to optimize data transfer.

Quality
Our products and systems cannot and do not fail. Right products, to specification, every time, on time. Quality is not a silo at Meissner, it's an elementary commitment, a critical component of our organization that drives continuous improvement.

Meissner Focus

Specialization
We are the best in class at what we do and won't provide a commodity for the sole purpose of rounding out a portfolio. This industry values expertise, and in those areas in which we specialize, we deliver this.

Customer Experience
The traditional vendor-customer paradigm does not apply to the space in which we interact with our clients. We establish open communication with our clients at multiple levels within the organization, creating cross-functional teams and a long-term intimate relationship. We take pride in quickly addressing our client's needs, whether technical, logistical, or product based. We ensure the shortest path possible to our team of experts, delivering rapid access to the answers sought, and answering questions at the first contact with our organization.

Scientific Expertise
We understand and expand the science behind our products and apply it early to your process. Our clients rely on us for this knowledge and we continuously focus on enhancing our capabilities, knowledge base, and the level of support we provide.

Engineering Acumen
We provide personalized engineering, which is akin to personalized medicine. The solutions our engineering teams develop for your process are customized for your specific needs. They use fundamental building blocks based on our well-established engineering design space, and leverage our knowledge base pertaining to best practices.

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St. Charles, MO 63304, USA

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WEBSITE
www.natoli.com

NUMBER OF EMPLOYEES
320

DATE FOUNDED
1973

CORPORATE CAPABILITIES

Natoli Engineering Company, Inc.

Company Description
Natoli Engineering Company, Inc., is the recognized global leader in tablet press tooling manufacturing. Founded on the uncompromising principle to manufacture and deliver only the highest quality tablet compression tooling, presses and replacement parts at a fair price with exceptional customer service, Natoli has been at the forefront of the tablet compression industry for more than 40 years. Our state-of-the-art manufacturing facilities, award-winning engineering team and dedicated production crew enables us to offer clients competitive pricing without compromising personalized customer service.

Technical Services
- Tooling design
- Tablet design
- Tablet press refurbishing
- Technical training
- Formulation testing and analysis
- Metallurgical analysis

Facilities
Located in St. Charles, Missouri, Natoli's 10-acre campus includes administrative, manufacturing, refurbishing, training, and laboratory and scientific research facilities.

Major Products/Services
Tablet compression tooling: Natoli manufactures single and multi-tip punches and dies of unparalleled quality—available in simple and complex designs from more than 15 steel types and 10 specialty coatings.

Tablet presses: A full range of cost-effective options from single-station R&D laboratory models to heavy-duty rotary presses with extra fill capabilities and extended dwell times.

Tablet press replacement parts: Natoli maintains an extensive inventory of tablet press replacement parts and turrets for virtually all press types with most parts available for same day shipping.

Tablet Compression Accessories Catalog: We offer the most comprehensive accessories catalog in the industry featuring hundreds of items to help you care for, analyze, and prolong the life of your tooling and equipment.

Technical training: Learn the latest tablet technologies while improving processes through hands-on training from world-renowned academic and industry experts.

Tablet and tooling design: Natoli Engineering provide expert tablet and tool design services to ensure tablet quality, maximize production, and enhance product lifecycle. We also offer a free web-based tablet design software, TabletCAD, which enables tablet manufacturers to design their own tablets to desired specifications.

Markets Served
We serve the pharmaceutical, veterinary, nutritional, confectionery, and industrial tableting industries through distributors in major markets around the world, including South America, Europe, the Middle East, Africa, and the Asia-Pacific region.

NATOLI
YOU DEMAND. WE DELIVER.

When it comes to tablet production, our multi-tip punches make rabbits look like amateurs.
And as your tablet production increases, your operating costs shrink.
Contact your Natoli representative today!

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THE GLOBAL LEADER IN
TABLET COMPRESSION TOOLING

NATOLI

Aseptic Processing

2017 SCHEDULE

OPTION 1
Week 1: January 23-27
Week 2: February 20-24

OPTION 2
Week 1: March 27-31
Week 2: April 24-28

OPTION 3
Week 1: May 15-19
Week 2: June 12-16

OPTION 4
Week 1: July 24-28
Week 2: August 21-25

OPTION 5
Week 1: October 9-13
Week 2: November 6-10

FOR MORE INFORMATION CONTACT:
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Assistant Manager
Laboratory Operations
Tel: +1 (301) 656-5900 ext. 103
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LOCATION:
PDA Training and Research Institute
4350 East West Highway, Suite 150
Bethesda, MD 20814
Tel: +1 (301) 656-5900
Fax: +1 (301) 986-1093

The most comprehensive course in the preparation of sterile parenteral products

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- Evaluate and improve current aseptic processing procedures at your facility
- Correlate basic microbiology concepts and techniques to multiple aspects of aseptic processing
- Evaluate your environmental monitoring program to collect appropriate data, identify and interpret trends
- Develop robust media fill protocols including appropriate interventions, observations and documentation procedures
- And much more!

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*PDA **Education** – Where Excellence Begins*

PDA is accredited by ACPE and offers continuing education for professional engineers.

***PDA Education** – Where Excellence Begins*

Stay up to Date on Pharmaceutical Manufacturing Technologies – **turn to PDA for your continuing education needs!**

When you need high-quality, relevant education and training in pharmaceutical sciences and associated technologies, PDA is the place to go.

PDA Education courses provide hands-on, intensive, job-focused training you can bring back and apply immediately on the job. Courses are developed and instructed by noted industry experts with decades of experience and are uniquely targeted to both new and experienced professionals, who are directly or indirectly involved in the development and manufacture of quality pharmaceutical and biopharmaceutical products. A combination of traditional lecture courses and hands-on laboratory courses are offered.

PDA's Training and Research Institute

Lab courses are taught in PDA's Training and Research Institute (TRI) facility, the only stand-alone facility of its kind. It features an aseptic processing suite with a fill room, gowning/degowning rooms, clean staging area and a component prep room; clean-in-place lab; microbiology lab; and biotechnology lab. It is fully equipped to enable students to apply their classroom-acquired knowledge and gain experience with the operation of equipment typical of that used in the manufacture and testing of drug products.

Customized Training

If you have a group of staff that needs expert training on a specific bio/pharmaceutical topic, PDA can bring training to you! PDA can design and deliver training solutions with expert instructors right to your facility. We can develop a curriculum tailored specifically to your company's needs.

PDA lecture, laboratory and onsite training cover a broad range of topic areas, including aseptic processing, biotechnology, environmental monitoring, filtration, microbiology, quality/regulatory affairs, training and validation. Specialized courses are also offered on topics such as supply chain, lyophilization, pre-filled syringes and visual inspection.

Visit pdatraining.org to see the complete list of PDA's course offerings.

PDA is accredited by the Accreditation Council for Pharmacy Education and is an approved provider of Continuing Professional Competency (CPC) credit by the New Jersey State Board of Professional Engineers and Land Surveyors. PDA is also an approved sponsor of CPC activities for Professional Engineers licensed in North Carolina.

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WEBSITE
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NUMBER OF EMPLOYEES
70

DATE FOUNDED
1989

CORPORATE CAPABILITIES

Powder Systems Limited (PSL)

Company Description
PSL is an award-winning international manufacturer providing quality innovative technology. Our solutions provide unique solutions enabling pharmaceutical manufacturers to bring new-generation drugs into the market place faster. At PSL, we are proud to be improving patient's lives all around the world.

Markets Served
PSL has been supporting the pharmaceutical, biopharmaceutical, specialty chemical, and laboratory worldwide industries since 1989. Our innovative technologies enable blue-chip companies and contract manufacturers to produce high-quality pharmaceutical products such as APIs, HPAPIs, sterile, oncology, hormone, and many other chemical compounds in a safe manner.

Major Products/Services
PSL provides a full range of filtration, drying, and high containment powder handling solutions from small-scale production to full process systems.

PSL's process experts developed the MicroSphere Refiner™ for the aseptic formulation of polymeric microspheres used as drug delivery devices.

PSL filtration and drying solutions also include the innovative CakeStand vacuum tray dryer for direct and uniform drying, and a large

range of Agitated Nutsche Filter Dryers that are ergonomically designed for washing and isolating solids, even in the most difficult production processes, with direct scale-up capability including the lab nutsche filter dryer, the GFD®.

As an original pioneer of high-containment systems for the production of highly potent APIs including cytotoxic, oncology, hormones, and many other active compounds, PSL provide containment solutions such as gloveboxes and isolators protecting the operator, environment, and product down to nanogram levels.

Facilities
PSL headquarters are in Liverpool UK. The company has five overseas operations with offices in USA, France, Czech Republic, Singapore, and Australia. With more than 1200 installations worldwide, we continue to increase our number of global offices, agents, and distributors to aid the smooth distribution of equipment to any part of the world.

Our award-winning engineering department works closely with our process team to successfully transform best practice process designs into production. All control systems are designed and built by our in-house control engineers, interfacing new equipment where necessary. Our partners feel confident that they are receiving the most suitable solutions, designed and engineered using the latest technology by a reliable, experienced team of professionals.

psl
Serving our customers since 1989

OUTSOURCING and Consulting Services

AbbVie
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+1.847.938.8524

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WEBSITE
www.abbviecontractmfg.com

AbbVie

Company Description

AbbVie continues a legacy reflecting more than a century at the forefront of pharmaceutical development and manufacturing. For more than 30 years, AbbVie Contract Manufacturing has offered contract manufacturing services that spans biologics, potent, drug product, prefilled syringes, fermentation, as well as selling high quality active pharmaceutical ingredients (APIs).

AbbVie Contract Manufacturing has a portfolio of ten state-of-the-art facilities, offering a broad range of capabilities in North America and Europe. AbbVie Contract Manufacturing handles customers' projects with the same dedication employed to its own products, and clients gain access to the capabilities of a highly experienced developer and manufacturer.

Draw on AbbVie's exceptional technical experience and expertise for your next project. AbbVie has one of the most trusted reputations for quality, productivity, innovation, and regulatory in the industry.

Company Background

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. Together with its wholly-owned subsidiary, Pharmacyclics, AbbVie employs more than 28,000 people worldwide and markets medicines in more than 170 countries.

Markets Served

AbbVie Contract Manufacturing offers global capabilities in biologics, potent, drug product, prefilled syringes, fermentation and APIs. It serves companies seeking to outsource in these areas, as well as businesses looking to procure APIs from our existing portfolio of products. Our client base includes early stage development through commercial launch.

Products, Services & Capabilities

AbbVie's technical depth is a key strength and what sets us apart as we provide support and solutions in the following areas:

- Mammalian biologic API development and commercial launch. Includes services of cell line development, cell culture, purification, characterization, commercial API and syringe filling production.
- Potent/cytotoxin capabilities for both drug product and APIs capable and potent levels down to < 1 ug/m^3.
- A global drug product manufacturing of tablets, capsules and liquids including regional packaging facilities.
- Aseptic best-in-class prefilled syringes capability.
- One of the largest classical fermentation manufacturing operations in North America.
- A wide range of compendia-grade APIs.

abbvie

CONTRACT MANUFACTURING

Biologics | Potent | Drug Product | Fermentation
Prefilled Syringe | Hot Melt Extrusion | APIs

abbviecontractmfg.com

EXPERIENCE UNRIVALED

Drug Product

When it comes to delivering drug product, you need a CMO with longstanding commercial expertise to ensure fast time to market.

CMO LEADERSHIP AWARDS 2016 CAPABILITIES

CMO LEADERSHIP AWARDS 2016 COMPATIBILITY

CMO LEADERSHIP AWARDS 2016 EXPERTISE

CMO LEADERSHIP AWARDS 2016 QUALITY

CMO LEADERSHIP AWARDS 2016 RELIABILITY

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www.AdarePharma.com

NUMBER OF EMPLOYEES
650+

DATE FOUNDED
2015

CORPORATE CAPABILITIES

Adare Pharmaceuticals

Company Description
Adare is a global specialty pharmaceutical company inspired to improve the lives of patients whose treatment needs are not fully addressed by current medications. We use our unique combination of experience, proprietary capabilities, and resources to create meaningful products.

Adare is a high-growth company with a long history of success from concept through commercialization. Our ability to create differentiated drugs guides the identification and development of our novel pipeline products and our acquisition strategy.

Technical Services
- Global specialty pharma
- Drug delivery and formulation experts (wide range of therapeutic areas)
- Proprietary pipeline (GI and CNS)
- Eight distinct oral formulation proprietary technologies
- Taste-masking and ODTs
- Customized drug release
- Bioavailability enhancement
- Small molecule
- Rx and OTC finished formulation in-licensing, product out-licensing
- GI portfolio microbiome franchise
- Acquisitions

Facilities
With our R&D Formulation Center of Excellence in the USA and global manufacturing facilities located in USA, Canada, Italy, and France, Adare has the capacity to bring complex products from development to commercialization. Our facilities have robust quality systems and processes. We manufacture more than one billion doses per year.

Major Products/Services
We overcome complex formulation challenges and add valuable IP to new and existing products. Over 40 products incorporating the

proprietary technologies of Adare have been commercialized around the world. Products available for out-licensing in select territories include:
- Cyclobenzaprine ER 15 mg, 30 mg Extended Release Capsules with Diffucaps® Customised Drug Release Technology
- Paracetamol ODT 250 mg, 500 mg Orally Disintegrating Tablets with Microcaps® Taste Masking Technology and AdvaTab® Orally Disintegrating Tablets
- Diphenhydramine ODT 25 mg Orally Disintegrating Tablets with Microcaps® Taste Masking Technology and AdvaTab® Orally Disintegrating Tablets
- Propranolol HCL 80 mg, 120 mg Extended Release Capsules with Diffucaps® Customized Drug Release Technology

Markets Served
Quality and regulatory expertise in global markets including North America, Japan/Asia, Europe, and Africa.

ADARE Pharmaceuticals™

Adare Pharmaceuticals:

Patients and our partners are at the heart of everything we do

Adare is a global specialty pharmaceutical company inspired to improve the lives of patients whose treatment needs are not fully addressed by current medications. We use our unique combination of experience, proprietary capabilities, and resources to create meaningful products for them.

Our entrepreneurial and performance-driven culture encourages us to take risks, identify promising ideas, and see those opportunities through to completion. Our collaborative spirit and dedication to developing strong partnerships provide Adare and our partners with significant advantages in competitive markets.

Adare can help you overcome complex formulation challenges and add valuable IP to commercialized products and products in development. Over 40 products incorporating Adare taste masking, customized drug release, and bioavailability enhancement proprietary technologies have been commercialized around the world.

Adare also has an extensive patent portfolio, which includes more than 360 granted patents and 225 pending patent applications.

Experience a partnership focused on the needs of patients and your company's goals. Schedule a meeting with us at **BusDev@adarepharma.com**.

Discover how our taste masking, customized drug release, and bioavailability enhancement experts can help solve your complex formulation challenges. Email us at **BusDev@adarepharma.com**.

Visit www.AdarePharma.com

ADARE Pharmaceuticals™

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WEBSITE
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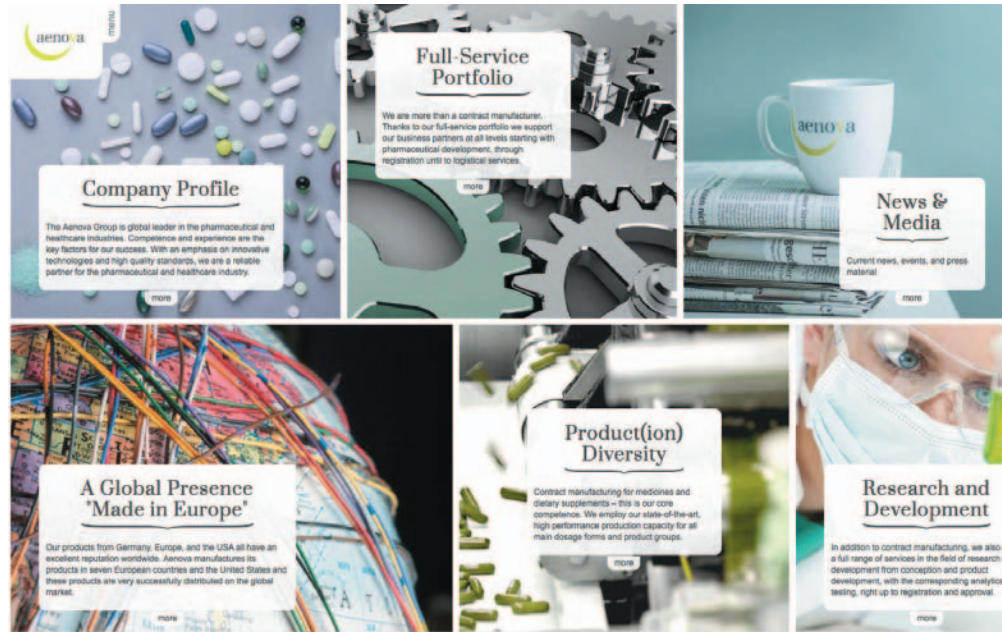
CORPORATE CAPABILITIES

OUTSOURCING and Consulting Services

Aenova



Aenova is a global leader in contract manufacturing of finished dose forms for pharmaceutical and dietary supplements. Offering a large portfolio of services and manufacturing expertise at every stage within your product lifespan, from development to commercial manufacturing. With 21 manufacturing sites located throughout the United States and Europe, Aenova distributes products worldwide. Our core customer service foundation is built on a simple but important principle; consistently deliver high quality and excellent customer service. Operating under common cGMP practices backed by global and local regulatory agency approvals, quality is never an afterthought. Aenova stands by its strong financial performance, offering contract manufacturing supply stability in a wide variety of dosage forms such as, Softgel capsules, solids, semi-solids, liquids, parenterals, and other specialty dosage forms.

Members of the Aenova Group:
C.P.M. · Dragenopharm · EVP · Haupt Pharma · Swiss Caps · SwissCo · Temmler

Solids
- Tablets
- Hard Capsules
- Softgel Capsules
- Granules
- Pellets

Liquids & Semi-solids
- Pure or Colloidal Solutions
- Emulsions, Suspensions
- Ointments
- Gels

Packaging
- Blisters
- Bottles (Solids & Liquids)
- Cartons
- Labeling
- Pouches

Specialty
- Cytotoxics
- Hormones
- Beta-Lactam Antibiotics
- Cephalosporins

Injectables
- Lyophilization
- Aseptic Manufacturing
- Terminal Sterilization

aenova

Global Reach With A Breadth of Services

The Aenova Group's services cover the entire value chain for the development and production of all the main dosage forms and product groups in pharmaceuticals and dietary supplements. With more than 4,000 employees and over 21 sites, Aenova is one of the leading companies in the pharmaceutical and healthcare industries...and the right choice for your next project.

Solids

- Tablets
- Hard Capsules
- Softgel Capsules
- Granules
- Pellets

Liquids & Semi-solids

- Pure or Colloidal Solutions
- Emulsions, Suspensions
- Ointments
- Gels

Packaging

- Blisters
- Bottles (Solids & Liquids)
- Cartons
- Labeling
- Pouches

Specialty

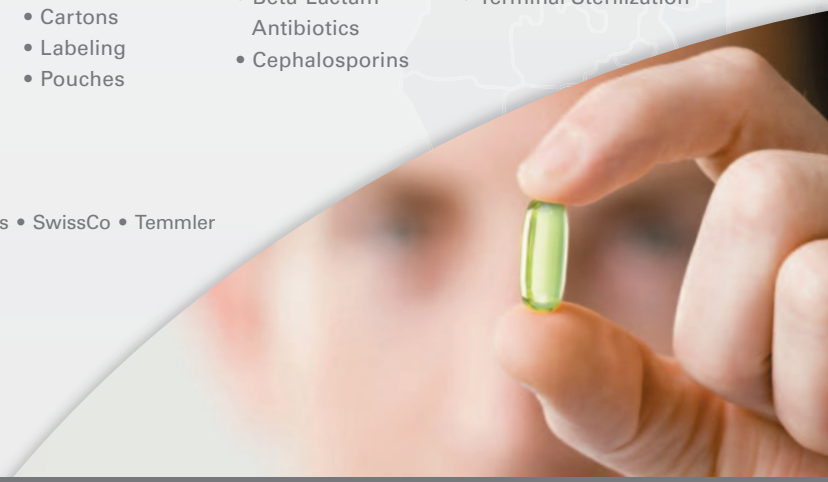
- Cytotoxics
- Hormones
- Beta-Lactam Antibiotics
- Cephalosporins

Injectables

- Lyophilization
- Aseptic Manufacturing
- Terminal Sterilization

Members of the Aenova Group

C.P.M. • Dragenopharm • EVP • Haupt Pharma • Swiss Caps • SwissCo • Temmler



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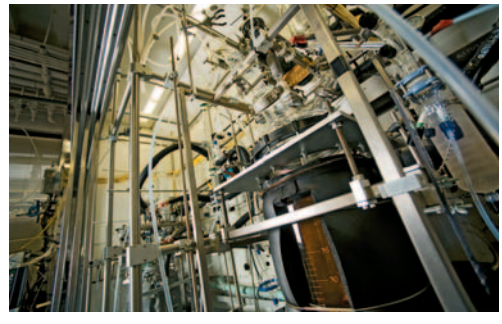
CORPORATE CAPABILITIES

Albemarle Corporation

Albemarle Corporation (NYSE: ALB), headquartered in Charlotte, NC, is a global specialty chemicals company whose Fine Chemistry Services division offers innovative chemistry development for new markets through a world-class Contract Manufacturing Operation. Albemarle has leading positions in lithium, bromine, refining catalysts, and powers the potential of companies in many of the world's largest and most critical industries, from energy and communications to pharmaceuticals, agriculture, and electronics. Working side by side with our customers, we develop value-added customized solutions that make them more competitive. Our solutions combine highly capable and diverse assets, both cGMP and non cGMP, with the knowledge and know-how of our highly experienced and talented team of operators, scientists, and engineers.



Technical Services Offered

Process chemistry:
- Route screening
- Route development
- Process hazard screening and analysis
- Process optimization
- Quality by design
- High throughput experimentation
- Kilo-Labs for first scaleup

Analytical services:
- Method transfer
- Method development
- Method validation
- Impurity identification and analysis

Process engineering:
- Process evaluation
- Cost analysis
- Pilot plant
- Process design
- Scale-up to commercial
- Process validation
- Batch to continuous
- Process optimization/improvement/ cost reduction

Capabilities
- Cryogenic reactions (to -90C) at commercial scale
- Corrosion-resistant reactors
- Corrosion-resistant solids separation
- Corrosion-resistant distillaton (columns and WFEs)
- Deep vacuum thin film evaporation
- High-pressure reactions
- Batch and continuous processing
- Registered starting materials
- Ultra-high purity materials
- Highly flexible process equipment
- Lab to commercial at one site

Facilities

Albemarle implements cGMPs at our Active Pharmaceutical Ingredient manufacturing facility in South Haven, MI and offers ISO-quality manufacturing services at Tyrone PA, including the production of regulatory starting materials. Additionally, we custom manufacture high volume products at our Pasadena, TX plant and conduct R&D and scale-up activities at our Process Development Center (PDC) in Baton Rouge, LA.

Albemarle Fine Chemistry Services

Albemarle has been an industry leader in contract pharmaceutical, agrichemical, lubricant, and specialty chemicals manufacturing for more than 40 years. Our worldclass facilities and advanced R&D capabilities enable our Fine Chemistry Services team to aid in every stage of product development—from contract research through commercial-scale manufacturing.

As a worldwide leading producer of lithium and bromine, Albemarle's well-conceived back integration can offer a near seamless access to an abundant supply of important raw materials, as well as critical knowledge of unique chemistries.

ALBEMARLE®

INDUSTRY-LEADING FINE CHEMISTRY SERVICES FOR MORE THAN 40 YEARS.

Albemarle partners with companies across the global pharmaceuticals, agrichemicals, base oil lubricants and specialty chemicals industries.

With world-class facilities and advanced R&D capabilities, our Fine Chemistry Services team can help with product development at every stage, from contract research through commercial-scale manufacturing. Work with us and you'll discover a powerful combination of knowledge, experience, resources, creativity and service. It's how we say **yes** to our customers every day.

Learn more about what we can do for you at **Albemarle.com/FCS**.

ALBEMARLE®

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NUMBER OF EMPLOYEES
<1000

DATE FOUNDED
1979

CORPORATE CAPABILITIES

Alcami

Company Description

Alcami is a world-class supplier of comprehensive pharmaceutical development and manufacturing services headquartered in Wilmington, NC. With nearly 1000 employees operating at seven sites in the United States and Europe, our combined capabilities include 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. We offer a world class end-to-end outsourcing opportunity that can be integrated for a less fragmented and faster pathway for products through the clinical toward commercialization, as well as individualized development and manufacturing services.

Alcami makes it easy for our partners to bring their products through the clinic to commercialization. We embrace an approach that integrates our operations in a unique and highly effective way and where a product's potential is turned into reality day-after-day. With a flexible and responsive approach, our Project and Program Management group will ensure the focus is always on the best possible outcome for your product at every level.

We meet all applicable local, state and federal regulatory requirements, including current GMPs and country guidelines for the US, Canada, EU, and EU Member State regulatory bodies (e.g., EMA, MPA, IMB). We also incorporate international standards as part of the quality management system and meet expectations established by the *USP*, *EP*, and *JP*. We comply with all regulations and standards, including those regarding controlled substances (DEA), radioactive materials (NRC), environmental protection

(EPA), child-resistant container-closures (CPSC), and employee safety (OSHA).

Facilities

Alcami offers all phases of pharmaceutical drug product development for small and large molecules through two laboratories located in Durham and Wilmington, North Carolina. These facilities have supported more than 500 investigational New Drug (IND) filings and over 50 NDAs, ANDAs, and NADAs since 1985. Two cGMP API facilities in Germantown, Wisconsin and Weert, Netherlands support Alcami's process development/scale-up and clinical and commercial supply of APIs for customers worldwide. The Weert facility also serves as the company's Center of Excellence for Solid State Chemistry. Regional cGMP analytical laboratories in St. Louis, Missouri, Wilmington, North Carolina, and Edison, New Jersey provide comprehensive analytical testing solutions for Alcami customer's new drug entities and biopharmaceuticals, as well as generic drugs, chemicals, and animal health, and medicated consumer health products. Alcami's cGMP drug product manufacturing facilities support clinical and commercial supply. Our Charleston, South Carolina facility is focused on processing parenteral products while the Wilmington, North Carolina facility is dedicated to solid oral dose manufacture. Both are fully integrated with Alcami's packaging and distribution center.

alcami™
Connected At Every Level

alcami™

Connected At Every Level

Alcami is the new CDMO you already know. With world-class capabilities we are focused on the best possible outcome for your product on every level. Building a personalized connection with transparency, trust, quality and innovation ensures an unparalleled customer experience, and the rapid advancement of your project. Alcami offers comprehensive pharmaceutical development and commercialization services.

Connect with us.

www.alcaminow.com

AAIPharma Services and Cambridge Major Laboratories are now Alcami.

AMRI
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Albany, NY 12203
General Inquiries: 518-512-2000
Investor Inquiries: 518-512-2261
Email: clientservice@amriglobal.com
Web: amriglobal.com

SSCI
800-375-2179
Email: info@ssci-inc.com
Web: ssci-inc.com

Whitehouse Labs
908-823-9300
Email: Mark.Stier@amriglobal.com
Web: whitehouselabs.com

SSCI and Whitehouse Labs: Now Part of AMRI

SSCI provides industry-leading contract solid-state and analytical testing services to help companies in the pharmaceutical, food, agrochemical and other chemical industries develop better products and get them to market more quickly.

Whitehouse Labs provides life science companies with one-stop-shop testing: materials, micro, packaging, containers, distribution, medical device and drug delivery testing.

SERVICES OFFERED

SSCI

PARTICLE ENGINEERING
Our dedicated group of crystallization experts has a legacy of success in process development, particle size analysis and technology transfer.

METHOD DEVELOPMENT
The method development team follows a rigorous approach that results in reliable methods for any of your needs from raw materials testing to commercial release of drug substance and drug product.

MATERIAL SCIENCE
We provide a range of screens built with the ICH Q6A guideline in mind to identify the best solid form to overcome developability issues, including bioavailability, or to modulate properties for new uses. Polymorph and enabling form screens determine the propensity of different solid forms and their most important properties, often as a precursor to developing a robust crystallization process.

LITIGATION SUPPORT
Technical packages are designed for ease of use in preparing patent applications. We routinely assist attorneys and agents with the science and technical muscle required to support the patent applications of our mutual clients, helping these patent professionals with all that is necessary to draft effective and comprehensive claims based on the invention and the characterization data.

ANALYTICAL SERVICES
We offer advanced analytical technologies including spectroscopy, X-ray diffraction, mapping and imaging, thermal analysis, and microscopy.

Whitehouse Labs

CONTAINER CLOSURE INTEGRITY (CCI)
A global leader in CCI, we deliver numerous state-of-the-art options for assessing package system integrity as outlined in USP <1207>.

CONTAINER TESTING
We provide testing of all containers and components and are fully functional on the new USP <661>.

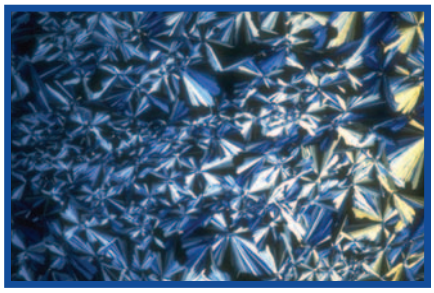
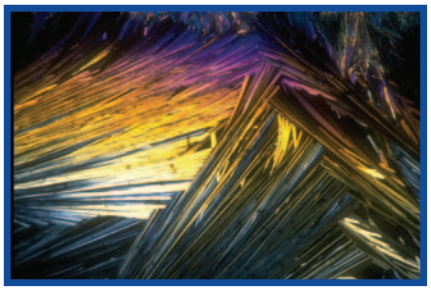
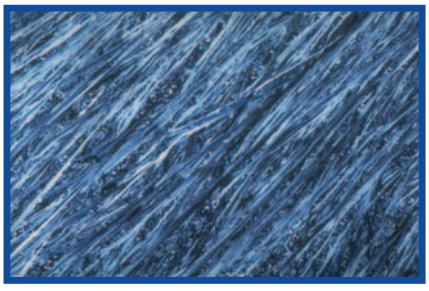
PACKAGING AND DISTRIBUTION
Our laboratory covers all ISTA and ASTM requirements for your package and distribution testing needs.

MEDICAL DEVICE AND DRUG DELIVERY
We perform physical and functional testing for drug delivery devices and ISO 11608, “Needle-Based Injection Systems for Medical Use — Requirements and Test Methods.”

EXTRACTABLES/LEACHABLES AND IMPURITIES
We are capable of determining extractables/leachables and impurities in bio/pharmaceutical products.

ANALYTICAL SERVICES
We offer heavy metals testing in accordance with USP <232> and <233>, ICP-MS testing and testing for residual solvents and other materials.

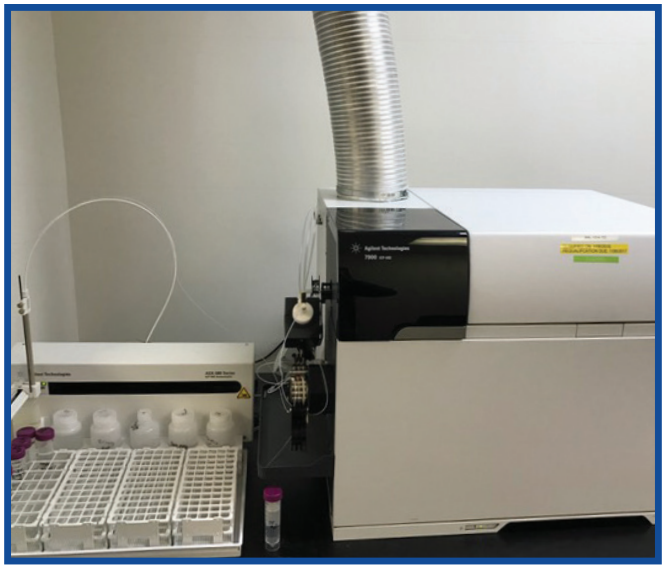
MICROBIOLOGY
Antimicrobial effectiveness, enumeration, specified microorganisms, biological reactivity and water for pharmaceutical purposes.

LOTS OF IMITATORS.
ONLY ONE TRUE INNOVATOR.
– WORLD LEADERS • SINCE 1991 –

SSCI and Whitehouse Labs: Now Part of AMRI

AMRI is the leader in analytical science innovations. Our services – including method development, material science, container closure integrity, container testing, packaging and distribution, extractables/leachables and impurities testing – lead the way in drug discovery and development, API and drug product manufacturing, worldwide.



North America | Europe | Asia | amriglobal.com

amri

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pharmasolutions.com

CORPORATE CAPABILITIES

OUTSOURCING and Consulting Services

Baxter BioPharma Solutions

Company Description

Baxter's BioPharma Solutions business collaborates with pharmaceutical companies to support commercialization objectives for their molecules. As a parenterals specialist with more than 80 years of expertise, BioPharma Solutions offers contract manufacturing form/fill/finish services and solutions for injectables designed to meet complex and traditional sterile manufacturing challenges. As a global injectables specialist, we can help solve unique challenges with confidence of delivery, service, and integrity.

Markets Served

Baxter's expansive network offers more than 50 manufacturing facilities across six continents, and our global presence provides opportunities for unique sterile contract manufacturing collaborations. The power of an extensive global network lies in the coordination of, and efficiencies resulting from, a systemic approach to cGMP manufacturing. Baxter has manufacturing sites across the globe in support of a diverse portfolio of delivery systems and manufacturing solutions.

Major Products/Services

Our Parenteral Delivery Systems include: prefilled syringes, liquid/lyophilized vials, cartridges, frozen premix systems, liquid premix systems, BIO-SET luer system, diluents for reconstitution, ampoules, powder-filled vials, and sterile crystallization.
Our Drug Categories include: small molecules, biologics, vaccines, cytotoxics, highly potent compounds, ADCs (antibody-drug conjugates), and cephalosporins/pencillins.

Facilities

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

Bloomington, Indiana USA —The Bloomington, Indiana, USA 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, an industry-leading resource center focused on the development of high-quality freeze drying.

Halle/Westfalen, Germany— The Halle/Westfalen, Germany facility is recognized as a premier CMO that specializes in parenteral pharmaceuticals. The facility has recently completed an approximate 1,800-square-meter capacity expansion designed for oncology drugs. This additional capacity further expands our leadership position as one of the largest capacity CMOs for lyophilized cytotoxic parenterals, and continues to support the growing needs of cytotoxic manufacturing.

Round Lake, Illinois USA —Baxter is the world's leading provider of manufacturer-prepared IV solutions and our Round Lake facility is a best-in-class aseptic solution manufacturer. Baxter's portfolio of premixed drugs is the broadest in the industry, and we are the only CMO to offer a manufacturer-prepared, commercial-scale aseptic filling process for premixed drugs in flexible IV bags.

Baxter

FOYA 2016
Facility of the Year Awards
CATEGORY WINNER
Operational Excellence

Your Premier CMO
for Specialized Sterile Injectables

Whether you face formulation challenges, clinical supply hurdles, surges in demand due to market fluctuations, risk mitigation concerns, or patent expiry challenges, we offer tailored, versatile solutions–and over 80 years of parenteral experience–to help you achieve your commercialization objectives.

Ultimately, our goal is to make you feel confident and secure in choosing BioPharma Solutions as your CMO–assisting you to avoid the unexpected and guiding you through marketplace complexities to help you achieve the full potential for your molecule.

Learn more about us at:
baxterbiopharmasolutions.com

Your Premier CMO

BioPharma Solutions

Capsugel
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Suite 200C
Morristown NJ 07960
United States of America

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862.242.1700

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solutions@capsugel.com

WEBSITE
www.capsugel.com

NUMBER OF EMPLOYEES
More than 3600

DATE FOUNDED
1931

CORPORATE CAPABILITIES

Capsugel

CAPSUGEL, ENGINEERING MEDICINES TO LIFE
Capsugel designs, develops, and manufactures a wide range of innovative dosage forms for the biopharmaceutical and consumer health and nutrition industries. The company's unique combination of science, engineering, formulation, and capsule expertise enables its customers to optimize the bioavailability, targeted delivery, and overall performance of their products. Capsugel partners with more than 4000 customers in over 100 countries to create novel, high-quality and customized solutions that align with its customers' evolving needs and benefit patients and consumers.

With a unique range of capabilities from early-phase design through clinical and commercial-scale manufacturing, Capsugel provides tailored solutions that address bioavailability and drug delivery challenges faced by biopharmaceutical customers. Capsugel's unbiased, model-based approach to product design results in optimized, fit-for-purpose finished dosage forms that can successfully advance its customers' compounds. Capsugel's integrated product and process development capabilities allow customers to rely on one partner from design through production—minimizing risk, time, and complexity.

Design

Capsugel provides formulation expertise and depth in key enabling technologies necessary to bring design to the CDMO space. By utilizing its proprietary predictive models, developed from the experience of advancing thousands of molecules from early feasibility to clinic and commercial-scale manufacturing, Capsugel can rapidly identify the enabling technologies best suited to meet customers' target product profiles and commercial objectives.

Areas of expertise include:

Product design

- Bioavailability enhancement
  - Micronization & nano-milling
  - Spray-dried dispersion & hot melt extrusion technology
  - Lipid-based formulations
- Targeted and modified drug delivery
- Lipid & liquid-based formulations
  - Low-dose/high potency applications
  - Colonic delivery
- Pediatric dosage forms
- Inhalation formulations
- Taste & odor masking
- Biotherapeutics

Drug Product Intermediates

- Spray-dried dispersions
- Micronized/nano-milled compounds
- Multiparticulates

Finished Dosage Forms

- Softgels
- Liquid-filled hard capsules
- Tablets
- Encapsulated formulations & multiparticulates

Capsules

- HPMC, gelatin & alternate polymer capsules
- Specialized clinical capsules
- Enteric capsule technologies
- Sprinkle capsules
- Inhalation (DPI) capsules
- Enrobing gelcap technology

Development

Capsugel's experienced scientists and engineers, working closely with customers, develop phase-appropriate products for preclinical and clinical assessments. Dedicated development suites, utilizing phase-appropriate and specialized processing equipment, facilitate the rapid development of drug products across a wide range of dosing formats. Isolation capability is in place to ensure safe and efficient handling of potent and highly potent compounds. Ultimate 'manufacturability' is incorporated early in the product development process to allow for rapid scale-up, technology transfer, and commercialization.

Manufacture

Capsugel has 13 manufacturing sites and three research and development centers in nine countries across North America, EMEA, and Asia, producing billions of capsules and more than 800 pharmaceutical finished products annually.

WWW.CAPSUGEL.COM

ENGINEERING MEDICINES TO LIFE

Capsugel®

RISING TO THE CHALLENGE

Tomorrow's complex medicines face challenges to overcome low bioavailability and optimize drug delivery. This calls for a partner with the credibility, ingenuity and flexibility to deliver both the product and process design required to make your compound a commercial reality. With a unique range of technology and integrated product development from design to commercial manufacturing, Capsugel is that partner.

Catalent
Pharma Solutions
14 Schoolhouse Road
Somerset, NJ 08873

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+1.888.SOLUTION
(+1.888.765.8846)

E-MAIL
solutions@catalent.com

WEBSITE
www.catalent.com

Catalent Pharma Solutions

Corporate Description

Catalent is the leading global provider of advanced drug delivery technologies and development solutions, providing worldwide clinical and commercial supply capabilities for drugs, biologics, and consumer health products. With more than 80 years serving the industry, we have proven expertise in bringing more customer products to market faster, enhancing product performance, and ensuring reliable product supply.

We serve thousands of innovators, both established and emerging, in more than 80 markets, including 48 of the top 50 pharmaceutical and 41 of the top 50 biotech companies. Our team of more than 1400 talented scientists has supported over half of all new molecular entities approved by the FDA in the past 10 years, and we have more than 450 active development programs for new customer products. We have 18 development teams in 10 markets. Over 30 global sites serve more than 1000 customers in over 80 countries supplying over 70 billion units annually. Our significant intellectual property includes over 1300 patents and patent applications.

Whether you are looking for a single, tailored solution or multiple answers throughout your product's lifecycle, we can improve the total value of your treatments—from discovery to market and beyond.

Catalent. More products. Better treatments. Reliably supplied.™

Development

With our wide range of expert services—including analytical, biologics, pre-formulation, and formulation— we drive faster, more efficient development timelines and produce better products. Catalent has recently bolstered its capabilities and capacity with the acquisition of spray dry dispersion specialist Pharmatek, and now offers the broadest toolkit of development and bioavailability enhancing technologies available.

Our robust GPEx® mammalian cell line engineering technology accelerates large molecule drugs from discovery to clinic and our award winning OptiForm® Solution Suite combines our delivery technologies into a robust, data driven, parallel screening platform which quickly and efficiently assesses the optimal formulation pathway for both small molecules and biologics for oral delivery potential. With our deep expertise and our extensive formulation capabilities across a wide range of dose forms, we can solve even the most complex bioavailability, solubility, and permeability challenges.

Delivery

We are a world leader in drug delivery solutions with a proven track record of helping our customers create better treatments by boosting bioavailability, solubility, and permeability; improving ease and route of administration; and increasing patient compliance. Our unique delivery technologies—including RP Scherer softgel and OptiShell™ capsules, Zydis® fast-dissolve, controlled release and OptiMelt™ hot melt extrusion, as well as inhaled and injectable dose forms—improve how products work in and for patients.

Supply

We reliably supply our customers through operational and quality excellence, and we have regulatory inspection results exceeding the industry average. As a seamless extension of your supply chain, we offer global, integrated manufacturing and packaging solutions to take your product from design to clinical trial to plant and to pharmacy. We manufacture oral, sterile, and inhaled dose forms and produce biologics for pre-clinical and clinical studies.

Catalent®
DEVELOPMENT

your molecule has so much potential.
we share your passion to unlock it.

As the #1 global leader in drug development and delivery, we have a passion to help you bring better treatments to your patients, faster.

Our broadest expertise and superior technologies helped optimize thousands of molecules from pre-formulation through all development stages. Our integrated analytical, clinical, and manufacturing services along with patient-centric dose design streamlines and accelerates your path to patients.

OPTIFORM® SOLUTIONS SUITE
PRE-FORMULATION / FORMULATION
BIOAVAILABILITY ENHANCEMENT
STABILITY & SCALABILITY
ORAL DOSE FORM DEVELOPMENT
MODIFIED RELEASE
COMPREHENSIVE
ANALYTICAL SUPPORT

DEVELOPMENT DELIVERY SUPPLY

Catalent. More products. Better treatments. Reliably supplied.™

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

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877.274.8371

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978.988.9236

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askcharlesriver@crl.com

WEBSITE
www.criver.com

NUMBER OF EMPLOYEES
1000 + Globally

DATE FOUNDED
1947

CORPORATE CAPABILITIES

Charles River

Company Description
Charles River is a global provider of comprehensive, innovative microbial QC products and testing solutions. We can help you meet the necessary global regulatory requirements to get your products to the patients and consumers that need them the most. We offer full-service solutions, including rapid endotoxin testing, microbial detection and identification, and strain typing to ensure safe manufacture and timely product release.

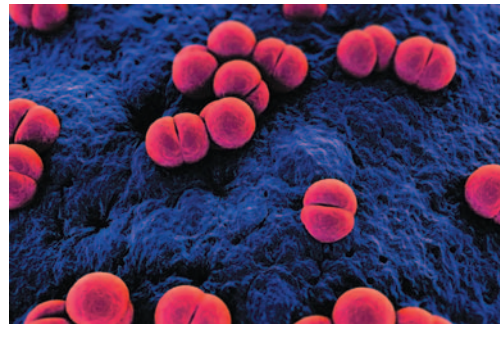
We are committed to providing precision, confidence, and robustness in QC testing and methods to help manufacturers meet their specifications for product safety and customer confidence. Our investment in new product research and development is matched by our high-quality standards and dedication to client-focused problem solving.

Company Background
With 65 facilities in 15 countries, Charles River offers a wide range of products and services that span the entire drug discovery and development continuum and can be tailored to specific research conditions. Our portfolio covers four distinct phases: basic research, drug discovery, safety assessment, and manufacturing support.

Markets Served
Charles River can help you standardize your microbial QC testing needs and carry out your comprehensive microbial quality assurance program. With a growing list of laboratory and agent locations in North America, Europe, South Korea, Australia, India, and Singapore, we serve customers in more than 400 countries, providing customer support in 46 languages across 24 time zones.

Products, Services, and Capabilities
With a purposefully-designed portfolio and proven innovation, we offer QC testing solutions and methods that provide relevant and measurable data that allows for accurate decision-making on product quality for release. Our products and services adhere to global regulations, including *EP, USP* and *JP* documents.

- Endosafe® endotoxin testing systems
- FDA-licensed LAL cartridges, reagents, and accessories
- Endotoxin testing instrumentation and software
- Endotoxin contract testing services
- Celsis® microbial detection systems
- Accugenix® microbial identification and strain typing products and services
- Data management solutions for environmental monitoring



charles river

DO YOU KNOW WHAT'S FLOATING AROUND IN YOUR PRODUCT?

Rest assured, if it's in there, we'll find it – and tell you what it is. Our purposely-built portfolio of micro QC products and services delivers the rapid, accurate and reliable data you need to fuel quick decisions on product quality for release. Place your confidence in Charles River Microbial Solutions to help you identify the bugs, so you can keep your manufacturing process moving forward. **Learn more at www.criver.com/micro.**

charles river

MICROBIAL SOLUTIONS | www.criver.com/micro

ENDOSAFE®
Rapid Endotoxin Testing

ACCUGENIX®
Microbial Identification Services

CELSIS®
Rapid Microbial Detection

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480 Neponset Street
Canton, MA 02021

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781.821.5651

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lcw@chemiclabs.com

WEBSITE
www.chemiclabs.com

NUMBER OF EMPLOYEES
45

DATE FOUNDED
January, 1998

CORPORATE CAPABILITIES

Chemic Laboratories, Inc.

Who We Are

Chemic Laboratories, Inc. is a full service cGMP/GLP contract analytical chemistry laboratory. Chemic provides an array of R&D and cGMP contract testing services including; Extractables/Leachables analysis, CMC Method Development & Validation, Quality Control analysis, Release testing, Raw Materials analysis, Compendial testing, Organic Synthesis/Formulation Development & ICH Stability testing.

Chemic continually strives to exceed the requirements and expectations of our sponsors. We are committed to providing quality services to our clients in support of their product development needs.

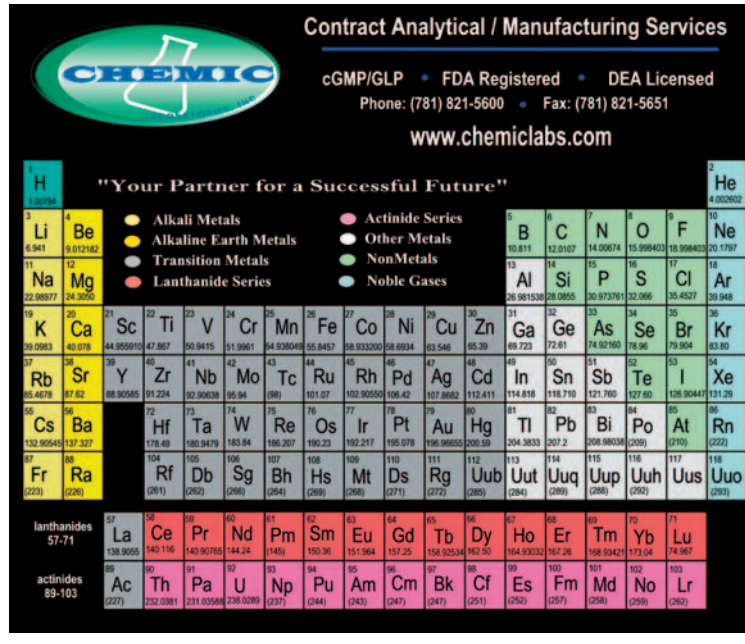
Major Markets

Chemic Laboratories, Inc. is located in Canton, Massachusetts and provides cost-effective outsourcing solutions to a broad spectrum of global clients in the pharmaceutical, medical device and biopharmaceutical industries. We are committed to developing long term strategic alliances with our clients. Chemic offers the ideal blend of expertise and experience that is critical to our clients' success.

Services Offered

Chemic Laboratories, Inc. offers a wide array of cGMP/GLP contract testing services including:

- Quality Control Testing of raw materials, API's and finished products
- Monograph Testing (USP,EP, BP and JP)
- CMC Method Development & Validation
- Degradate Quantitation
- Extractables and Leachables Analysis
- Container Closure Assessment
- ICH Storage and Accelerated Stability Studies
- GLP Method Development and Validation
- Organic Synthesis and Formulation Development



CHEMIC
LABORATORIES, INC.

Who We Are

Chemic Laboratories, Inc. is a full service cGMP/GLP contract analytical chemistry laboratory. Chemic provides an array of R&D and cGMP contract testing services including; Extractables/Leachables analysis, CMC Method Development & Validation, Quality Control analysis, Release testing, Raw Materials analysis, Compendial testing, Organic Synthesis/Formulation Development & ICH Stability testing. Chemic continually strives to exceed the requirements and expectations of our sponsors. We are committed to providing quality services to our clients in support of their product development needs.

Major Markets

Chemic Laboratories, Inc. is located in Canton, Massachusetts and provides cost-effective outsourcing solutions to a broad spectrum of global clients in the pharmaceutical, medical device and biopharmaceutical industries. We are committed to developing long term strategic alliances with our clients. Chemic offers the ideal blend of expertise and experience that is critical to our clients' success.

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Tel. 781-821-5600
Fax 781-821-5651
www.chemiclabs.com

Services Offered

Chemic Laboratories, Inc. offers a wide array of cGMP/GLP contract testing services including:

- Quality Control Testing of raw materials, API's and finished products
- Monograph Testing (USP, EP, BP and JP)
- CMC Method Development & Validation
- Degradate Quantitation
- Extractables and Leachables Analysis
- Container Closure Assessment
- ICH Storage and Accelerated Stability Studies
- GMP/GLP Method Development and Validation
- Organic Synthesis and Formulation Development

CMIC CMO USA Corporation
Cedar Brook
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WEBSITE
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NUMBER OF EMPLOYEES
60

DATE FOUNDED
2007

CORPORATE CAPABILITIES

CMIC CMO USA Corporation

Corporate Description

CMIC CMO USA Corporation specializes in the pharmaceutical development and commercial manufacturing of NDA and ANDA oral solid dosage products. We provide fully integrated development solutions from early development through high-volume clinical and commercial manufacturing. We are committed to creating robust processes that provide seamless transfer to commercial manufacturing.

Because we believe analysis is an essential ingredient, we offer a full range of testing services, stability studies and expertise from development of test methods during the early phases through validation support for product release.

A highly qualified and skilled staff, with an average tenure of 17+ years, supports our commercial manufacturing. We deliver a strong expertise in fluid bed technology including Wurster processes and granulation, as well as compression, encapsulation, and pan coating operations. Even when working with the most challenging processes, you'll find our people are attentive and responsive to your requirements and deadline commitments.

CMIC development services specialize exclusively on solid dosage processes, which include:

- API and excipient interaction and compatibility
- Formulation and process development
- Expertise with controlled release and sustained release processing
- Dry blending capabilities
- Rotor and high shear granulations and drying
- Fluid bed processes (granulation and drying)

- Wurster bead drug layering and coating
- Tablet compression
- Encapsulation
- Aqueous film coating
- Manufacture drug product for use in clinical trials
- Conduct manufacturing scale up and registration batches
- Provide the technology expertise and validation for commercial manufacturing.

Our analytical services include:

- Analytical methods qualification/transfer
- Analytical method development/ qualification/verification
- Cleaning verification method development/ method validation and testing
- Analytical testing support for development work for selection of optimized formulation
- Raw material and final product testing and release
- Stability studies.

CMIC commercial services specialize exclusively on solid dosage processes, which include:

- API and excipient purchasing and release
- Cleaning validation
- Clinical trials materials (CTM) manufacturing
- Registration batch manufacturing
- Process validation
- Commercial manufacturing
- In-process and finished product testing
- Bulk packaging.

All services are offered at our FDA registered site in Cranbury, New Jersey

What the right CMO feels like.

Attentive. Responsive. Knowledgeable. Our customers notice the difference.

Ask any CMIC customer and they'll tell you … we work harder than our competition. What's more, we stand behind our quality and deadline commitments. Whether your product is powder, granule, tablet or capsule, we can handle your clinical to commercial manufacturing. We have strong expertise in fluid bed technology including Wurster processes and granulation as well as compression, encapsulation and pan coating operations. Even when dealing with the most challenging controlled release formulations, our people and processes will deliver complete service and complete satisfaction.

If you can't say this about your current CMO, then it's time to contact Maureen Bell, Business Development Administrator, at 609-454-7871 or bd@cmiccmousa.com. Maureen and the CMIC team are eager to discuss your requirements and show you around our expanding facility.

CMIC *is* what the right CMO feels like.

CMIC is a contract manufacturing organization that specializes in formulation development and commercial services for oral solid dose products.

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www.cmiccmousa.com

CMIC
Pharmaceutical Value Creator

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E-MAIL
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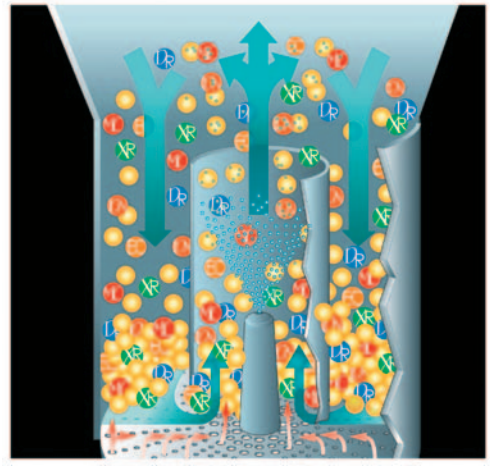
WEBSITE
www.coatingplace.com

NUMBER OF EMPLOYEES
200

DATE FOUNDED
1976

CORPORATE CAPABILITIES

Coating Place, Inc.



Corporate Description

Coating Place is the leading Wurster fluid bed coating services supplier in the industry with more than 40 years of experience. We offer unsurpassed knowledge and expertise in the microencapsulation of powders, granules, and crystals. We have the capability to handle a wide range of project requirements from laboratory services, feasibility studies, modified release properties, particle engineering, and more. Our status as an FDA- and EMA- approved GMP and GLP contract manufacturing facility ensures the highest quality products available. We operate out of two manufacturing locations, providing roughly 300,000-sq-ft of modern facility space for Wurster coating and support services.

Markets Served

Coating Place provides contract Wurster coating of pharmaceutical, nutraceutical, and specialty chemical products, including:

- Rx, branded, and generic
- OTC
- Controlled substance (Schedule II-V)

Technical Services

Coating Place provides a complete range of services from formulation development, feasibility studies, technology transfer, scale-up to commercial manufacturing, all with full analytical support. Formulation services include controlled oral delivery such as enteric, delayed- or extended-release coating using our Oradel® Platform. Other coating applications include moisture or oxygen barrier and taste masking. CPI has extensive expertise and numerous patents in the area of controlled release using ion exchange technology. Our scientists have successfully developed a wide range of formulations and applied them to an equally wide range or core materials.

Facilities

Our 200,000-sq-ft FDA registered pharmaceutical facility is located in Verona, Wisconsin. In 2012, Coating Place expanded with the purchase and expansion of a new 190,000-sq-ft specialty chemical facility, located in Sauk City, WI. Production suites are equipped with a wide range of Wurster fluid bed coating units that accommodate batch sizes from 0.010 up to 800kg. Coating Place continues to develop, manufacture, and operate cutting edge, proprietary Wurster coating equipment. Our services include bead layering, extrusion/spheronization, roller compaction, capsule filling, tablet compression, and pan coating. Coating capabilities include softgels, hard shell capsules, and tablets. The facility is capable of handling and disposing of organic solvents allowing formulations to be developed in either organic solvents or aqueous coating processes. All products at Coating Place are developed and manufactured with an integrated total quality management philosophy and will be handled in a confidential manner.

COATINGS®

Coating Place

Innovative Controlled Delivery

Development through Commercial Manufacturing

Our manufacturing facilities are equipped with twenty proprietary, technically advanced Wurster fluid bed coating units, linear scaled for research and commercial production. No other CDMO offers a comparable record of bringing microencapsulated products to commercial viability as quickly and efficiently as Coating Place.

Coating Place, Inc., PO Box 930310, Verona, Wisconsin 53593 U.S.A. • 1-608-845-9521 • coatingplace.com

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WEBSITE
www.dalton.com

NUMBER OF EMPLOYEES
<100

DATE FOUNDED
1986

CORPORATE CAPABILITIES

Dalton Pharma Services

Company Description

Dalton is a Health Canada approved, FDA–registered, cGMP contract service provider of integrated chemistry, drug development, and manufacturing services to the pharmaceutical and biotechnology industries. We accelerate drug development programs by integrating formulation, process development, and manufacturing of API and finished dose forms at a single location. Our clients benefit by having fully optimized and scalable processes with reduced timelines and costs throughout all phases of development and manufacturing.

Our Steriles made Simple[sm] programs continue to bring your sterile liquid injectables to the clinic even faster. With in-stock consumables and pre-defined development programs, we can accelerate your early phase sterile liquid injectables manufacturing.

Our ongoing commitment to our clients is reflected in CMO 2016 Leadership Awards in the categories of quality, reliability, capabilities, expertise, and compatibility, including on-time delivery, and right first time. In 2016 Dalton was certified as A Great Place to Work®.

Technical Services

Dalton offers chemistry, API, and finish dose services for research and cGMP requirements. With a focus on sterile manufacturing, Dalton can produce everything from sterile APIs, sterile liquid injectables, lyophilized parenterals, and sterile powder filled vials. Our services include:

- Medicinal Chemistry
- Custom Synthesis and Process Development
- cGMP API (bench top to multi-kg scales)

- Formulation Development
- Analytical Services
- cGMP Sterile liquid, lyophilized and powder dosage forms (vials)
- cGMP Powder Filled Capsules—Solid Oral
- Dalton Research Molecules (DRM) Catalog

Facilities

Dalton operates modern 42,000-square-foot (3900-square-meter) cGMP facilities, centrally located in Toronto. Our cGMP facilities have recently undergone significant upgrades including expanded and upgraded sterile powder filling and sterile liquid vial capabilities, as well as new R&D Chemistry laboratories.

Major Products

Our chemistry services cover a wide range of molecule and reaction types. These services are fully supported by Dalton's in-house analytical services, which can characterize your molecule and provide analytical development, validation, release, and stability services. We can then formulate and fill your dosage form in a variety of formats, including steriles or solid oral capsules. Our sterile filling services are scaled perfectly for Orphan Drug Products.

Dalton's Research Molecules business carries more than 2000 standards, building blocks, metabolites, and impurities in its growing catalog available for direct purchase. Dalton's catalog products are North American manufactured by us, and come with substantial analytical characterization.

Discover, Develop, and Manufacture with Dalton.

30 YEARS DALTON Pharma Services

Discover Develop Manufacture

Dalton Pharma Services provides high quality contract services to support the rapid development and manufacture of your pharmaceutical and biologic products.

We integrate activities across our full range of services to save you valuable time and resources. With innovative chemistry, API and finished dose services all in one location, Dalton is ready to meet your requirements at virtually any stage.

- Medicinal Chemistry
- Custom Synthesis
- Process Development
- cGMP API Production
- Analytical Services
- Dosage Form Development
- Solid Dose Manufacture
- Sterile Liquid & Powder Filling

Our Dalton Research Molecules catalog includes over 2,000 molecules. Visit our website to view a complete list of available compounds.

Accelerate your program with Dalton today.

30 YEARS DALTON Pharma Services

Since 1986

Toronto, Canada
1.800.567.5060 • 416.661.2102
dalton.com

CMO LEADERSHIP AWARDS 2016

Winner in all 5 Core Categories

QUALITY
RELIABILITY
CAPABILITIES
EXPERTISE
CAPABILITY

A Great Place to Work® 2016

*Recognized for **On-time Delivery** and **Right First Time***

Integrated Drug Discovery, Development and Manufacturing

EAG Laboratories
4780 Discovery Dr,
Columbia, MO 65203,
USA

TELEPHONE
800.538.5227

WEBSITE
www.eag.com/
pharmaceuticals

NUMBER OF EMPLOYEES
1200+

CORPORATE CAPABILITIES

EAG Laboratories

EAG Laboratories
(ABC Laboratories is now part of EAG Laboratories)
EAG offers the pharmaceutical industry an analytically focused CRO with deep experience in method development, program design, and complex study execution. A true development CRO, we deliver comprehensive CMC analytical support including multi-disciplinary, multi-technique analytical method development and validation, complete stability program management and in-depth extractables and leachables expertise—plus in-house custom synthesis and cGMP radiolabeling services. EAG also offers specialized materials testing to support supply chain and packaging initiatives, and the full range of environmental fate, metabolism, and toxicology studies required to evaluate a pharmaceutical's potential environmental impact.

www.eag.com/pharmaceuticals

Technical Services
- Method development and validation (drug and drug product)
- Stability testing and storage
- Protein characterization
- Bioassays and cell-based potency assays
- Dose formulation testing
- Extractables and leachables programs
- Container/closure qualification
- Impurity isolation, ID and characterization
- Reference standard synthesis, characterization, and storage
- QC/release testing
- Custom synthesis and radiolabeling (including CGMP)
- Environmental risk assessments
- Specialized materials testing and failure analysis

Facilities
EAG operates 23 locations across the United States, Europe, and Asia. We perform GLP and cGMP-compliant drug development primarily at two locations in Columbia, Missouri, formerly doing business as ABC Laboratories: the original, 56-acre campus with 81,000 square feet of laboratory and office space, and a 90,000-square-foot, purpose-built facility located at University of Missouri's Discovery Ridge Research Park. Advanced materials testing, exploratory and investigative studies are conducted at several other locations worldwide.

Company Background
EAG, Inc. is a global scientific services company serving clients across a vast array of technology-related industries. Through multi-disciplinary expertise in the life, materials, and engineering sciences, EAG helps companies innovate and improve products, ensure quality and safety, protect intellectual property, and comply with evolving global regulations. EAG employs 1200+ employees in seven countries, serving more than 4000 clients worldwide. We have brought together the most respected names in contract research and testing services to offer the pharmaceutical industry a comprehensive scientific services partner. How do you make better development decisions faster? Ask EAG. We KNOW HOW.

Markets Served
Pharmaceutical, biopharmaceutical, animal health, generic manufacturers, medical device

EAG LABORATORIES

Eurofins Lancaster Laboratories Professional Scientific Services®
2425 New Holland Pike
Lancaster, PA 17601

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717.656.2300

E-MAIL
pha@EurofinsUS.com

WEBSITE
www.EurofinsLancaster-Labs.com

Eurofins Lancaster Laboratories Professional Scientific Services®

Corporate Description
Eurofins Lancaster Laboratories Professional Scientific Services® (PSS) is a global, award-winning insourcing solution that places our people at your site dedicated to running and managing your laboratory services while eliminating headcount, co-employment, and project-management worries.

We infuse our 55-year track record of scientific and laboratory operations expertise, as well as HR and great place to work best practices, to recruit, hire, train, and manage highly qualified scientists to perform laboratory services at your site, using your quality systems and equipment. Our teams will even help you set up your laboratory and validate equipment according to your SOPs and Lean laboratory practices as needed.

Eurofins Lancaster Laboratories PSS employs and manages full-time employees and provides a comprehensive benefits package, as well as training, development, and career advancement opportunities. Offering these additional benefits allows us to attract, retain, and motivate high-caliber employees to serve you. Our on-site dedicated leaders manage our full-time employees and provide you with scientific insourced services free from co-employment. PSS also solves the challenges associated with the EU Temporary Agency's Workers Directive 2008/104.

Facilities
With more than 1400 employees worldwide, Eurofins Lancaster Laboratories PSS provides services at more than 65 sites in over 13 countries throughout North America and Europe and is part of Eurofins BioPharma Product Testing, which operates 24 laboratory locations, totaling more than 700,000 ft^2 across 12 countries worldwide.

Major Products/Services
Our PSS program provides solutions for clients who require scientists and related support staff at their facility. We have proven success providing dedicated staffing for a variety of technical disciplines that span the drug-development pipeline, including:

- Analytical chemistry
- Microbiology
- Environmental monitoring
- Proteomics
- Biochemistry
- Quality assurance
- Sampling
- Stability
- Biopharmaceuticals
- Process development
- Biomedical engineering
- Method development/method Validation
- Microscopy
- Bioinformatics
- Genomics
- Cell & molecular biology
- Immunochemistry
- Sample management
- Medical device testing
- Engineering
- Project management
- Bioassay characterization.

Markets Served
With more than 65 client sites worldwide, Eurofins Lancaster Laboratories PSS provides the optimal insourcing solution for pharmaceutical and biopharmaceutical companies around the world.

Tired of Your Temps Bouncing?

eurofins | Lancaster Laboratories PSS Insourcing Solutions

Partner and prosper with our award-winning PSS.

Eliminate the ups and downs of continually replacing and retraining temps by retaining our scientists at your site. Hired, trained and managed by us, our award-winning Professional Scientific Services® (PSS):

- Eliminates headcount, co-employment and project management worries
- Avoids Temp turnover rate with managed insourcing
- Costs you less than your own full-time employees
- Delivers a 50-year history of regulatory compliant technical expertise in your lab
- Holds numerous client awards as the top insourcing service provider for the past 10 years

Choose the PSS Insourcing solution that enables us to keep staff grounded.

www.EurofinsLancasterLabs.com

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140 Front Avenue SW,
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Grand Rapids, MI 49503
USA

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grandriverasepticmfg.com

WEBSITE
www.grandriveraseptic-
mfg.com

NUMBER OF EMPLOYEES
100+

DATE FOUNDED
2011

CORPORATE CAPABILITIES

Grand River Aseptic Manufacturing

Company Description
Grand River Aseptic Manufacturing (GRAM) is a parenteral contract manufacturing organization supporting new product development and cGMP manufacturing. With a state-of-the-art cleanroom and highly trained staff, GRAM provides clinical trial and commercial material in vials or syringes for the life-sciences industry.

Technical Services
- Aseptic filling of vials 2 mL to 50 mL
- Process development & validation
- Lyophilization
- Labeling and packaging
- Terminal sterilization
- DEA Controlled Substances (CSIII-V)
- Analytical and microbiological services
- Regulatory support
- Test method development and validation
- Formulation development
- On-site warehouse and material storage

Markets Served
GRAM serves customers in the pharmaceutical and biotech space. GRAM is fortunate to call some of the world's top pharmaceutical and biotech firms loyal customers.

Facilities
Manufacturing Facility:
- 12,000 ft^2
- cGMP compliant
- FDA approved
- Validated sytems/processes
- Building monitoring system
- Backup power supply
- QC laboratories
- Just-in-time warehousing

Finishing Facility:
- 28,000 ft^2
- cGMP compliant
- FDA approved
- QC laboratories
- Validated systems/processes
- Backup power supply
- Finishing activities
  - Terminal sterilization
  - Inspection
  - Labeling and packaging
- Storage and distribution

GRAND RIVER
ASEPTIC MANUFACTURING

From Development Through Commercialization

Grand River Aseptic Manufacturing (GRAM) is a full-service, contract parenteral manufacturer located in Grand Rapids, Michigan. We are committed to superior regulatory performance and it is our mission to deliver quality products and services. As a result of our commitment to excellence, our last FDA inspection resulted in no Form 483 issued. This is reflective of the level of quality standards with which GRAM has successfully manufactured and launched numerous clinical and commercial products. At GRAM, we treat every client project as if it were our own.

New in 2016:

- No Form 483 Issued During Last FDA Inspection
- Three Commercial Products
- Expanded Disposable Technology Capabilities

Services Offered:

- Pharmaceutical Development
- Clinical and Commercial Parenteral Manufacturing
- Lyophilization
- DEA Controlled Substances (CSIII-V)
- Storage and Distribution

GRAND RIVER
ASEPTIC MANUFACTURING

www.grandriverasepticmfg.com

bd@grandriverasepticmfg.com

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WEBSITE
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NUMBER OF EMPLOYEES
500

DATE FOUNDED
2006

KEY PERSONNEL:
Lee Karras, CEO;
Barry Lederman, CFO;
James Cherry,
VP/General Manager,
Whippany, NJ;
Maryse LaLiberte,
VP/General Manager,
Mirabel, Quebec;
Anthony Qu, PhD,
VP Pharma Development

CORPORATE CAPABILITIES

Halo Pharmaceutical, Inc.

Who We Are

We are the CDMO that makes contracting go smoothly. Customers choose Halo Pharma for our comprehensive product development, commercial and clinical manufacturing, testing, and packaging services. They stay with Halo because of our agility, flexibility, experience, collaboration, and accessibility.

Our experience in a wide variety of dosage forms (complex oral solids, topicals, and oral liquids) is unmatched in the CDMO space. This includes specialization in the manufacture of CI-CV controlled substances for the US and Canadian markets, with additional expertise in abuse-deterrent technologies and dosage forms. We focus on solving complex formulation, analytical, and manufacturing challenges for both new molecules and generics.

We leverage our expertise in the areas of tech transfer, process and product development, production, scale-up and validation, and analytical method development to move your product to market more quickly, efficiently, and on budget. You can partner with Halo from development through commercialization, or at any point along the way.

Major Markets

Halo Pharma has solved challenges for a wide variety of clients, from the world's largest pharmaceutical companies to emerging and established biotech companies, to specialty pharma and select generic manufacturing companies. Halo has regulatory approvals for commercial supply for the US, Canada, and for Europe.

Services Offered

Pharmaceutical development, formulation and pre-formulation, commercial and clinical manufacturing (solid, semi-solid, liquid), testing services, and primary and commercial packaging services.

Manufacturing and Development Expertise in:

- Controlled substances (DEA Schedule I-V)
- Extended/modified release tablets/capsules
- Hot-melt extrusion
- Extrusion/spheronization
- Sustained release beads
- Micro and mini tablets
- Film-coated tablets
- Solvent-based formulations
- Powders
- Liquids
- Creams
- Non-sterile ointments
- Sterile ointments
- Suppositories

Facilities

Whippany, NJ offers 175,000 square feet of state-of-the-art equipment and technologies for developing, manufacturing, and finishing oral dosages, liquids, suppositories, and sterile ointments, as well as for handling all dosage forms for DEA Schedule I-V drugs. It is approved by FDA/MHRA.

Mirabel, Québec provides 226,000 square feet for the development to commercialization of liquids, ointments, creams, suppositories, and oral solid dosage forms. The plant is approved by Health Canada/FDA and EMEA.

We make contracting go smoothly.

Outsourcing the clinical development and commercial manufacturing of your drug product doesn't need to be difficult. Make the outsourcing process easier by choosing Halo Pharma.

At Halo Pharma we provide the full range of contract drug development and manufacturing services, delighting our customers with our agility, flexibility, experience, collaboration and accessibility.

Project plans are made. Problems are solved. Partnerships are born.

HALO PHARMA

Partnerships for Life.

Experience flexible outsourcing.
Get started at http://halopharma.com/flexible

Letzner Pharmawasseraufbereitung GmbH
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42499 Hückeswagen,
Germany

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E-MAIL
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WEBSITE
www.letzner.de

CORPORATE CAPABILITIES

Letzner Pharmawasseraufbereitung GmbH

Specialist in Pharmaceutical Water Purification
Founded in 1990, LETZNER Pharmawasseraufbereitung GmbH specializes in consulting, design, and engineering as well as manufacturing and maintenance of water treatment systems for the pharmaceutical industry. All components of the water treatment systems—pretreatment, reverse osmosis systems, multi-effect stills, pure steam generators, CIP/SIP systems, and storage and distribution systems—are customized based on the specific needs of the site. Also, standardized components, modules, and solutions are individually assembled according to specific customer needs and industry standards. Purified water, water for injection, and pure steam are processed in our plants according to the latest *Ph.Eur.*, *USP*, *JP*, GMP, ISPE, and FDA requirements while observing the highest quality standards.

Markets Served
Pharmaceutical industry

Major Products/Services
Purified Water Systems, Water for Injection Systems, Pure Steam Generators, TOC-Devices, Turnkey Installations, Maintainance, Calibration, Validation (GMP), Documentation (GDP)

Turnkey Systems and Complete Solutions
LETZNER is delivering turnkey systems worldwide: ready for operation solutions from drinking water to the point of use in the cleanroom. The plant and vessel manufacture as well as piping can be realized without any cutting point using high-quality pharmaceutical grade components. Similar to modular design, different qualities, components, and technologies can be chosen in terms of material, surface structure, type, and processing due to the need

required. The total commitment from LETZNER includes consideration of all customers' needs and demands, all regulatory standards and guidelines, and the given composition of the feed water.

Complete One-Stop Service
LETZNER is the right company to contact for all phases of your system implementation: consulting and design, storage vessel, and piping manufacturing, the production and installation of the plants as well as the delivery and integration into existing environments. Furthermore, LETZNER does the after sales service and maintenance of the whole lifecycle attended by a 24-hour service hotline for an uninterrupted operation. Get in touch with us—It is worth it!

LETZNER - your best choice
- Best-in-class experience and hands-on knowledge in the generation of pharmaceutical water and steam
- High flexibility due to our own design, planning, and manufacturing
- Individual engineering for all kind of situations
- Sanitary systems completely designed in stainless steel
- Maintenance contracts and 24-hour service in case of emergency
- Complete documentation and qualification according pharmaceutical standards
- Short lead time cycles
- Your wishes and our knowledge will deliver the perfect solution

Facilities
Headquarters: Germany,
Cooperations Worldwide

YOUR GLOBAL RESOURCE

ON EQUIPMENT AND SUPPLIES FOR BIO/ PHARMACEUTICAL DRUG DEVELOPMENT AND MANUFACTURING

Pharmaceutical Technology's print issues and online portfolio address key trends in drug development, including equipment and manufacturing trends. Subscribe free today and read expert editorial coverage on emerging trends, strategies, and best practices in this key area!

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NUMBER OF EMPLOYEES
11,000+

DATE FOUNDED
1897

CORPORATE CAPABILITIES

OUTSOURCING and Consulting Services

Lonza

Corporate Description

Lonza is a leading partner to the pharmaceutical, healthcare, and life science industries. For over 25 years Lonza Custom Manufacturing has been helping emerging and large biotech and pharmaceutical companies improve and advance their products. Whether for clinical or commercial supply, Lonza's complete development services, industry-leading manufacturing processes, and broad technology platforms enable products to reach their full potential.

Fine chemicals, advanced intermediates, highly potent APIs, antibody drug conjugates, peptides, recombinant proteins, monoclonal antibodies, research products, custom media and cell-based therapeutics … Lonza Custom Manufacturing has the know-how and proven track record to handle nearly any pharmaceutical or biotechnology challenge, around the globe.

Long-term Cost Savings: Our cutting-edge development services, advanced technologies, backward integration and strategic global sourcing can improve your process and lower your total cost of goods.

Speed to Market: Our broad manufacturing experience in both chemistry and biotechnology helps to streamline processes and minimize delays.

Improved Quality: Advanced technologies and processes help take your product to the next level of product quality.

Flexibility: Global sites, multi-purpose facilities, customer-tailored programs and a broad offering give you just what you want, when you want it.

Lower Financial Risk: Our existing plants, capacity, and infrastructure mean you do not need to build or expand your own facilities, which saves you time and resources

Focus: Outsourcing with Lonza allows you to focus on your core competencies.

Major Products/Services

For flexible, high-quality contract manufacturing, development services and products, we can help:

- Active Pharmaceutical Ingredients (APIs)
- Advanced Intermediates
- Highly Potent APIs (HPAPIs)
- Biocatalysis
- Biotransformations
- Antibody Drug Conjugates (ADCs)
- Peptides
- Vaccines
- Plasmid DNA
- Recombinant Novel Proteins
- Fragmented Antibodies (Fabs)
- Monoclonal Antibodies (mAbs)
- Cell therapy
- Custom Media & Buffers

Worldwide State-of-the-Art Facilities

Lonza can be found around the globe including areas of Belgium, Denmark, France, Germany, Great Britain, Hungary, Italy, Poland, Russia, Spain, Switzerland, The Netherlands, and The United States.

Pharma&Biotech

Lonza

Focused on Your Success

Committed to Global Innovation for Human Health

Lonza has been a reliable partner in the life sciences industry for over 30 years. Our experience in biological and chemical development and manufacturing has allowed us to create a broad platform of technologies and services for fine chemicals, advanced intermediates, active pharmaceutical ingredients (APIs), functional ingredients, biologics, cell and viral therapies.

We are committed to continued innovation with a focus on future scale-up technologies and emerging markets. Whether you are an established pharmaceutical company or an emerging biotech, Lonza is prepared to meet your outsourcing needs at any scale.

Why Outsource with Lonza?

- Full range of services from preclinical risk assessment to full-scale commercial manufacturing
- Advanced technologies and optimized processes to streamline your product pipeline
- 10 contract development and manufacturing sites worldwide
- Experience with worldwide regulatory authorities
- Track record in meeting accelerated timelines associated with breakthrough therapy designated products
- Dedicated project teams committed to comprehensive and timely communications
- Lean, sustainable processes that minimize waste and environmental risk

For more information, contact us at:
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Europe and Rest of World: +41 61 316 81 11
custom@lonza.com

www.lonza.com/oursites

Lyophilization Technology, Inc.
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E-MAIL
inquiry@lyo-t.com

WEBSITE
www.lyotechnology.com

DATE FOUNDED
1992

CORPORATE CAPABILITIES

Lyophilization Technology, Inc.

Corporate Description
A dedicated staff supports clients bringing new products to patients and improving existing products and operations. Clients gain with successful development and clinical manufacturing, bridging discovery through product approval and commercial manufacturing. Support services span product development, process engineering, clinical manufacturing and technical service. Internationally recognized as an industry leader, clients have fostered our reputation for providing innovative solutions, achieving desired results, and exceeding expectations. This reputation is demonstrated by successful collaborative relationships with clients for over 23 years.

Major Products/Services
LTI successfully developed formulations, processes or prepared clinical material for over 851 diverse products:
- Anti-infectives
- Human/Recombinant Biologics
- Vaccines
- Nanoparticles/emulsions
- Oncolytics/HPCs
- Small Molecules/Therapeutics
- Diagnostics
- Bioengineered materials

Capabilities
- Pre-clinical through Phase III Clinical Materials, lyophilized/liquid products
- Containment for cytotoxic/high potent products
- Dedicated/disposable equipment
- Vials: 2 to 160 mL: novel delivery systems
- Cartridges/syringes: 1 to 50 mL
- Lyophilizers: 0.2 m^2 to 4.5 m^2
- Praxair ControLyo™
- Bulk Lyophilization
- Batch sizes: up to 75L
- Drug and Device Registration/DEA license
- US/EU compliant

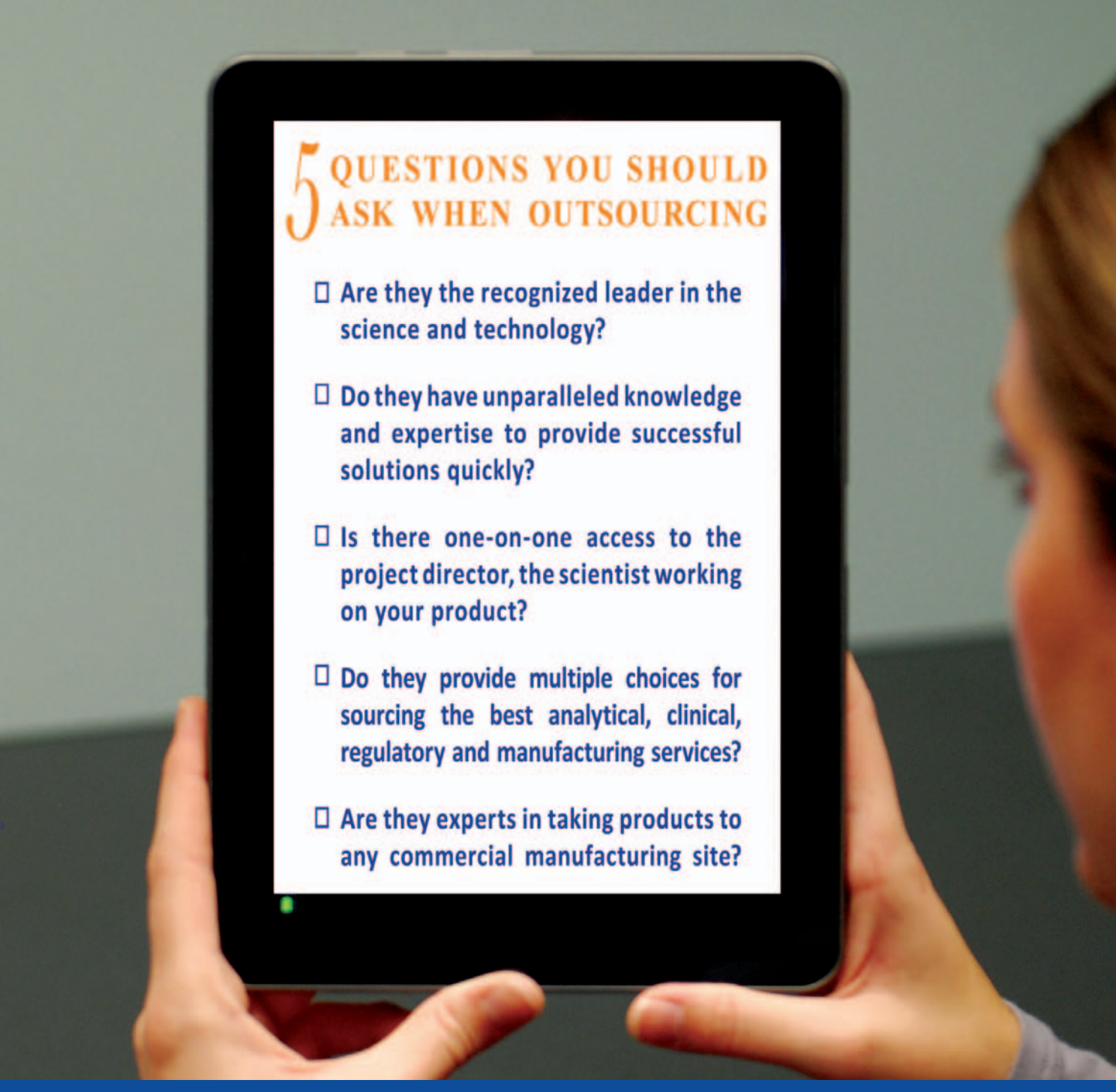
Development Sciences lab focuses on formulation through product characterization. The Process Lab provides capacity for small/medium scale lyophilization. Filtration, filling, stoppering and loading qualified pilot-scale lyophilizers are in certified Class A/100

environments, emulating aseptic manufacturing conditions.
- Thermal Analysis
- Product Design
- Formulation Development
- Product/Process Feasibility
- Cycle Design/Refinement
- Product Characterization
- Toxicology Material
- Stability Batches

Clinical Manufacturing Area (CMA) for preparation of clinical material is for processing a wide range of products, including unique requirements. The CMA includes an aseptic suite featuring unique disposable negative pressure isolators for containment/isolation technology, inspected and approved for handling BSL-2, cytotoxic and highly potent material.
- Aseptic compounding
- Pre-clinical through Phase III
- Small to medium batch sizes
- Liquid/diluents

Technical services are available providing support for all aspects of lyophilization.
- Customized Training
- Qualification/Validation Support
- Investigations
- Quality/Compliance

Major Markets
LTI provides Development and Clinical Trial Material Manufacturing to more than 436 biopharmaceutical companies spanning virtual, small, large and multi-national companies. Gaining an international reputation, projects are with clients in US, Canada, Mexico, Eastern and Western Europe, Australia and Japan.



Benefit from the focused expertise gained from working on 534 diverse products, collaborating with 380 companies over 20 years.

Talk with the people who can provide you the right answers

Development Sciences Clinical Manufacturing Technical Services

LYOPHILIZATION TECHNOLOGY, INC.
Integrating Science and Technology

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Metrics Contract Services
1240 Sugg Parkway
Greenville, NC 27834

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252.752.3800

WEBSITE
www.metricscontractservices.com

NUMBER OF EMPLOYEES
200+

DATE FOUNDED
1994

CORPORATE CAPABILITIES

Metrics Contract Services

Company Description
Metrics Contract Services is a leading full-service pharmaceutical development and manufacturing organization serving clients worldwide. We deliver proven scientific and operational excellence for oral dosage forms. Today, as a subsidiary of Mayne Pharma Group, we offer clients more resources and capabilities than ever before.

Metrics is a full-service provider of:
- Quality pharmaceutical formulation development
- First-time-in-man (FTIM) formulations
- Clinical material manufacturing (CTM) for Phase I, II, and III trials
- Commercial manufacturing
- Analytical laboratory testing services
- Specialty technologies for controlled release and bioavailability enhancement.

Areas of Expertise
- *Formulation development.* Our formulation development scientists offer expertise in poorly soluble and unstable actives, highly potent API, immediate and modified release, and small molecule oral delivery.
- *Potent and cytotoxic products.* Our cGMP compliant, dedicated and segregated facility features custom-engineered containment. With no open processes and one-way material flow, containment is achieved at 30 nanograms/m^3.
- *Fast-track development.* Metrics has successfully delivered materials for more than 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.
- *Analytical laboratory testing services.* With 90+ analytical chemists on staff, our services include methods development and validation, chromatography (LC and GC), dissolution (UV and LC finish), moisture, particle size, ion chromatography, AA/ICP, FTIR, titrations, particulate matter (HIAC), cleaning methods (LC and TOC), and LCMS.

- *Clinical trial manufacturing Phase I, II, III.* Our CTM capabilities offer capacity for up to 450 kg batch sizes. We also offer expertise in over-encapsulation for comparator studies and potent drug handling capabilities.
- *Commercial Manufacturing.* Larger scale registration or commercial manufacturing of solid oral dose formulations, including DEA II-V controlled products.

Facilities and Additional Services
The parent company of Metrics Contract Services, Mayne Pharma, is investing $80 million to significantly expand facilities and equipment at its site in Greenville, NC. The strategic capital investment will fund a new 126,000 ft^2, oral-dose commercial manufacturing facility, quadrupling the company's US manufacturing capacity, while re-purposing space to create 10+ new analytical laboratories and formulation development suites.

The new facility means Metrics Contract Services can offer a more 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

From Concept To Commercialization. Now Metrics Delivers Across The Spectrum.

With an $80 million expansion underway, Metrics Contract Services will soon be your solution for oral-dose pharmaceutical development through commercial manufacturing – all in one contiguous location. No site transfers. And the same great customer experience our clients have come to expect.

Customers will also find expanded and improved state-of-the-art potent facilities designed to meet regulatory requirements of international agencies. At Metrics, we're committed in our pursuit to be the most sought-after oral-dose CDMO.

Find out why there's never been a better time to talk to Metrics. To learn more, visit MetricsContractServices.com/expansion.

Formulation Development • Analytical Testing • Commercial Manufacturing

Greenville, NC, 252-752-3800, www.metricscontractservices.com

metrics contract services

Mikart, Inc.
1750 Chattahoochee Ave.
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NUMBER OF EMPLOYEES
250

DATE FOUNDED
1975

CORPORATE CAPABILITIES

Mikart, Inc.

Corporate Description

A recognized leader in contract manufacturing, Mikart specializes in the development, manufacturing, and packaging of solid-dose and liquid-oral dose products. The company's services include formulation development; analytical, manufacturing, packaging, and regulatory services; and complete project management. Mikart offers clients more than 40 years of experience, a responsive working relationship, and the ability to take products from formulation development through full-scale commercial production.

Technical Services

- Formulation development
- Analytical methods development
- Process validation
- Stability testing
- Clinical supplies manufacturing and packaging
- Immediate- and controlled-release tablet manufacturing
- Capsule manufacturing
- Liquid manufacturing
- CII–CV controlled-drug manufacturing
- Film coating
- Fluid-bed and high-shear granulating

- Solid-dose and liquid-bottle packaging
- Bottle powder filling
- Blister packaging/card sealing/cartoning
- Laminated foil pouch packaging
- Liquid unit dose
- Low humidity manufacturing
- Cold storage
- Regulatory services.

Facilities

Mikart has more than 234,000 ft^2 of development and production facilities located in Atlanta, Georgia. The company's Science Center provides product development and analytical services. Equipped with advanced technologies, this 40,000-ft^2 center houses quality control, analytical services, and a complete pilot-scale manufacturing operation. Processes include fluid-bed granulating, roller compacting, and high-shear granulating. The facility enhances Mikart's ability to take products from initial development through commercial production. The company has recently completed an expansion of its manufacturing operations and now has an annual production capacity in excess of 2 billion tablets and 2 million pints.

Markets Served

Mikart provides products and services to the pharmaceutical industry, including PhRMA, specialty pharmaceutical and biotechnology companies.

Mikart is the Contract Development and Manufacturing Organization (CDMO) that delivers the services you need, plus the speed and responsiveness you want.

Why put up with inflexible procedures and unreturned calls? At Mikart, you have our full attention. And we're quick to respond with personalized solutions that get your projects completed faster and to your individual requirements.

The Cure For (CDMO) Attention Deficit Disorder.

Our professional services include: Formulation Development, Clinical Trial Supplies, Regulatory Filing Support, plus Manufacturing and Packaging solutions.

You'll find Mikart has everything you're looking for in a pharma partner: innovative technology and equipment, highly skilled people and 38 years of solid CDMO experience.

To experience just how responsive we can be, contact us at 1-888-4MIKART or send us an email to info@mikart.com

Ready. Responsive. **Mikart** *Right for You.*

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NUMBER OF EMPLOYEES
1300+

DATE FOUNDED
1995

CORPORATE CAPABILITIES

MPI Research

Company Description

MPI Research, with global headquarters in Mattawan, Michigan, provides safety evaluation, discovery, bioanalytical, and analytical—and now phase I clinical—services to the biopharmaceutical, medical device, animal health, and chemical industries. The company also offers comprehensive imaging solutions including preclinical and clinical imaging, radiochemistry, and data analysis. Scientific knowledge and experience, responsiveness, integrity, trust, teamwork, and dedication to strong and enduring Sponsor relationships are the defining attributes that characterize MPI Research as a high-performance, high-quality organization that is committed to bringing safer and more effective products to the world. Learn more about how MPI Research can take you further at www.mpiresearch.com.

Technical Services

- Metabolic Disease
- Cardiovascular
- Orthopaedic
- Renal
- Neurosciences
- Inflammation
- Infectious Disease
- Immune Disorders
- Oncology
- Ophthalmology
- Orphan/rare diseases

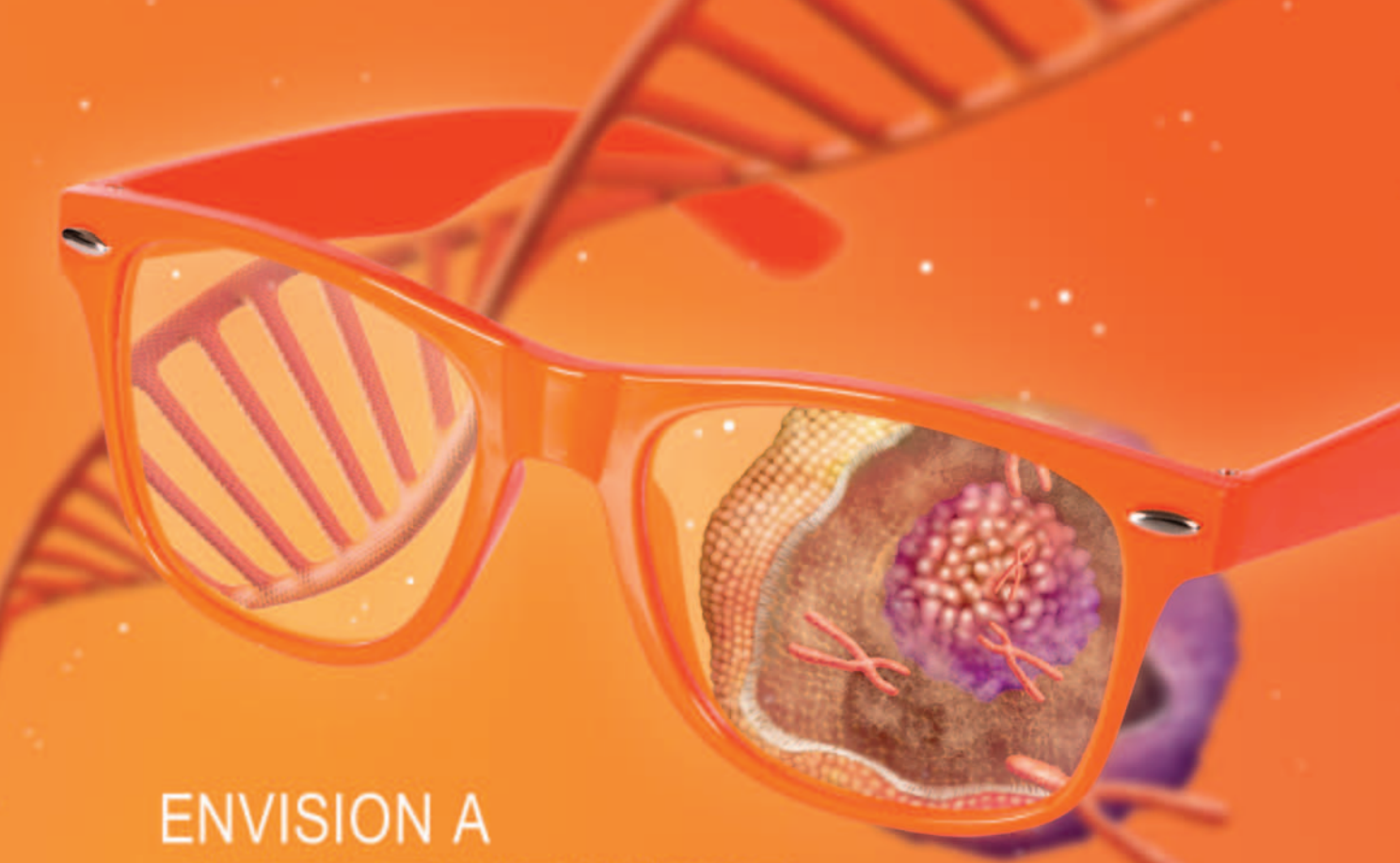
Facilities

With more than one million square feet at the company's headquarters in Mattawan, Mich., MPI Research is the world's largest, single site, preclinical research facility. Our early-stage clinic, located in Kalamazoo, Mich., operates a 50-bed unit that uses up-to-date clinical technology and offers quality support service for our study participants.

Major Products/Services

Our extensive capabilities support virtually all aspects of drug safety/preclinical sciences, discovery sciences, surgical services, medical device evaluation, and bioanalytical and analytical sciences, in both small and large molecules, and in all major therapeutic areas. The company tests a wide and diverse range of compound classes, provides all routes of administration (except inhalation) and offer studies with numerous species and models. With ample physical and technical capacity, MPI Research can accommodate multiple requirements simultaneously, adjust schedules readily, and produce results quickly.

MPI® RESEARCH



ENVISION A PARTNER WITH MORE.

More Services. More Insights. More Support.

Take a closer look at MPI Research to find more of what you're looking for. You deserve a strategic, responsive and efficient partner for your early stage drug development. MPI Research offers that and more.

With an impressive breadth of discovery, preclinical and clinical scientific knowledge and services, our team of highly trained research scientists and world-class facilities provide the insights to see your project through. We do everything we can to make your vision a reality.

When you want more from your CRO, look to MPI Research.

To take a closer look, visit www.mpiresearch.com.

- DRUG SAFETY
- DISCOVERY SCIENCES
- BIOANALYTICAL & ANALYTICAL
- SURGICAL SERVICES
- MEDICAL DEVICE EVALUATION
- TRANSLATIONAL IMAGING
- CLINICAL RESEARCH

MPI® RESEARCH

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A Healthier World.
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@patheon.com

WEBSITE
www.patheon.com

NUMBER OF EMPLOYEES
8700

DATE FOUNDED
1974

Patheon®, A Healthier World. Delivered.

Patheon® is a leading provider of outsourced pharmaceutical development and manufacturing services.

The company delivers a comprehensive, integrated and highly customizable range of active pharmaceutical ingredient, or API, and finished drug product services to our clients, from formulations development to clinical and commercial-scale manufacturing, packaging, and lifecycle management. Our services address both small molecule and large-molecule biological drugs.

Patheon is the only end-to-end integrated provider of such services, which combines with the company's scientific and regulatory expertise and specialized capabilities, allows clients to partner with a single outsourced provider to address complex development and manufacturing challenges. Patheon is #1 in product development services, #2 in commercial-scale product manufacturing, and is #1 in quality.

Transforming the Industry

Patheon is transforming the pharmaceutical supply chain model with innovative, flexible and customized end-to-end pharmaceutical development and manufacturing solutions that reduce complexity, increase quality, and shorten time to market, enabling biopharmaceutical companies to focus on their competencies.

With Patheon, clients gain access to the broadest range of drug substance, pharmaceutical development, and drug product solutions for large and small molecules, including an array of oral solid, sterile, and softgel dosage forms. This unique combination of depth and breadth across the drug development continuum provides flexibility to choose the most appropriate CMC technologies with the confidence that the program will be delivered on time and right the first time.

Facilities

Patheon, with employees numbering 8700, including more than 634 scientists in more than 25+ locations in North and South America, Canada, Europe, Australia, Japan, and Asia, has provided development and manufacturing services for approximately 700 products and molecules.

The company provides a comprehensive suite of capabilities. Specialized capabilities address 75 percent of all dosage forms with expertise and specialized capacity in high potency, controlled substances, low solubility, sterile, modified release, and Softgel technologies.

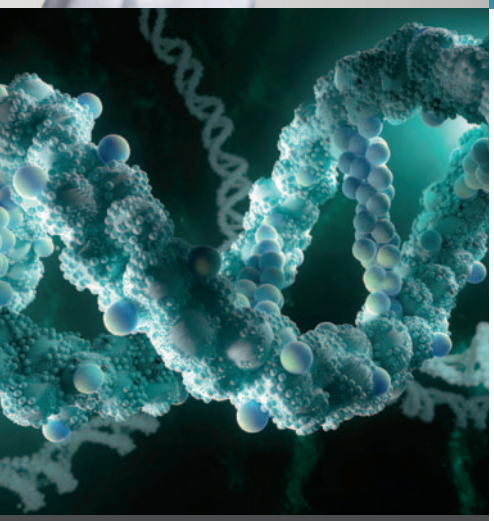
Major Product/Services

Patheon provides pharmaceutical and biotechnology companies with direct access to the expertise, quality, and full range of small- or-large molecule drug substance and solid and sterile dosage forms:

- Small-Molecule API
- cGMP Production
- Process Development
- Generic API and Pharmaceutical Intermediates Portfolio
- Biologics
- Mammalian cGMP and non cGMP manufacturing
- Process Development
- Early Development
- Drug Substance Characterization
- Analytical Development & Validation
- Formulation Development
- Clinical Trial Material Manufacturing
- Late Development
- Process & Method Development
- Release & Stability Testing
- Regulatory Support
- Lifecycle Management Services
- Commercial Manufacturing
- Manufacturing and Packaging
- Tech Transfer/Scale-Up Management
- Risk Mitigation Services

Patheon®
A HEALTHIER WORLD. DELIVERED.

A healthier world.
Delivered.



Because you created it when no one else could…
Because you know it has the potential to change everything…
Because you need to scale it up by millions while keeping it safe for millions…
And because you believe medical hopes deserve to become realities…

You believe tomorrow's breakthroughs should never have to wait in yesterday's supply chain.

They don't have to anymore.

We are Patheon, and we bring to bear 40 years of experience and expertise from development to manufacturing. Global reach. An unrelenting dedication to quality and innovation. And a supply chain solution designed to simplify complexity and speed up the process.

So bring us your brilliant discoveries. Your small molecules and biologics. Your most complex approvals and manufacturing impossibilities.

And we'll work towards a day when the medicines people need will be waiting for them.

The world is waiting.

Let's make the world healthy...together.

800

Drugs manufactured or developed

+1 866.PATHEON
www.patheon.com

Patheon
A HEALTHIER WORLD. DELIVERED.

TRUST

Tt

80% of our top clients work with us in more than one business unit.

Pfizer CentreOne
Corp HQ 235 E. 42nd Street, New York, NY 10017

TELEPHONE
API: 269.833.6164
Drug Product: 224. 212.2267

WEBSITE
www.pfizercentreone.com

NUMBER OF EMPLOYEES
More than 1700 employees support Pfizer CentreOne

DATE FOUNDED
Division founded over 40 years ago

CORPORATE CAPABILITIES

Pfizer CentreOne

Corporate Description
Pfizer CentreOne™ is a global contract manufacturer that focuses on API synthesis and sterile injectables fill-finish. For 40+ years, we've manufactured complex compounds for our biopharmaceutical partners. Our dedicated team of contract manufacturing experts guide your drug safely from development through commercialization, backed by the quality and resources of Pfizer. Our core capabilities include small-molecule steroid and hormone intermediates and APIs; custom small-molecule API synthesis; and sterile injectables fill-finish, where we are known for our experience with complex biologics and lyophilization. Pfizer CentreOne is the union of CMOs Pfizer CentreSource and Hospira One 2 One. Learn more at www.pfizercentreone.com.

Pfizer CentreOne™ is a global contract manufacturer that focuses on API synthesis and sterile injectables fill-finish.

What is our history?
Our company was born of the September 2015 union of Pfizer CentreSource, a global leader in specialty APIs, and Hospira One 2 One, one of the world's premier sterile-injectables CMOs. As a combined organization, we've brought together the best of our manufacturing capabilities to provide a wider array of services and technologies to our biopharmaceutical partners.

Although Pfizer CentreOne is a new name, we're not new to the industry, with more than 40 years of contract manufacturing experience.

What are our services?
We concentrate on segments and specialties where we excel, while constantly seeking to expand our service offerings and manufacturing footprint to meet your needs. Today, we're aligned into two primary areas of expertise: API and drug product. Specifically, we focus on:

- Small-molecule steroid and hormone intermediates and APIs
- Custom small-molecule API synthesis
- Sterile injectables fill-finish.

How are we structured within Pfizer, and how does that benefit you?
Pfizer CentreOne is a self-contained CMO embedded within Pfizer. We have our own dedicated team that reports through Pfizer's Essential Health commercial organization. This means that we make decisions based solely on your needs, while harnessing the quality, capabilities, and regulatory strength of Pfizer global manufacturing on your behalf.

Moreover, because our CMO is dedicated to growth, Pfizer has reserved capacity—time, equipment, and resources—for Pfizer CentreOne across the facilities that manufacture our partners' drugs. Now and for the long haul, we're dedicated to you and your compound.

Learn more at www.pfizercentreone.com.

Bringing together the best of ONE2ONE™ Pfizer CENTRESOURCE

Pfizer CentreOne

Contract Manufacturing

When it's **YOUR** compound, every step matters.

www.pfizercentreone.com

API

DRUG PRODUCT

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Morton Grove, IL 60053

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847.967.6000

FAX
847.967.5876

E-MAIL
sales@registech.com

WEBSITE
www.registech.com

NUMBER OF EMPLOYEES
85

DATE FOUNDED
1956

Regis Technologies

Company Description
Regis Technologies, Inc., a Chicago-based CMO focused on small-molecule active pharmaceutical ingredients (API), partners with pharmaceutical companies to expedite drugs to the clinic and ultimately to the market. We offer synthesis, analytical, and separation services to advance your API from initial process development to final validation and commercial manufacturing. Let our veteran project managers successfully guide your molecule through the IND and NDA processes.

Technical Services
- cGMP scale-up manufacturing from 100 grams to 100 kilograms
- Continuous-flow process development and scale up
- Impurity synthesis and structure elucidation
- Potent compound manufacturing to about 500 grams
- Process development services include route scouting, optimization, and critical process parameter studies
- Analytical method transfer, development, and validation
- Stability studies
- cGMP Chiral separations by SFC

Facilities
Regis Technologies operates an FDA-inspected cGMP facility with approximately 36,000 square feet of production space housing eight reactor suites from 25 to 500 gallons. Each suite contains a matched pair of reactors and has an air make-up system with HEPA filtered air, minimizing the potential for contamination between rooms. Regis' well-equipped process development and analytical laboratories were built in recent years.

Markets Served
Regis' primary focus is the innovator pharmaceutical industry, especially emerging pharma companies. In addition, Regis has the experience to develop generic API processes under exclusive agreements. Regis has performed numerous projects in other healthcare related fields such as diagnostic products, imaging agents, nutraceuticals, and green chemistry.

60th Anniversary REGIS® TECHNOLOGIES, INC. CUSTOM PHARMA

Rommelag CMO

Rommelag CMO, works Holopack Verpackungstechnik GmbH
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WEBSITE
www.rommelag.com

Company Description
Rommelag CMO provides you with quick and easy access to BFS technology without having to invest in either the mandatory GMP environment that goes with it or the specialists required to operate and maintain the machines. What we offer is the whole spectrum, including the entire infrastructure itself, over 50 years' experience in bottling using BFS aseptic systems, and the expertise you'd only get from the inventors of bottelpack technology.

With over 50 systems in a whole host of different configurations, Rommelag CMO runs one of the world's largest, most state-of-the-art bottelpack system ranges. It goes without saying, we're ideally placed to meet your bottling needs in no time at all and at minimum cost. So whether you're looking for help with trial batches, the development phase (including feasibility studies, stability tests, and clinical samples) or getting batches ready for market, we've got it all covered.

Markets Served
Certified by authorities such as FDA/EMEA/ANVISA according to GMP rules and according to ISO 13485 and ISO 9001, Rommelag CMO is able to serve markets worldwide. The new manufacturing building Pharma 2020 and the biological facilty up to Biosafety Level 2 sets the benchmark for modern BFS-contract-manufacturing. It is the key element for the bottelpack® PharmaSuite concept, which provides dedicated areas for high sophisticated drug products.

Major Products/Services

We are able to fill the following applications:

Drugs and medical devices according to GMP
- Eye, ear, and nasal drops
- Homeopathy
- Inhalations
- Infusions and injections
- Rinsing solutions
- Orals
- Cremes, ointments, and gels

- Wound care products
- Vaginal applications
- Rectal applications
- Disinfectant solutions
- Diagnostics
- Biologicals
- Vaccines
- Biotechnological products

Non-GMP-products
- Cosmetics
- Food supplements

Technical Products
- Pheromones
- Machine oil and Motor oil
- Detergents

Facilities
Holopack Verpackungstechnik GmbH
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ROMMELAG CMO

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WEBSITE
www.ropack.com

NUMBER OF EMPLOYEES
300

DATE FOUNDED
1976

CORPORATE CAPABILITIES

Ropack Pharma Solutions

Ropack Pharma Solutions (RPS) provides commercial manufacturing and packaging for solid oral dosage: encapsulation, powder blending, bottle, flip-top vial, blister, stick-pack, sachet. Our BEC 300 blister line will be serialization-ready by May 2017, well ahead of the DSCSA deadline, and all other primary and secondary packaging formats will be ready by November 2017. If you are challenged by serialization requirements, send your packaged pharma products to RPS's international serialization hub in Montreal for serialization and distribution to your chosen destination. The result is a reduction in your capital expenditures, personnel, and coordination that serialization requires.

Technical Services

- Serialization
- Commercial packaging
- Clinical packaging and in-country distribution
- Encapsulation
- Powder blending

RPS operates in Montreal, Quebec— facility totaling 256,000 square feet. RPS's newest addition is the Uhlmann BEC300, a single-lane unit which integrates blistering and cartoning. This highly efficient blister line is now accepting volumes.

Tracking and tracing a pharmaceutical product throughout its distribution is a complex task. Our serialization specialists have integrated meticulous strategies and industry-leading technology to create precise serialization processes. You can entrust your serialization to Ropack with confidence. If you or your third-party packaging partner is not serialization-ready by November 2017, our international serialization hub is an effective solution.

RPS services solid oral-dosage projects in the pharmaceutical and nutraceutical industries operating in Canada, the United States, and Western Europe.

ROPACK
PHARMA SOLUTIONS
for solid oral dosage

ROPACK®

40 YEARS 1976-2016

PHARMA SOLUTIONS
for solid oral dosage

IN NOVEMBER 2017, SERIALIZATION WILL BE COMPULSORY IN THE US.

WE'LL BE READY.

Outsourcing your serialization requirements to an experienced contract packager with serialization capabilities reduces time and the internal cost of implementing a track-and-trace counterfeit protection program.

When you outsource your serialization to Ropack Pharma Solutions, you can be assured of a serialized supply chain that is proficient, verified and ready to safeguard your drug – and the patients who depend on it.

Certified cGMP Current Good Manufacturing Practice · FDA · Health Canada

Your Trusted Serialization Partner

ropack.com

Paul Dupont, *VP, Marketing and Business Development*
paul.dupont@ropack.com • (513) 846.0921

Rottendorf Pharma

Rottendorf Pharma

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www.rottendorfus.com

NUMBER OF EMPLOYEES
800+

DATE FOUNDED
1928

CORPORATE CAPABILITIES

Company Description
Rottendorf Pharma, a global Top 20 contract development and manufacturing organization (CDMO), has been formulating, manufacturing, and packaging solid oral dosage forms for pharmaceutical clients worldwide for more than 85 years. Its commitment to Total Process Ownership reduces clients' management oversight requirements and costs, while improving the supply chain and product quality. Clients choose Rottendorf for its broad-ranging expertise, global regulatory capabilities, commitment to quality, state-of-the art equipment and facilities, and exceptional customer service.

Technical Services
Analytical development services: development, validation, and transfer of analytical methods; release analytics, ICH stability studies, and analytical support throughout the product manufacturing process.

Formulation development services: optimization, upscaling, regulatory affairs support, and development of granulates, blends, tablets, capsules, film and sugar coats, pellets, and hot-melt extrusion and granulates; also manufacturer of clinical-trial batches for all clinical phases.

Contract manufacturing services: Available for all solid dose forms, including high potency products. Product transfer, validation, qualification, procurement of APIs and excipients.

Packaging services: full range—blister packs, bottles, granulate filling, and Alu-wrap©; supply-chain services for procurement of packaging materials and distribution.

Facilities
Rottendorf has state-of-the-art development, manufacturing, and packaging facilities in Ennigerloh, Germany. The Rottendorf Development Center provides best-in-class technical equipment in line with GMP and FDA standards. It produces batches from 2kg to 150kg, while its manufacturing facilities produce batches up to 750kg.

Major Products/Services
As a top 20 CDMO providing analytical development, formulation development, contract manufacturing, and packaging services to the global pharmaceutical market, Rottendorf Pharmaceuticals relies on a Total Process Ownership philosophy to serve our clients. This means we assume a much higher degree of ownership over the processes we use to bring your pharmaceuticals to market than a typical CDMO. At Rottendorf, you are not simply renting equipment or out-tasking. You are outsourcing critical components of your business to a trusted partner. We bring more than 85 years of experience, serving 200 clients and producing more than 600 products, to each project.

Markets Served
Rottendorf Pharma, serves the global pharmaceutical market—big, small, and virtual—with contract development, manufacturing, and packing services for solid oral dosage forms. All facilities are GMP compliant and inspected by regulatory agencies worldwide, including the FDA, EMA, ANVISA, and others. Rottendorf does not manufacture its own brands, and therefore is never in competition with its clients.

Advancing Development & Manufacturing

Pharmaceutical Technology®

PharmTech.com

We're more than just a magazine...

Print & Digital Magazine

Pharmaceutical Technology provides readers with authoritative peer-reviewed research and expert analyses in the areas of process development, manufacturing trends, formulation, analytical technology, regulatory compliance, packaging and outsourcing, API synthesis, quality assurance, and industry best practices.

ePharmTechnology (ePT)

Weekly | The latest business, scientific, and regulatory news, plus feature articles, delivered to your inbox every Thursday.

PharmTech First Look

Monthly | Preview the latest issue of *Pharmaceutical Technology* with quick links to online content, expanded coverage, and the digital edition of the magazine.

Sourcing and Management

Monthly | Reports, analysis, and updates on innovations, regulations, and technology advancements to guide bio/pharmaceutical experts in navigating the contract services and supplier marketplace.

Equipment & Processing Report (ePR)

Monthly | Focus on pharmaceutical manufacturing processes and technology, providing analysis of manufacturing news, regulatory issues, and current trends. Each issue features a showcase of processing equipment.

PharmTech Whitepaper Alert

Monthly | Receive free technical whitepapers and application notes submitted by leading pharmaceutical manufacturing product and solution providers.

PharmTech.com

With an average of over 58,000 monthly visitors, *PharmTech.com* is your comprehensive information source for all professionals in the global pharmaceutical manufacturing drug development community, providing professionals with dynamic and reliable cutting-edge peer-reviewed content and features.

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www.sgs.com/lifescience

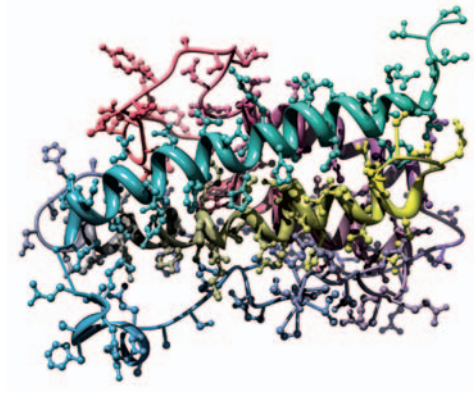
NUMBER OF EMPLOYEES
Life Science Services worldwide: 1600
SGS Group: 85,000

DATE FOUNDED
1878

CORPORATE CAPABILITIES

SGS Life Sciences

Company Description
SGS is a leading life science contract service organization providing clinical research services, analytical development, biologics characterization, utilities qualification, biosafety, and quality control testing. SGS provides Phase I-IV clinical trial management and services encompassing PK/PD simulation and modeling,



data management, pharmacovigilance and regulatory consultancy. SGS also offers contract laboratory services (detailed below) that include analytical chemistry, microbiology, stability studies, method development, and protein analysis. SGS is the world's leading inspection, verification, testing, and certification company.

Technical Services
- Quality control testing of raw materials, APIs, and finished products
- Monograph testing (*USP*, *EP*, *BP*, and *JP*)
- Analytical method development and validation
- Microbiological testing
- Container testing (extractables and leachables)
- Stability testing according to ICH guidelines or customer specifications
- Utilities qualification (air, gas, water & surface)
- Preformulation and formulation development
- Medical device testing
- Protein/peptide analysis and quantification
- Glycosylation analysis
- Biologics safety testing (endotoxin, virus and mycoplasma)
- Cell-line characterization
- Host-cell impurity testing (residual DNA)
- Virus testing (cell bank and virus seeds characterization)
- Antibody product analysis
- Bioanalysis (mass spectrometry, immuno- and cell-based assays)

Facilities
With truly global coverage and a strong local footprint in North America, SGS has four laboratories in the U.S. (Chicago, Los Angeles, New Jersey, and Philadelphia), three laboratories in Canada (Mississauga, Montreal, and Markham), and a clinical trial management office in Germantown, Maryland. SGS's laboratories operate according to high quality standards (cGMP, GLP, ISO 17025) and have been inspected by the US FDA or local regulatory authorities.

Markets Served
SGS serves various lifescience companies including pharmaceutical, biopharmaceutical, biotechnology, and medical device manufacturers. SGS operates a global, wholly-owned network of 21 life science laboratories with facilities in the US, UK, Canada, Belgium, France, Germany, Italy, Switzerland, China, India, and Singapore. The Top 20 pharmaceutical companies trust SGS as a partner for their quality control testing needs.

SGS

GLOBAL NETWORK, LOCAL SOLUTIONS FOR CONTRACT ANALYTICAL SERVICES

SGS is a leading, life science, contract service organization providing pharmaceutical development, biologics characterization, biosafety testing, bioanalysis, and quality control product release, as well as Phase I-IV clinical research services. Whether your organization is large and global or small and regional, rely on SGS as your partner for outsourced testing. Operating a harmonized network of 21 wholly-owned laboratories in 11 countries across Europe, North America, and Asia, SGS offers lean quality standards, reliability and regulatory / technical expertise.

WWW.SGS.COM/LIFESCIENCE
pharmaqc@sgs.com

JOIN OUR SCIENTIFIC COMMUNITY
sgs.com/LinkedIn-Life

SGS IS THE WORLD'S LEADING INSPECTION, VERIFICATION, TESTING AND CERTIFICATION COMPANY

WHEN YOU NEED TO BE SURE

SGS

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WEBSITE
steerlife.com

STEER*Life*

Corporate Description

STEER*Life*, a part of STEER Group, is a unique synergy between engineering sciences and pharmaceutical expertise to create technologies that effectively replace conventional batch processing with true continuous manufacturing and help develop unique drug-delivery platforms for lifecycle management, line extension, or pediatric extension of existing products as well as commercializing new products. The company is committed to **changing the way medicines are made and taken.**

Technologies and Product Applications

STEER*Life's* novel proprietary fractional lobe co-rotating twin screw processor overcomes difficulties with current continuous systems, helping the industry transition to true continuous processing in a consistent and streamlined manner. It keeps the input, process material, and output in continuous flow, while every cross-section of the vessel remains fully wiped clean, with particles moving as a highly stratified process stream. Energy transfer is made effective using thermal or mechanical means at wide ranging magnitudes with minimal shear or pressure peaks which helps in handling sensitive input materials. The multifold increase in output capacity and built-in process control has wide-ranging applications such as bioavailability/solubility enhancement, containment, drug abuse deterrence, effervescence, extended release, and taste masking.

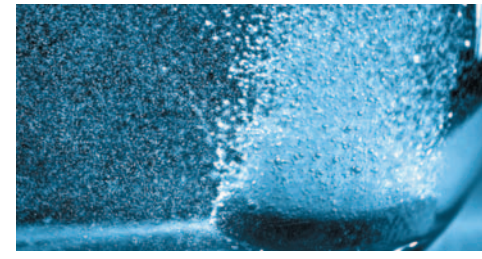
Our novel processing platforms include:

- Novel hot-melt extrusion (B2C-E): to replace hot melt extrusion (HME).
- Hot-melt fragmentation (B2C-F): to replace spray drying or spray congealing.
- Activated granulation (B2C-G): to replace conventional wet, dry, and melt granulation.

PROPRIETARY EFFERVESCENT (EVT) TECHNOLOGY

STEER*Life's* proprietary effervescent (EVT) platform is a continuous production process with the capability to ensure consistently high quality with reduced batch-to-batch variability within a minimum foot print. Key advantages include:

- Significantly enhanced product attributes (higher fizz, >90% gas retention)
- Faster disintegration time (<60 seconds)



- Improved taste of the resulting solutions/dispersions.
- No solvents
- Significantly lower processing costs

Ideal for preparing effervescent tablets/granules for oral solutions/suspensions, rapidly disintegrating tablets for oral solutions/suspensions and orally dissolving/disintegrating tablets.

Services

STEER*Life* provides end-to-end solutions from lab to commercial scale:

- **B2C technology solutions** for processing of large volume API/formulations, co-processed API, and containment.
- **Licensing opportunities** for new brands, lifecycle management, line extension, and pediatric dosage forms
- **Differentiated products** including directly compressible API and OTC, nutraceutical, food, and beverage products.

Collaborations

STEER*Life* is partnering with academic institutions of repute to establish technical centers.

- A joint collaboration with University of Mississippi (USA) a four-year research program, using **STEER***Life's* proprietary continuous processing technology for the development of advanced pharmaceutical applications and processing of semi solids.
- A joint collaboration with Manipal University (India) to establish a Centre of Excellence to further research on continuous processing and develop solutions in highly diversified areas of life sciences.

STEER*Life*

STEER*Life*

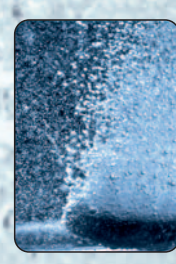
CHANGING THE WAY WE MAKE AND TAKE MEDICINES

Transform your business with our unique proprietary True Continuous Effervescent (EVT) Platform that delivers enhanced Convenience, Compliance, Efficacy & Manufacturing Efficiency.

Customized solutions for lifecycle management, line extension or pediatric extension of existing products as well as commercializing new products.

At **STEER***Life*, we combine engineering and pharmaceutical sciences to create advanced technologies and platforms that are changing the way we make and take medicines. Our proprietary effervescent (EVT) platform, for instance, is a continuous production process with the capability to ensure consistently high quality with reduced batch-to-batch variability, within a minimum footprint and with lower energy requirements. It ensures higher yields and requires considerably lower manpower compared to conventional manufacturing.

Unique advantages of STEER*Life's* Effervescent Platform



Significantly enhanced attributes (higher fizz, > 90% gas retention)

Faster disintegration time (<60 seconds)

Improved taste of the solutions / dispersions, No solvents used

Ideal for effervescent tablets / granules for oral solutions / suspensions, rapidly disintegrating tablets for oral solutions / suspensions and orally dissolving / disintegrating tablets

ALSO AVAILABLE: Bioavailability / Solubility Enhancement, Containment, Drug Abuse Deterrence, Extended Release and Taste Masking solutions

DIFFERENTIATED PRODUCTS
- Proprietary Effervescent Technology
- Directly Compressible API
- Beyond Therapeutics (Over-the-counter, Nutraceuticals, Beverages)

LIFECYCLE MANAGEMENT
- New Brands
- Lifecycle Management
- Line Extension
- Pediatric Dosage Forms

B2C TECHNOLOGY SOLUTIONS
- Revolutionary Batch to Continuous Process
- Large Volume Formulations / API
- Co-Processed API
- Containment

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WEBSITE
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DATE FOUNDED
2007

Velesco Pharma

Corporate Description

Velesco applies nimblocity to your early stage drug development projects, with our proven formulation of expertise, flexibility, dedication, and velocity to clinic.

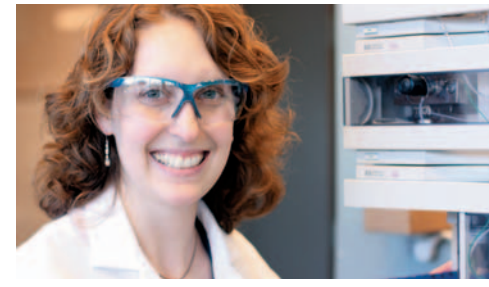
Velesco is a CMC contract research organization, founded and staffed by pharmaceutical scientists from Pfizer's former Michigan R&D campus. Our team has experience with more than 200 drug development programs.

Our nimble processes and focused expertise enable us to overcome even the most challenging obstacles. Our team is responsive, accommodating, and eager to help you reach the full potential of your compound, quickly and efficiently.

As experts in pharmaceutical analytical chemistry, drug formulation development, and cGMP clinical supply manufacture, Velesco scientists have a proven track record of moving compounds through the critical early drug development process with *nimblocity* and unrivaled success.

Technical Services

Analytical Method Development/Validation
- Stability-indicating methods
- Drug substance and drug product
- Complex dosage forms
- Potency/Assay/Impurities
- Forced degradation
- Content Uniformity
- Dissolution
- Cytotoxic and high potency
- Routine testing (HPLC, UV/VIS, viscosity, etc)
- Method troubleshooting
- Method optimization



- Tech transfer
- Experienced with lipids, carbohydrates, and peptides

cGMP Clinical Supplies
- Topical products
- Hand filled soft gel capsules
- Powder in capsule/bottle
- Oral liquids
- Simple blends
- Over-encapsulation
- Cytotoxic and high potency

Formulations
- Clinical and non-clinical
- Topical products
- Ophthalmic
- Hard and soft gel capsules
- Solubility screening
- Oral liquids
- Cyclodextrin based
- Injectables

Consulting Support
- Formulation development
- Project management
- Clinical supply chain management
- Vendor selection and oversight
- Regulatory assistance
- Due diligence

Facilities

Velesco Pharma's headquarters and state-of-the-art research facility is located in Plymouth, MI. Velesco's GMP manufacturing facility is located in Kalamazoo, MI.

Vetter Pharma International

Company Description
Vetter is a leading contract development and manufacturing organization (CDMO) that specializes in the aseptic filling of syringes, cartridges, and vials. The company has extensive experience with biologics and other complex compounds, including monoclonal antibodies, peptides, interferons, and vaccines. 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. The company offers state-of-the-art technology and innovative processes to promote product quality and maximize API yield.

Technical Services
- Formulation support
- Process development
- Clinical trial manufacturing
- Fill and finish
- Analytical service
- Regulatory support
- Customized packaging development
- Proven platform technologies
- Packaging services
- Serialization services
- Logistic services

Major Products/Services
Vetter Development Service
At Vetter Development Service, we partner with our clients from preclinical development through Phase III. Because we plan for commercial production from a product's earliest stages, we develop processes that mirror those at our commercial production facilities. That enables seamless product transfer at Phase III to Vetter Commercial Manufacturing for scale-up and large-scale production.

Vetter Commercial Manufacturing
Vetter Commercial Manufacturing provides Phase III manufacturing through global market supply. To strengthen security of supply, we take active steps both downstream and upstream to maintain the integrity of the supply chain, including regular quality reviews of all suppliers and cross-linked IT systems to monitor manufacturing processes.

Vetter Packaging Solutions
Vetter Packaging Solutions helps clients match their product with the appropriate drug-delivery system (primary packaging); secondary packaging, such as cartoning or blister packing; and packaging services, such as pen-system assembly.

Markets Served
Vetter is collaborating with pharmaceutical and biotech clients worldwide.

VETTER

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NUMBER OF EMPLOYEES
Approx. 3900

DATE FOUNDED
1950

CORPORATE CAPABILITIES

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america.com

DATE FOUNDED
1999

CORPORATE CAPABILITIES

ACG North America LLC

Corporate Description

ACG North America (NA), the US subsidiary of ACG Worldwide has a strong commitment to serving the pharmaceutical and dietary supplement market of the United States, Canada, and Mexico. For more than a decade, ACG NA has brought ACG Worldwide's innovative products and services to the North American market, providing excellent customer service and technical assistance from our headquarters in New Jersey.

ACG Worldwide is the second largest capsule manufacturer in the world and a global pioneer in innovative processing, manufacturing, and packaging solutions for the pharmaceutical and nutraceutical industry. With more than five decades of technological leadership, ACG Worldwide serves customers in more than 100 countries.

Products and Services

ACG NA offers a wide range of hard capsules that meet the requirements of the pharmaceutical and nutraceutical industries which are compliant to global regulations. Complementing the range of capsules, it offers a series of capsule-filling machines. Starting with R&D-scale processing units that help pharma companies develop suitable, scalable, and efficient processes, ACG offers support for improved productivity for small, medium, and large-scale production at the manufacturing level.

ACG NA also offers an array of high barrier packaging films and foils that protect products from damaging elements whilst serving as strong brand differentiators and effective anti-counterfeit measures. The range of proven and efficient blister packing and cartoning machines from ACG NA meets myriad packaging requirements across industries. These machines are integrated with vision inspection and serialization systems to ensure quality and traceability to meet regulatory requirements.

Areas of Excellence

ACG NA has a team of technical experts, located in New Jersey, that offer support to its customers at every step of machine installation, conduct comprehensive training programs for production teams, and help customers improve productivity and machine performance.

ACG North America

ACG North America

www.acg-northamerica.com

THINK PACKAGING
THINK ACG

FILMS AND FOILS

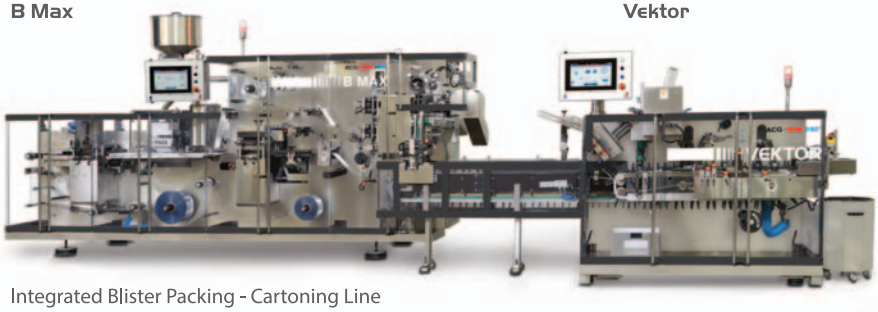
- High barrier pharmaceutical-grade, camera-inspected packaging films for pharmaceutical, personal care and food packaging industries
- Compliant to global regulations

BLISTER PACKING AND CARTONING EQUIPMENT

- Wide range of blister packing and cartoning solutions designed to meet customer specifications

B Max

Vektor



Integrated Blister Packing - Cartoning Line

Matrix

Stretch Banding Machine

ACG North America LLC

229, Durham Ave., South Plainfield, NJ 07080, USA. Tel: +1.908.757.3425; Fax: +1.908.757.3287; Toll Free: +1.877.618.3344

Email: sales.pt@acg-world.com

Comprehensive Range of Pharmaceutical Machinery & Consumables

Fluid Bed Equipment | Empty Hard Capsules | Capsule-filling Machines | Softgel Encapsulation Lines
Tableting Machines | Tablet Tooling | Tablet Coaters | Barrier Packaging Films | Blister Packing Machines
Cartoning Machines | End-of-line Packaging Solutions | Vision Inspection Systems | Track & Trace Solutions

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WEBSITE
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NUMBER OF EMPLOYEES
85

DATE FOUNDED
2006

PACKAGING Equipment and Supplies

Corporate Description

CoreRx®, a contract development manufacturing organization (CDMO) with a focus on clinical-phase drug product development, offers state-of the-art facilities to support your supply chain needs throughout the entire clinical trial process. Our integrated offerings provide comprehensive services for the development, manufacturing, and testing of solid, liquid offerings, and semi-solid dosage forms.

At CoreRx, the biggest asset is our people. CoreRx's experienced scientists and pharmaceutical professionals lend their expertise to produce safe, effective, and innovative drug products; on time, and on budget. Our senior scientists are personally involved in every aspect of your project. Not only does CoreRx have the expertise to handle the most complex formulations, we pride ourselves on unsurpassed communication, innovative problem solving, and overall dedication to meet your timelines and project expectations.

SO SMALL IT'S HUGE

CoreRx Pharma is the only CDMO in the US to offer leon-nanodrugs' proprietary nanotechnology platform – the MicroJet Reactor (MJR®).

It is estimated over 60% of pharmaceutical API's are poorly soluble in water.

leon's MJR technology offers reformulation options that can increase solubility, bioavailability, reduce inter patient variability and improve onset of action. Utilizing nanotechnology reduces costs and allows for scale up on demand.

core Rx®

DEVELOPMENT AT OUR CORE

www.corerxpharma.com I 14205 Myerlake Drive Clearwater, FL 33760 I 727.259.6950

[SOLID] [SEMI-SOLID] [LIQUID]

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973.808.8421

E-MAIL
sales@mgamerica.com

WEBSITE
www.mgamerica.com

NUMBER OF EMPLOYEES
20

DATE FOUNDED
1988

CORPORATE CAPABILITIES

MG America

Corporate Description
The US subsidiary of MG2, Bologna, Italy, MG America is a recognized leader in the supply of precision-crafted processing and packaging machinery to the pharmaceutical, nutritional, cosmetic food, and general packaging industries in the US, Canada, and Puerto Rico. Its equipment, which is designed for flexibility, compact operation, ease of use, and maximum reliability, includes capsule fillers, primary and secondary packaging equipment, material handling and aseptic machinery, and line integration solutions. Headquartered in Fairfield, NJ, its staff provides sales, field service, spare parts, machine trials, and a clean room for testing customer products on MG2 capsule fillers.

Entrance into Tablet Press Market through Strategic Partnership with *kg-pharma*
MG America entered the North American tablet press market in 2016 by becoming a distributor for a line of tablet presses from Germany-based machinery manufacturer *kg-pharma*. The three-machine series is suitable for both R&D and pilot-scale production, with the most high-production press, the Futorque X-1, capable of producing up to 108,000 tablets/hr. The machines comprising *kg-pharma's* line of tablet presses are the RoTab T 2.0, the RoTab Bilayer, and the Futorque X-1. Each features automatic weight regulation by filling depth, and comes with a fully instrumented R&D package including specialized software. All offer benefits from pre-production phases and R&D stages through production itself, and are ideally suited for scale-up purposes and production optimization, offering substantial potential savings through this versatility.

Next-Generation: PLANETA 200 Capsule Filler
The PLANETA 200 Capsule Filler is the latest evolution in a line of well-established continuous motion machines. It produces up to 200,000 capsules/hr, but its primary advantage is its premium flexibility: its modular design results in a highly configurable platform suitable for a wide array of production requirements, including an ability to fit several dosing units simultaneously, enabling one capsule to be filled with differing products. Dosing units ascribe to a "no capsule, no dosage" concept, ensuring superior machine cleaning as well as reduction of both product waste and its exposure to the greater processing environment.

Premium Side-Loading, Continuous Motion Cartoner
MG America offers the Cariba C300, a side-loading, continuous motion cartoner suitable for packaging pharmaceutical, cosmetic, and personal care products. Featuring balcony-style construction for easy cleaning and fast maintenance operations, the C300 can produce up to 300 cartons/min, with all mechanical movements driven by belts and separated from the carton operation area. Product insertion is precise even at high speeds, thanks to an innovative transportation "puck" system.

MG AMERICA
A partnership for success

From processing to packaging, we'll show you the way

Products with unique needs require carefully-engineered solutions, not a limited menu of options. That's why MG America brings unrivaled expertise in processing and packaging machinery to help custom-craft a solution that is perfect for your individual product needs.

Innovation? We've got that too, from our groundbreaking MultiNETT™ Weight Control System to our state-of-the-art packaging lines, we're advancing into exciting new areas to meet your growing needs.

Put your vision in our hands...and start seeing things in a whole new way.

MG AMERICA
A partnership for success

Fairfield, New Jersey
973-808-8185 • 866-962-3090
mgamerica.com

CAPSULE FILLING
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ASEPTIC EQUIPMENT
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SECONDARY PACKAGING
LINE INTEGRATION
CHECKWEIGHING
TABLET & CAPSULE INSPECTION

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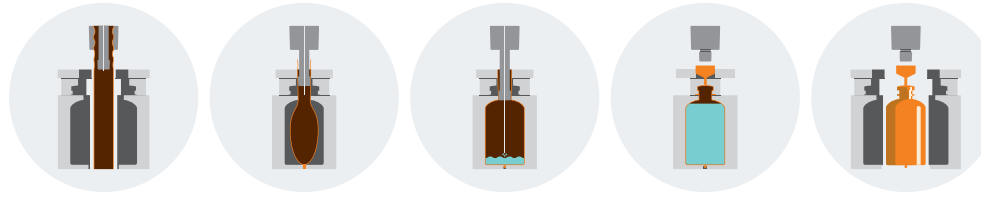
Rommelag ENGINEERING

Bottelpack BFS Process



Company Description

Rommelag ENGINEERING is the inventor of blow-fill-seal technology (BFS) and the global market leader in the aseptic filling of liquids and semisolids with its bottelpack machines. Our machines are primarily used in the pharmaceutical, chemical, and food industries. Together with our customers, we develop innovative packaging solutions tailored precisely to the specific packaging task in hand.

Markets Served

The blow-fill-seal process is an excellent choice in many fields when flexible, rapid, and cost-effective manufacturing solutions are required:

- Pharmaceutical industry (injection solutions, opthalmic products, etc.)
- Chemical industry (cleaning products, lubricating oils, antifreeze, etc.)
- Veterinary medicine (medication, etc.)
- Food industry (functional food, etc.)
- Automotive (oil, grease, lubricant, etc.)
- Agriculture industry (pheromones, etc.)
- Cosmetics industry (creams, gels, lotions, etc.)

Major Products/Services

Rommelag's bottelpack machines are capable of manufacturing up to 34,000 containers an hour in a wide variety of forms and plastic blends, with filling volumes ranging from 0.04 to 10,000 mL, aseptically, and taking all the applicable pharmaceutical regulations into account. The advantages of contamination-free filling in shatterproof plastic containers are complemented by an almost unlimited array of application-specific packaging designs, low production costs, high output rates, and a minimal machinery footprint.

Facilities

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bottelpack bp430 aseptic filling system

ROMMELAG ENGINEERING

TASI TEST– SEPHA, BONFIGLIOLI & ALPS

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CORPORATE CAPABILITIES

Company Description

TASI TEST represents a new force in the packaging leak detection market by combining three top industry players, ALPS, Bonfiglioli, and Sepha, to provide an unrivalled range of solutions across diverse global markets.

All three companies are owned by TASI Group, a group of global businesses that share a common focus on test, inspection, and measurement. With a focus on packaging test and inspection across several vertical markets, TASI TEST has the integrity testing solution for all of your primary packaging requirements.

Individually, each of these companies has developed a strong brand reputation in its field, based on high-quality products and exceptional customer service. By combining development, manufacturing, and sales operations of the three, TASI TEST offers clients increased confidence in the high quality, value-added testing solutions that they have come to expect from each individual brand, with increased technical expertise and global customer service support.

Markets Served

TASI Test's brands boast over 100 years combined experience across the diverse markets of pharmaceuticals, food & beverage, metal can & aerosol, and plastics. As such, they have developed an in-depth knowledge of clients' packaging quality control requirements and have used this expertise to develop a wide range of innovative products that offer real value-added improvements to these processes.

Major Products/Services

TASI Test's SEPHA Standard Solutions is a range of complete products, most of which are used in the creating testing and emptying of pharmaceutical solid-dose packaging. While there is always scope for customization, these are comprehensive designs that have been installed and validated in numerous organizations throughout the world, including many of the top global pharmaceutical manufacturers.

Sepha VisionScan is a tool-less, non-destructive leak detection device that offers a deterministic alternative to the traditional blue dye test in line with changing industry guidelines. The Sepha range also includes product recovery devices for blister packs including child resistant packs and small-scale blister packaging equipment for pharmaceutical and medical products.

TASI Test's BONFIG Pharmaceutical range is comprised of a variety of leak testing methods as well as visual inspection and headspace gas analysis technologies for a range of packaging types. For more information on improving your quality control processes, visit www.tasitest.com.

Facilities

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Corporate Capabilities 2016

INDEX OF COMPANIES

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