Corporate Capabilities 2019
Pharmaceutical Technology

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MISSION
Protect the Joint Force from weapons of mass destruction by generating affordable capabilities.

VISION
A resilient Joint Force enabled to fight and win unencumbered by a chemical, biological, radiological, or nuclear environment; championed by innovative, agile, results-oriented acquisition professionals.

Medical CBRN Defense Consortium
Other Transaction Agreement (MCDC OTA)
FY-19-21 Forecast
Pharmaceutical Technology's Corporate Capabilities print issue and our online Marketplace, PharmTech.com/marketplace, offer our audience information on key suppliers for ingredients, cleanroom, laboratory, manufacturing, outsourcing, and packaging equipment and services.

This print issue provides detailed information on available state-of-the-art technologies and services from some of the industry's leading suppliers, offering readers a quick hands-on tool available within reach. Additional equipment and services options may be found on our online Marketplace, which provides a searchable listing of a wide range of companies that provide manufacturing and laboratory equipment, ingredients, facility design, packaging supplies, and outsourcing services.

And as always, PharmTech.com offers in-depth technical articles, opinion papers, webcasts, news, and more on topics ranging from manufacturing best practices, formulation topics, peer-review scientific papers, API synthesis, regulatory requirements, and much more!

It is our hope that with these print and online tools, you will have a successful 2020!
Here's Why the Right Size Matters

Every project has a specific set of needs. When choosing a CDMO, bigger often isn’t better. You need the right mix of size and experience to complete your project on time, on budget, and within specifications.

At TEDOR, we help customers meet their development and commercial launch timelines, achieve regulatory approvals, and solve complex formulation challenges. We offer a full range of oral solid dose services, including formulation development, analytical methods, and Phase I-III clinical trial material manufacturing through to full-scale commercial manufacturing.

No matter what stage your product is in, our experienced development and manufacturing teams can help ensure a smooth and successful outcome.

TEDOR
THE RIGHT SIZE CDMO

FLEXITAB Tablets Maintain Their Drug Release Profile When Broken

FLEXITAB tablets can be broken precisely and easily by the patient while ensuring precise dosing in each segment. Conventional ER tablets may dose dump their contents if broken, but FLEXITAB tablets are reliable and simple for both patients and physicians.
Protected.

20
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See how Emergent protects lives.

ebsi.com/CDMO
800-441-4225 | CDMO@ebsi.com

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Contec, Inc.

Company Description
Contec is a leading manufacturer of contamination control products for critical cleaning in manufacturing environments worldwide. With more than 28 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.
So much more than a clean surface

Research & Development
Technical Specialists
Quality Built In
Global Presence
Complete Range
Industry Experts
Validation
Innovation
Experienced
Collaborative

It's not just about the products. It's more than just a clean surface. Contec prides itself on its longstanding technical expertise, innovation and commitment to quality. Continued improvements in lean manufacturing, safety initiatives, vertical global integration as well as Research and Development, drive our critical environments product range forward.

For more information, contact Contec at wipers@contecinc.com or by calling 1-864-503-8333.
Perfex Corporation

Company Description
Perfex is a leading manufacturer of professional-grade cleaning tools for contamination control in critical manufacturing environments. With over 90 years of experience, we understand the critical cleaning requirements associated with cleanroom manufacturing from top to bottom. Our customer service and technical support team includes highly qualified industry professionals to aid customers in reaching their specific sanitation goals.

Markets
Perfex’s cleanroom mopping systems are used in diverse industries across the globe such as pharmaceutical, semiconductor, bioengineering, medical device, and life sciences. Perfex Corporation maintains a robust distribution network throughout North America, South America, Europe, and Asia.

Products/Services
Perfex’s exclusive TruCLEAN product line for cleanrooms and controlled environments includes:
- Multi-bucket mopping systems
- Compact disinfection systems
- Stainless steel mopping components
- Microfiber and antimicrobial mops
- Sponge mops, blocks, and wipes
- 12’ and 18’ adjustable mop handles

Mopping Systems
TruCLEAN Mopping Systems effectively capture and isolate contaminants, ensuring the delivery of pure cleaning agents. No more reapplying dirty water or weakened solutions. Durable stainless-steel components and temperature-resistant polypropylene buckets included, compatible with gamma, ethylene oxide, and autoclave sterilization. Multiple configurations and colorways available, suited for large and small area cleanrooms of any grade.

Sponge and Fiber Mops
TruCLEAN Mops are available in a variety of materials to accommodate any cleanroom surrounding. Facilitate compliance with the latest infection control protocols and prevent dangerous cross-contamination. Our TruCLEAN Sponge Mop is ideal for applying cleaning solution to floors, walls, and ceilings, while our fiber mops offer functionality, high absorbency, and cost-effective advantages.

Facilities
Perfex Corporation has an established manufacturing and distribution facility located in the charming upstate village of Poland, New York. With our head office and manufacturing in one streamlined location we effectively reduce production costs and cut lead-time in half, profiting our customers. Perfex employs a team of dedicated sales representatives for on-site evaluations, product support, and technical advice to customers worldwide.
INNOVATIVE CLEANING TOOLS for CONTROLLED ENVIRONMENTS

TruCLEAN Mop Frame
Easily maneuvered over floors, walls, ceilings, and baseboards.

TruCLEAN Wringer
Unique wringing action significantly improves release of contaminants.

36 Liter Bucket
Temperature-resistant polypropylene with embossed graduations.

TruCLEAN Adjustable Handle
Lightweight handle with super-smooth finish to prevent microbial growth.

Capture and isolate contaminants effortlessly!
High-grade stainless steel components and temperature-resistant polypropylene buckets, all in a compact design for easy use in confined areas.

Compatible with gamma, ethylene oxide, and autoclave sterilization.

perfexonline.com/truclean-products

CUSTOMER SERVICE:
1-800-848-8483
Veltek Associates, Inc.

Company 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 challenges of contamination control within aseptic manufacturing and controlled environments. With over 135 patents, we are committed to continual innovation and improvement in our products to satisfy current and future regulatory requirements.

Facilities
VAI is headquartered in Malvern, PA USA with satellite sales offices located worldwide. VAI, in addition, is able to serve the pharmaceutical and biotechnology industries in an even greater capacity through our 120 distribution partners.

Products/Services
Chemicals—VAI offers a complete line of sterile and non-sterile chemicals. With EPA-registered disinfectants and sporicides and cleaners including buffers, water, residue removers, and lubricants, operations are able to maintain critical environments while staying compliant.

Dry and Saturated Wipes—VAI’s wipers offer excellent particulate performance and are for use in all cleanroom settings. A variety of VAI’s sterile chemicals are available in saturated wipers including sterile sodium hypochlorite and hydrogen peroxide wipes.

Process Cleaners—VAI offers a complete line of clean-in-place detergents for manual, soak, or spray applications. Our process cleaners remove a wide array of organic or inorganic soils.

Cleanroom Documentation—VAI’s line of cleanroom documentation offers a synthetic writing substrate with extremely low particulation, customizable documentation, and a HEPA filtered printer to print directly in controlled environments.

RFID Tracking—VAI’s Core2Scan system is an identification and tracking system that pairs RFID asset and procedural identification devices, readers, and software tracking technology with a facility’s equipment, products, and/or procedures.

Garments—VAI has launched a redesigned line of sterile disposable garments that include low particulation, high breathability, and comfort while maintaining an athletic design and personal protection.

Cart Transfer Systems—VAI’s Cart2Core® simplifies correct aseptic cart transference by allowing the cart top to detach from the base. With one lift of the handle and a slide, any cart top is transferred from one cart base to another, leaving the potential contamination behind.

Environmental Monitoring—VAI’s viable monitoring equipment has been an industry standard for over 30 years by helping operations monitor, capture, and evaluate the ingress of viable contamination. In addition to viable monitoring, VAI offers a complete line of particle counters.

Cleaning Equipment—VAI offers a completely sterilizable, all in one, spray, mop and fog cleaning system. The Core2Clean is an innovative way to ensure cleaning and disinfection within the cleanroom is being done correctly and efficiently.

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
SMA MicroParticle ICS
Non-Viable Particle Counters

THE NEXT LEVEL OF PARTICLE COUNTING

UNMATCHED ENVIRONMENTAL CONTROL

STERILE.COM
For more information, visit our website at sterile.com/particlecounters
Pharma Marketplace can help.

Pharma Marketplace gives you all the information you need to choose the right supplier. Our directory quickly connects you with 2,000 bio/pharmaceutical companies around the world.

pharmtech.com/marketplace
INGREDIENTS and Materials
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WEBSITE
www.ashland.com

NUMBER OF EMPLOYEES
6000

DATE FOUNDED
1924

Ashland Global Holdings Inc. (NYSE: ASH) is a premier global specialty chemicals company serving customers in a wide range of consumer and industrial markets, including adhesives, architectural coatings, automotive, construction, energy, food and beverage, nutraceuticals, personal care, and pharmaceutical. At Ashland, we are approximately 6000 passionate, tenacious solvers—from renowned scientists and research chemists to talented engineers and plant operators—who thrive on developing practical, innovative, and elegant solutions to complex problems for customers in more than 100 countries.

At Ashland, our solvers enable the efficacy, integrity, and usability of pharmaceutical formulations. Ashland is a manufacturer of pharmaceutical-grade excipients supported by cGMP manufacturing and R&D with expertise in polymer science, formulation development, solid dispersions, modified release, and bioavailability enhancement. Our pharmaceutical team prides itself on advancing drug delivery with sophisticated science-based solutions. We meet formulators’ needs by providing an unparalleled range of excipients and technologies, as well as longstanding polymer expertise and technical support from concept to commercialization for oral solids, liquids, topical, and parenteral dosage forms. Ashland’s solutions include: increasing API solubility, controlled release, disintegrants, film coatings, and tablet binders. Our full line of products combined with our global research and development capabilities can help deliver your drugs when and where they’re needed, resulting in better outcomes for patients and pharmaceutical companies alike.

Key Products
- Klucel™ hydroxypropylcellulose
- Benecel™ methylcellulose and hypromellose
- Plasdone™ povidone and copovidone
- Polyplasdone™ crospovidone
- Aquarius™ film coating systems
- Aquasolve™ hypromellose acetate succinate

Through a global network of technical service laboratories, we provide assistance with formulation development, problem-solving and analytical support. We operate two pharmaceutical centers of excellence in Wilmington, Delaware (USA) and Hyderabad, India, and regional laboratories to support customer needs. Our global manufacturing sites, that operate in accordance with cGMP standards, provide consistently high quality products regardless of origin. As a full-service resource, Ashland can help you bind, coat, dissolve, and deliver solutions that can yield better patient outcomes.

Ashland’s molecular scientists, chemists, formulators, and process engineers can help advance complex oral solid and oral liquid dosage formulations. Our problem-solving team leverages a diverse portfolio to provide comprehensive solutions, so when you’re ready to formulate, we’ve got you covered. We are always solving™.
who advances drug delivery?

we do.

Our solvers can help you apply pharmaceutical polymers that ensure the efficacy, integrity, and usability of your formulations. Our molecular scientists, chemists, formulators and process engineers can help advance complex oral solid dosage formulations. Our problem-solving team leverages a diverse polymer portfolio to enable comprehensive solutions for oral solids and injectable dosage forms.

Meet us at CPhI Worldwide, stand 8G62, and AAAPS PharmSci 360, booth 2336.

ashland.com/pharmaceutical
INGREDIENTS and Materials

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, Injectables, Highly Potent & Oncology, Small Molecules, and Antibiotics–CordenPharma experts translate complex ideas, projects and processes at any stage of development into high-value products.

Technical Services
Peptides, Lipids & Carbohydrates
• Synthetic Peptide API Production
  – Solid / Liquid-phase, Hybrid Synthesis
  – cGMP & non-cGMP
• Synthetic Lipids
• Carbohydrates

Sterile Injectables
• New Development & Commercial Suites for Aseptic Filling with >60,000 units per day (Pre-filled Syringes, Liquid or Lyophilized Vials)
• Packaging, Labeling, & Logistics
• Sterile Emulsion Technology
• Large Pre-Filled Syringes
• Clinical Trial Services

Highly Potent & Oncology
• API Development & Commercial Manufacturing (SafeBridge Category 4, OEL ≤1 ng/m³)
  – High Containment-Cytotoxic & Cytostatic APIs
• Low Volume Clinical Batches to Commercial Manufacturing
  – Highly Potent Small Molecules & Peptides (solid & solution phase)
• Oral Solid Dose
  – Highly Potent Drug Products, from Dev (100g) to Commercial Scale
  – Coated & Uncoated Tablets & Gelatin Capsules
  – Packaging (blisters & bottles)
  – Serialization & 2D Data Matrix Coding
• Injectables
  – Highly Potent Cytotoxic & Cytostatic Products
  – Sterile Liquid & Lyophilization
  – Packaging & Serialization

Small Molecules
• Development & Commercial Manufacturing
  – Intermediates
  – APIs & Excipients
  – Clinical Supply from Phase I–III
• Proprietary & Generic Advanced Intermediates & APIs

Antibiotics
• Non-segregated
  – Sterile Drug Products
• Segregated
  – Cephalosporins & Penicillins
  – Monobactams
• Primary & Secondary Packaging

Facilities
CordenPharma Bergamo–Italy
CordenPharma Boulder–USA
CordenPharma Brussels–Belgium
CordenPharma Caponago–Italy
CordenPharma Chenôve–France
CordenPharma Colorado–USA
CordenPharma Latina–Italy
CordenPharma Plankstadt–Germany
CordenPharma Switzerland–Switzerland
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PEPTIDES, LIPIDS & CARBOHYDRATES

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INJECTABLES

SMALL MOLECULES

ANTIBIOTICS

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Let Pharma Marketplace help.

Pharma Marketplace gives you all the information you need to choose the right supplier. Our directory quickly connects you with 2,000 bio/pharmaceutical companies around the world.

pharmtech.com/marketplace
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, CO2 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.
Want Better Accuracy?

**Eppendorf Xplorer® pipettes and ep Dualfilter T.I.P.S.®—accuracy’s dynamic duo**

The Eppendorf Xplorer pipettes are the perfect choice for all users who need advanced speed, safety and reliability every day. Intuitive operating system makes programming and everyday use simple. When used in combination with our expertly designed ep Dualfilter T.I.P.S., this system produces superior and accurate results for your assays.

> The Xplorer’s motorized piston helps reduce human error and normalizes pipetting variation
> Eppendorf ep Dualfilter T.I.P.S. are HEPA/EPA certified for the ultimate aerosol protection

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How do you choose the right supplier?

Get help with Pharma Marketplace. Pharma Marketplace gives you all the information you need to choose the right supplier. Our directory quickly connects you with 2,000 bio/pharmaceutical companies around the world.

pharmtech.com/marketplace
Elizabeth Companies

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WEBSITE
www.eliz.com

NUMBER OF EMPLOYEES
1200

DATE FOUNDED
1954

Company Description
Since 1954, Elizabeth Companies have become the premier global supplier of compression tooling, rotary tablet presses, spare parts, and services to the tableting industry. Our range of technologies include Elizabeth Carbide Die compression tooling, Elizabeth Scheu & Kniss replacement parts and services, Elizabeth-Hata tablet presses, Eliza-Press series of economical tablet presses, and Elizabeth Europe blister feeding and tooling solutions.

While our worldwide capabilities have grown, 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.

We are 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 multidiscipline organization, Elizabeth provides total tableting solutions to our customer’s problems. You can count on Elizabeth to support your needs before, during, and after your purchase. Experience the difference. The Elizabeth difference.

Products/Services
Our range of powder compression technologies include:

- Elizabeth Scheu and 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
- Technical training on tablet press operation
- Tablet press and turret refurbishment and repairs

Facilities
As a global supplier of powder compression technologies and blister packaging solutions, we have manufacturing centers in America, Europe, and Asia, and a vast network of experienced customer service and sales staff.

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

Elizabeth Companies

Manufacturing Equipment and Supplies

Elizabeth Companies
We understand that your products are trusted by consumers each and every day. Consistent quality of your solid dose products is expected and non-negotiable. Your products depend upon the integrity of your equipment and tooling. For over 65 years, Elizabeth Companies have put a personal guarantee on customer satisfaction and takes pride in delivering innovative solutions. We promise our customers an unequaled level of customer service, product performance, prompt and courteous communication, and trust. Experience the difference, THE ELIZABETH DIFFERENCE.
GEMÜ Valves
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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 1700 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 567 BioStar® Control Valve

Designed to precisely control low flow rates of high purity fluids or gaseous media required in the pharmaceutical, biotech, health care, and food and beverage industries.

- Extremely compact design
- Sizes 1/2" - 3/4"
- Linear or equal % flow characteristics
- Cv range .09 to 4.8 gpm
- Self-draining design for (CIP) and (SIP) systems
- Optional by-pass provides high flow velocities to facilitate cleaning
- FDA and USP Class VI compliance
- 3A Certification available
- Animal Derived Component Free (ADCF)

3800 Camp Creek Parkway SW • Building 2600
Suite 120 • Atlanta, GA 30331
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www.gemu.com
MFG Tray Company

Company Description
Molded Fiber Glass Tray, MFG Tray, is a leading manufacturer of high-strength, glass-reinforced composite containers, trays, boxes, flats, and totes for cannabis, pharmaceutical, and biotech processing industries as well as material handling, electronics assembly, food service, and confectionery industries. The company continually develops customized solutions for specific pharmaceutical challenges and applications. MFG Tray products combine outstanding performance features with long service life to ensure exceptional value.

Technical Services
**Gel Cap Drying Trays**
- Drop ends/sides for quicker drying
- Easy integration with process equipment
- Won’t bend, dent, or deflect under heavy loads
- Interlock stacking increases room efficiency
- Smooth surface is easy to clean

**Vial Trays**
- Autoclave, ETO, lyophilization, and gamma safe material
- Withstands automated handling
- Stackable trays in several depths and widths
- Tapered front lip for easy loading
- Temp range continuous -60° to 250°F; special formulation for 300° to 400°F
- 3 gate choices; polypropylene, polycarbonate, and stainless steel

**Storage Trays**
- Interlock stacking without warping
- Ensures product protection
- Saves valuable work and storage areas
- Smooth surface is resistant to mild acids and alkaline solutions

Facilities
MFG Tray is part of the Molded Fiber Glass Companies family, which is made up of 13 entities focused on different composite solutions, research facilities, and support locations. Molded Fiber Glass Companies has established the largest full-service network of molding facilities in North America.

Major Products/Services
MFG Tray manufactures vial trays, gel cap drying trays, and storage trays for the cannabis, pharmaceutical, and biotech industries. MFG Tray composite pharmaceutical handling products are inherently strong and dimensionally stable and will not bend, dent, or sag under heavy loads. The durability of composites translates into years of dependable performance.

MFG Tray composite material handling products are completely safe for pharmaceutical processing. All materials used in the construction of these products are listed in NSF Standard No. 2 and in the USFDA Code of Federal Regulations, Title 21.

Markets Served
Founded in 1952, MFG Tray’s business grew steadily over the years to the point where we have customers in over 40 countries. MFG Tray has over 250 different models, and we are the world leading manufacturer of fiber glass reinforced composite trays. Our customer base includes contract manufacturing organizations that produce vaccines, nutraceuticals, soft gel capsules, and array of other cannabis, pharmaceutical, and biotech products.
PHARMACEUTICAL TRAYS USED BY THE TOP PHARMA COMPANIES

Pharmaceutical processing & handling solutions that are easily integrated with automated machinery.

VIAL TRAYS
- Tapered front lip for easy loading
- Smooth, non-porous surface is easy to clean
- Vial gates available for various temp ranges

GEL CAP DRYING TRAYS
- Ventilated sides or ends for quicker drying
- Interlock stacking without warping or distortion
- Won’t bend, dent or deflect under heavy loads
- Smooth surface is easily cleaned
- Easy integration with process equipment

DEEP STORAGE TRAYS
- Ideal for storing gel caps prior to packaging
- Stacking design ensures product protection and saves valuable work and storage areas
- Smooth surface is resistant to mild acids and alkaline solutions

STERILIZATION & BIOTECH TRAYS
- Great for handling, storing and shipping small parts
- Slotted and unslotted containers available
- Ideal for Gamma, Autoclave and ETO environments
- Optional lids and dollies available

Reinforced composites bring a new level of performance to pharmaceutical processing and handling. And the leading name in FRP is MFG.
Company Description
The US subsidiary of MG2, Bologna, Italy, MG America is a recognized leader in supplying precision-crafted processing and packaging machinery to the pharmaceutical, nutritional, food, cosmetic, and cannabis industries in the US, Canada, and Puerto Rico. Its equipment includes capsule fillers, tablet presses, primary and secondary packaging equipment, material handling and aseptic machinery, and integrated line solutions. Headquartered in Fairfield, NJ, staff provides sales, service, parts, machine trials, and a cleanroom for testing customer products on MG2 capsule fillers.

MG2 Capsule Fillers
• Powders, pellets, mini-tablets, tablets, liquids, and combo filling
• Continuous and intermittent motion
• Lab scale through production
• Patented Extrudor™ powder filling using one dosing disk for multiple fill volumes
• High containment solutions OEB5

COMAS Filling and Closing Machines
• For vials, bottles, cartridges, and tubes
• Piston pump, peristaltic pump, and mass flow filling modules

Anritsu Capsule and Tablet Checkweighers
• Speeds from 75,000 to 230,000/h
• +/- 0.5mg weighing accuracy

Cariba Cartoners and Stretch Wrappers/Bundlers
• Side-load and top-load cartoners with intermittent and continuous motion
• Balcony style, intermittent motion bundler/stretch wrapper for cartons

MG2 Case Packers
• Side-load and top-load
• Serialization/aggregation-ready

Cos.Mec Material Handling and Granulation Equipment
• Various bins and lifts
• High shear mixers
• Bin, bicone, and V blenders
• Fluid bed granulators and dryers

Farmo Res Thermoformers
• Forming depths up to 40mm
• Ideal for syringes, ampoules, vials, and medical devices and liquid unit dose

MG2 Serialization Modules
• Bottle coding and verification unit handles 300 bottles/min
• Carton coding and verification unit achieves 400 cartons/min

KG Pharma Tablet Presses
• R&D to medium-scale production
• Bi-layer compression

MG America, Inc.
Company Description
The US subsidiary of MG2, Bologna, Italy, MG America is a recognized leader in supplying precision-crafted processing and packaging machinery to the pharmaceutical, nutritional, food, cosmetic, and cannabis industries in the US, Canada, and Puerto Rico. Its equipment includes capsule fillers, tablet presses, primary and secondary packaging equipment, material handling and aseptic machinery, and integrated line solutions. Headquartered in Fairfield, NJ, staff provides sales, service, parts, machine trials, and a cleanroom for testing customer products on MG2 capsule fillers.

MG2 Capsule Fillers
• Powders, pellets, mini-tablets, tablets, liquids, and combo filling
• Continuous and intermittent motion
• Lab scale through production
• Patented Extrudor™ powder filling using one dosing disk for multiple fill volumes
• High containment solutions OEB5

COMAS Filling and Closing Machines
• For vials, bottles, cartridges, and tubes
• Piston pump, peristaltic pump, and mass flow filling modules

Anritsu Capsule and Tablet Checkweighers
• Speeds from 75,000 to 230,000/h
• +/- 0.5mg weighing accuracy

Cariba Cartoners and Stretch Wrappers/Bundlers
• Side-load and top-load cartoners with intermittent and continuous motion
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MG2 Serialization Modules
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• Carton coding and verification unit achieves 400 cartons/min

KG Pharma Tablet Presses
• R&D to medium-scale production
• Bi-layer compression
it’s all about listening

To your challenges, needs, and goals. Paying attention to the finest details to ensure the smartest solutions. Delivering the results that you are seeking, rather than just the equipment we are offering. That’s the definition of partnership.

We’re MG America. And we hear you.
Natoli Engineering Company

Corporate Description
Natoli Engineering Company is the undisputed global leader in tablet compression tooling manufacturing. But we are far more. Founded on the uncompromising principle to manufacture and deliver the highest quality tablet compression products at a fair price with exceptional customer service, Natoli continues to build on 46 years of innovation and industry leadership. Our state-of-the-art manufacturing facilities, award-winning engineering team, and dedicated production staff enable us to offer competitive pricing without compromising our high standards of quality or customer service.

Major Products/Services
Tablet Compression Tooling: Natoli manufactures carbide-tip, multi-tip, single-tip, 3D exotic-shape, rotating heads/tips, and extended head flats punches, plus IMA Comprima tooling, lined dies, tool coatings, and more.

Tablet and Tooling Design: Natoli provides expert design services to ensure tablet quality, maximize production, and enhance product lifecycle. Natoli also offers TabletCAD, a FREE web-based tablet design program, which provides a simple way to create tablets to exact specifications, with a direct link to the manufacturing process.

Tablet Presses: Natoli offers a diverse line of best-in-class tablet press options from single-station R&D laboratory models to heavy-duty production rotary presses. Natoli AIM™ Analytical and Control System Software for R&D tablet presses, production tablet presses, encapsulation machines, high-shear granulators, and roller compactors.

Premium Tablet Press Replacement Parts: Natoli maintains an extensive inventory of tablet press replacement parts suitable for use with most major brands of tablet presses.

Tablet Compression Accessories: Natoli offers the most comprehensive accessories catalog in the industry featuring hundreds of items to help care for, analyze, and prolong the life of tooling and equipment.

Premium Encapsulation Machine Change and Spare Parts: Natoli offers premium spare parts, change parts, and change part kits for most major brands of encapsulation machines.

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

Additional Technical Services
Additional technical services include tablet press repair and refurbishing, tooling evaluation and repair, formulation testing and analysis, and metallurgical analysis.

Locations
Natoli headquarters in St. Charles, Missouri, include administrative, manufacturing, refurbishing, training, and laboratory and scientific research facilities. Natoli’s service centers, located in Long Island, New York; Southern California; and Szczecin, Poland, offer regional customer support with replacement parts, accessories, tooling refurbishing, maintenance, training, and more. Natoli Scientific’s laboratory facility in Telford, Pennsylvania, provides formulation evaluation, training, and contract research and consulting services.

Markets Served
Natoli serves the pharmaceutical, nutritional, veterinary, confectionery, and industrial tableting and encapsulation industries in major markets around the world.
THERE’S NOTHING PREDATORY ABOUT NON-OEMs

Don’t Take The Bait.

Some tablet press OEMs use scare tactics to keep customers from using non-OEM replacement parts.

At Natoli, we work hard to ensure that the quality and integrity of our parts meet—or exceed—OEM specifications. We spend hundreds of manhours each year testing the quality of our parts. We ensure your high expectations are met with premium products, substantial savings, and unbeatable delivery times.

Contact us today!

You Demand. We Deliver.

NATOLI ENGINEERING COMPANY, INC.
natoli.com • info@natoli.com • +1 636.926.8900
2020 Lineup of Events

FEBRUARY
25-26 2020 PDA Europe Parenteral Packaging
Basel, Switzerland | pda.org/EU/ParPack2020

MARCH/APRIL
3/30-4/1 2020 PDA Annual Meeting
Raleigh, NC | pda.org/2020Annual
   2 2020 PDA Pharmaceutical Manufacturing Data Science Workshop
21-22 2020 PDA Europe Visual Inspection Forum
Berlin, Germany | pda.org/EU/VIForum2020

JUNE
9-10 2020 PDA Europe Quality and Regulations Conference
Dublin, Ireland | pda.org/EU/QR2020
22-23 2020 PDA Europe Virus Forum
Brussels, Belgium | pda.org/EU/Virus2020
24-25 2020 PDA Europe Advanced Therapy Medicinal Products Conference*
Brussels, Belgium | pda.org/EU/ATMPs2020
24-25 PDA Advanced Therapy Medicinal Products Conference*
TBA, United States | pda.org/2020ATMPs

SEPTEMBER
8-9 2020 PDA Europe Medical Devices and Digital Healthcare Conference
Save the Date | pda.org/EU/MDCH2020

OCTOBER
5-6 2020 PDA Universe of Pre-Filled Syringes and Injection Devices
Las Vegas, NV | pda.org/2020UPS
   7 2020 PDA Combination Products Workshop
19-21 15th Annual PDA Global Conference on Pharmaceutical Microbiology
Washington, DC | pda.org/2020Micro
   21-22 2020 PDA Rapid Microbiological Methods Workshop
20-21 2020 PDA Europe Aseptic Animal Health Conference
The Hague, The Netherlands | pda.org/EU/Animal2020

For an updated PDA calendar of events, please visit:
pda.org/calendar

*Select sessions will be simulcast between Europe and the U.S.
Keep Pace with the Latest Industry Trends with PDA

The Parenteral Drug Association (PDA) is the leading global provider of science, technology, regulatory information, and education for the bio/pharmaceutical community. For nearly 75 years, since its founding as a non-profit in 1946, PDA has been committed to developing scientifically sound, practical technical information and resources to advance science and regulation through the expertise of our more than 10,500 members worldwide.

PDA is a truly global organization, with membership nearly equally divided between those working in the U.S. and in other regions around the world. Represented in this diverse membership is a growing number of young professionals and students. Recognized for our expertise and authority in the field of parenteral science and technology, PDA is leading the way in promoting the exchange of information on rapidly evolving technology and regulations to ensure high-quality pharmaceutical production.

PDA draws its strength from its members, which includes a corps of 2,500 active volunteers. Our conferences, meetings, and training courses bring together pharmaceutical manufacturers, suppliers, end users, academics, and regulatory officials for an unprecedented level of exchange on timely issues of mutual interest and concern.

Through the development of Technical Reports on pressing industry topics and responses to regulatory initiatives, PDA and its members influence the future course of pharmaceutical products technology. A natural progression was for PDA to expand this expertise into the world of creating standards that provide guidance to industry on best practices for drug manufacturing for patient use. In 2017, PDA was accepted as an ANSI-accredited standards developer. PDA's first standard is currently out for public comment, and work is currently underway on five additional standards.

Our internationally recognized publications, PDA Journal of Pharmaceutical Science and Technology and PDA Letter, keep pharmaceutical manufacturing professionals up to date on the latest science and current industry and regulatory news.

Together, these activities promote the advancement of pharmaceutical science in the interest of the ultimate end-user—the patient.
VAC-U-MAX

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WEBSITE
www.vac-u-max.com

NUMBER OF EMPLOYEES
75

DATE FOUNDED
1954

MANUFACTURING Equipment and Supplies

Pharmaceutical Solutions: Moving Powders & Bulk Materials to Processing & Packaging

VAC-U-MAX is a worldwide leader in the design and manufacture of sanitary pharmaceutical receivers and automated systems designed to convey free to non-free flowing powders, APIs, tablets, gel caps, and other dry bulk material to processing equipment and packaging machines. Since 1954, VAC-U-MAX has defined the leading edge of technology, developing air-powered venturi units and the first “Tube Hopper” material receiver for conveying bulk materials from source to destination. A UL-listed designer and manufacturer of control panels, VAC-U-MAX furnishes integrated control systems to provide coordination of material movement for batch and continuous processing with tie-in capabilities into existing control systems.

VAC-U-MAX components and systems are used in many applications including loading tablet press machines, pharmaceutical extruders, direct-charge loading of blenders, mix tanks, reactors, and for single/twin-screw feeder refill. Vacuum conveying components are USDA-accepted and constructed of stainless steel, with convey rates from 500 to 5000 pounds per hour and beyond. Variety of discharge valve types and finishes are available, including bead blast, satin, or mirror polish.

VAC-U-MAX Vacuum Conveying Systems consist of a pick-up point, vacuum receiver, vacuum producer, and control panel. Material is conveyed from 10 feet “up-and-in” to 100 feet, eliminating the need for hand scooping, heavy lifting, and climbing, in addition to eliminating fugitive dust and combustible dust issues.

In addition to a full line of vacuum conveying solutions for bulk ingredient handling, VAC-U-MAX offers pharmaceutical industrial vacuum cleaners for high volume recovery of fine powders and combustible dusts. Industrial vacuum cleaners run only on compressed-air, no electricity required, making them a “true intrinsically safe” system.

For more information, visit www.vac-u-max.com to learn more about VAC-U-MAX application and system expertise for the pharmaceutical and nutraceutical industries or call (800) VAC-U-MAX.

Major Products/Services

Product range includes:
- Vacuum Conveying Systems for Loading Tablet Presses
- Multi-Ingredient Handling Systems
- Vacuum Conveying Systems for Direct-Charge Blender Loading
- Batch-Weighing Systems
- Vacuum Conveying Systems for Refilling Volumetric/Gravimetric Feeders
- Mobile Vacuum Conveying Systems
- Vacuum Conveying Systems with Check Sieve
- Vacuum Conveying tablets, capsules, powders, and other materials to packaging lines.

VAC-U-MAX Vacuum Conveying Systems consist of a pick-up point, vacuum receiver, vacuum producer, and control panel. Material is conveyed from 10 feet “up-and-in” to 100 feet, eliminating the need for hand scooping, heavy lifting, and climbing, in addition to eliminating fugitive dust and combustible dust issues.

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For more information, visit www.vac-u-max.com to learn more about VAC-U-MAX application and system expertise for the pharmaceutical and nutraceutical industries or call (800) VAC-U-MAX.
Engineered Around You. Guaranteed by Us.

From sanitary components to fully automated batch or continuous systems, we create pharmaceutical processing solutions entirely around your needs & goals.

Providing 65-years of custom application experience in the pharmaceutical industry. Over 10,000 different powder and bulk materials handled—including Free-Flowing and Non-Free Flowing Powders. Technical expertise including FAT & SAT validation. And an airtight performance guarantee. It’s what makes VAC-U-MAX as unique and trusted as the pharmaceutical process automation solutions we design.

Let us solve your pneumatic conveying challenges. Visit vac-u-max.com/pneumatic or call 800-VAC-U-MAX.
How do you differentiate suppliers?

Pharma Marketplace can help.

Pharma Marketplace gives you all the information you need to choose the right supplier. Our directory quickly connects you with 2,000 bio/pharmaceutical companies around the world.

pharmtech.com/marketplace
AbbVie Contract Manufacturing has been serving our partners for more than 35 years across 10 of our manufacturing facilities located in both North America and Europe. Our contract development and manufacturing capabilities span both small- and large-molecule API including classical fermentation, chemical synthesis, and biologics. In addition to APIs, we offer extensive experience and technical solutions in the area of drug product manufacturing, which includes traditional tablet and capsule production with emphasis on DEA-controlled drugs, potent, and hot-melt extrusion. Lastly, we can also package your product regionally and also offer prefilled syringe manufacturing capabilities.

**Technical Services**
- Fermentation
- Drug product
- Potent
- AbbVie now offers aseptic fill/finish vial and prefilled syringe. The state-of-the-art vial line supports lyophilization for potent and biologics along with liquid fill vials
- Hot-melt extrusion
- Biologics
- APIs
- ADCs

**Facilities**
AbbVie Contract Manufacturing has an expanding suite of state-of-the-art facilities that connect companies with highly specialized manufacturing services throughout the world. These include some of the world’s most technologically advanced facilities for their respective specialties—supported by a robust and experienced team of scientific experts.

Combined, they offer global pharmaceutical companies a high degree of flexibility, scale, and wide-ranging capabilities.

**Corporate Description**
AbbVie Contract Manufacturing maintains well-established supply chains and leads the way with regional and global regulatory and compliance standards from every manufacturing base.

By choosing AbbVie Contract Manufacturing, your team gets so much more than the typical CMO engagement. Alongside our state-of-the-art cGMP manufacturing facilities, AbbVie’s partners gain integrated access to deep scientific expertise and processes that have successfully supported many small-molecule and biologic medicines through to commercialization.

**Markets Served**
AbbVie Contract Manufacturing global capabilities span development through commercial services in the following pharma markets:
- Pharmaceuticals
- Nutraceuticals
- Food additives
- Chemical applications
EXPERIENCE UNRIVALLED

When it comes to outsourcing focused on commercial success, you need a CMO that has been there many times through deep scientific expertise and world-class facilities.
Adare Pharmaceuticals

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

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

Facilities
Adare Pharmaceuticals has four sites located in the US and Europe with over 600 employees worldwide. We have the expertise to take your project from formulation development through commercial-scale manufacturing. Our sites are compliant with cGMP criteria and approved to handle controlled substances and solvents, and maintain excellent environmental credentials.

Our in-house regulatory and quality teams have a proven global track record with the FDA, AIFA in Italy, EMA in Europe, and ANVISA for Brazil.

Services and Capabilities
Adare has recently launched a new patient-centric dosage solution, the Parvulet™ Technology. The Parvulet™ Technology enables a solid powder or tablet to convert to a semi-solid in the presence of water within thirty seconds. The final dosage is easily administered, as a soft food-like texture, ideal for pediatric and geriatric populations (including those with dysphagia).

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

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

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

MMTS™ Multi Mini Tablet System Customized Release Technology combines the simplicity of a tablet formulation with the flexibility of multiparticulate dosage forms with high drug-loading capability. Adare has developed Ultra Microtablets—a smaller standard of tablets targeting diameters in the range of 1.2 mm to even 1.0 mm. The small size facilitates the development of products that can offer multiple drugs or varying release profiles within a single capsule.

BIORISE™ Bioavailability Enhancement technology breaks down drug particles to their thermodynamically activated form, creating new physical entities, that have increased solubility profiles. This process allows for oral dosing for poorly soluble drugs and can be applied to class II compounds with less than 10 to 500 μg/mL solubility.
A SPECIALTY CDMO TRANSFORMING ORAL FORMULATION CHALLENGES INTO PRODUCT SOLUTIONS

RIGHT DRUG, RIGHT PATIENT, RIGHT FORM

As a speciality CDMO, Adare provides extensive expertise and advanced knowledge to guide your project from product development through commercial manufacturing. We specialize in ODTs, taste masking, and customized drug release for the Pharmaceutical, Animal Health, and OTC markets. With over 30 years of proven legacy, Adare has successfully developed and manufactured more than 40 products sold by partners in more than 100 countries globally.

LEARN HOW ADARE PHARMACEUTICALS CAN MAKE YOUR PRODUCTS MORE PATIENT-CENTRIC
ADAREPHARMA.COM | BUSDEV@ADAREPHARMA.COM
AMRI

Company Description
AMRI, a global contract research and manufacturing organization, partners with the pharmaceutical and biotechnology industries to improve patient outcomes and quality of life. With locations in North America, Europe, and Asia, AMRI’s team combines scientific expertise and market-leading technology to provide a complete suite of solutions in Discovery, Development, Analytical Services, API Manufacturing and Drug Product.

We Offer
• Early discovery research, next-generation technology platforms, complex medicinal and synthetic chemistry, biology and pharmacology services that support hit identification through candidate selection
• Centers of excellence that accelerate drug discovery innovation for the development of therapeutics
• Specialty compounds such as T3P®, VPA and Oxa Acids that serve in a variety of innovative applications to yield high-quality products
• Extensive portfolio of more than 240 APIs
• Sterile and high potency APIs, steroids, generics, monobactams, boronic acids and controlled substances
• Global chemical development expertise for early stage compounds
• Custom synthesis and contract manufacturing expertise
• Technology expertise in specialty areas such as hydrogenation, fermentation, photocatalytic chemistry, biotransformation, industrial chromatography, flow chemistry and spray drying
• Analytical research and testing services, including solid state chemistry and container closure integrity testing
• Drug product experience spanning all compound categories for injectable, nasal and ophthalmic administration, and final dosage form flexibility across vials, syringes or dropper bottles

Our complete suite of capabilities across the drug discovery, development and manufacturing continuum include:
• Discovery: Comprehensive discovery biology, synthetic and medicinal chemistry, ADMET and bioanalytical services
• Development: Chemical process R&D and continuous flow, manufacturing of non-GMP and GMP intermediates and clinical-stage APIs, biotransformations, enzymatic reactions, pre-formulation/formulation and material science
• Analytical services: Method development and validation, stability testing, quality control and spectroscopy services, particle engineering, material science, container qualification and testing, packaging and distribution testing, medical device and drug delivery testing, extractables/leachables and impurities detection and microbiology
• API manufacturing: Chemical development and cGMP manufacture of complex APIs, including potent and cytotoxic compounds, sterile APIs, steroids and controlled substances
• Drug product: Integrated sterile dosage form expertise, including complex liquid and lyophilized formulation development, scale-up and cGMP supply
AT EVERY STAGE, WE DELIVER
THE EXPERTISE YOU NEED

AMRI has it down to an exact science.

Explore our expert solutions at amriglobal.com
Associates of Cape Cod

Specializing in chromogenic and turbidimetric reagent technologies, Associates of Cape Cod, Inc. (ACC) is proud to be celebrating 45 years as a global leader in endotoxin and (1→3)-ß-D-glucans detection products and services. ACC pioneered LAL testing methodology and was the first FDA-licensed company to manufacture LAL reagents; ACC has grown to be an internationally recognized leader in endotoxin detection.

Services and Facilities

Our worldwide headquarters are located in East Falmouth, Massachusetts. With a dedication to quality, ACC is certified to I.S. EN ISO 13485:2016 and ISO 13485:2016. We are FDA-inspected and operate DEA-licensed and CLIA-certified laboratories. Our endotoxin detection reagents, instruments, and software are used within the pharmaceutical, medical-device, biotechnology, compounding pharmacy, and dialysis industries for quality control, product release, and research. Our reagents are FDA-licensed and can be used for testing in compliance with USP, EP, and JP bacterial endotoxin test chapters, and our software is 21 CFR Part 11 compliant.

ACC also operates a Contract Test Services (CTS) Laboratory, which has specialized in testing for endotoxin and glucan contamination for over 30 years. Our CTS laboratory is GMP-compliant, ISO-registered, and DEA-licensed and is capable of handling all controlled drug substances except those included in Schedule 1. All testing services can be performed to FDA, USP, EP and/or JP regulatory guidelines. In addition to routine testing, our CTS Laboratory will customize endotoxin testing, troubleshoot difficult samples, develop and/or transfer LAL test methods, design and produce custom depyrogenation controls for oven validation, and perform low endotoxin recovery (LER) studies/protocols. ACC also offers a clinical diagnostic product line and operates a CLIA-certified laboratory specializing in (1→3)-ß-D-glucans analysis to support the diagnosis of Invasive Fungal Disease (IFD).
Easy to Use Pyros® eXpress

Endotoxin and Glucan Analysis Software for tube and plate readers.

Ease of Use
• Custom Home Screen Templates
• Fully Integrated Product Validation Workflow
• Custom Permission Settings

Efficient
• Real time Reports for Individual Samples
• Reagent, Product and Supply Libraries

Versatile
• The Software Supports Both Plate and Tube Reader Platforms

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Your Endotoxin & Glucan Experts
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WEBSITE
baxterbiopharma solutions@baxter.com

OUTSOURCING and Consulting Services

Company description
Backed by more than 85 years of Baxter innovation and expertise in parenterals, Baxter’s BioPharma Solutions (BPS) business collaborates with pharmaceutical companies to support commercialization objectives for their molecules. BPS is a premier CMO with a focus on injectable pharmaceutical manufacturing designed to meet complex and traditional sterile manufacturing challenges with confidence of delivery, service, and integrity.

Markets served
A global presence—Baxter has manufacturing sites across the globe in support of a diverse portfolio of delivery systems and manufacturing solutions.

Worldwide manufacturing expertise—The strength of Baxter’s global network lies in efficient, quality cGMP manufacturing—enabling Baxter’s BioPharma Solutions business to deliver cost-effective results built on best practices and operational excellence.

Major products/services
BPS can support your pharmaceutical needs with a broad portfolio of sterile fill/finish production capabilities and our reputation is built on the high-quality products we manufacture for our clients in a cGMP environment. Our delivery systems include: prefilled syringes, liquid/lyophilized vials, diluents for reconstitution, cartridges, powder-filled vials, and sterile crystallization. Our drug categories include: small molecules, biologics, vaccines, cytotoxics, highly potent compounds, and ADCs (antibody-drug conjugates). From formulation and development, through commercial launch, our extensive, customized support services can guide you through marketplace complexities, helping you achieve the full potential for your drug molecule. 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 and versatile solutions to help achieve your commercialization objectives.

Facilities
A leader in sterile contract manufacturing—Our facility in Bloomington, Indiana USA serves client needs from clinical through commercial launch.

A world-class manufacturer of oncology products—Our facility in Halle/Westfalen, Germany offers dedicated clinical through commercial production.

A best-in-class aseptic solution manufacturer—Our facility in Round Lake, Illinois USA produces ready-to-use premixed drugs in proprietary bags.

A leading resource for parenteral product development—Our Lyophilization Center of Excellence is staffed with scientists who can assist with modification and formulas to maximize the potential of your lyophilized products.

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

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

Learn more about us at baxterbiopharmasolutions.com

Maximize Your Molecule’s Full Potential
OUTSOURCING and Consulting Services

Cambrex

Corporate Description
Cambrex is the leading small-molecule company that provides drug substance, drug product, and analytical services across the entire drug lifecycle.

With over 35 years’ experience and a team of over 2000 experts, Cambrex is comprised of three business units — drug substance, drug product, and early stage development and testing, which operate at 13 locations across North America and Europe.

Drug Substance Capabilities
Cambrex provides custom development and manufacturing services with the expertise and flexibility to handle scales of projects from investigational new drug (IND) support, preclinical to Phase III clinical trials, and seamless technology transfer for commercial supply.

The company offers a number of specialized services and capabilities across its sites including the ability to handle and manufacture highly potent APIs and controlled substances, as well as use technologies including biocatalysis and continuous flow chemistry in the design and optimization of synthetic processes. Cambrex also undertakes solid-state services including salt screening, co-crystal screening, crystallization screening, polymorph screening, scale-up crystallization, physical properties testing, and particle engineering.

Cambrex is also a leading global supplier of generic APIs, with more than 100 generic APIs in its portfolio, and works with generic drug companies in advance of drug patent expiration to develop high quality, non-patent infringing manufacturing processes.

Drug Product Capabilities
Cambrex supplies services ranging from pre-formulation registration batches and clinical supply to commercial manufacturing and packaging. It has expertise in the formulation and development of conventional dosage forms including oral solids, semi-solids and liquids, as well as specialist dosage forms such as modified-release, fixed dose combination, pediatric, bi-layer tablets, stick packs, topicals, controlled substances, and sterile and non-sterile ointments.

Its expert team provides support throughout the CMC dosage form section of the NDA and its integrated analytical services provide the method development and validation expertise needed for a registration package.

Analytical Capabilities
Cambrex’s wide range of standalone analytical services include method development and validation studies to monitor potency and purity for raw materials, drug substances, and drug products, as well as stability storage and testing, material characterization, impurity isolation and identification, and compendial and release testing.

Additionally, Cambrex offers microbiology testing services that are fully compliant with all GMP and GLP testing standards, including sterility and endotoxin testing. Cambrex also has extensive cleanroom services to support ongoing and routine environmental monitoring, as well as personnel monitoring and cleanroom certification.
Your molecule
Our mission

Discover why we’re the small molecule company, with end-to-end capabilities and experts you’ll enjoy working with.

Vincent Talani
Mechanic, Packaging

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Catalent
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Somerset, NJ 08873

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+1.888.765.8846

E-MAIL
solutions@catalent.com

WEBSITE
www.catalent.com

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

Catalent has built this expertise through helping partners of all sizes, from the smallest innovators to the largest of biopharmaceutical leaders, to advance thousands of molecules through each phase of development and on to commercial supply. By arranging our expertise, capabilities, technologies, and capacity, we provide services from specific, tailored program support or comprehensive, integrated solutions that are fast, flexibility, reliable, and that help our partners reduce project risk. In fact, our team of nearly 13,000 at 35 sites develop more than 700 projects and help launch in excess of 200 products every year. We produce more than 72 billion doses of over 7000 products for more than 1000 customers — or 1 in 20 doses taken by patients globally. Our passion is to help unlock the full potential of your product.

More products better treatments reliably supplied™

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

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

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

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

Catalent.
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.
480 Neponset Street
Canton, MA 02021

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FAX
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E-MAIL
lcw@chemiclabs.com

WEBSITE
www.chemiclabs.com

NUMBER OF EMPLOYEES
45

DATE FOUNDED
January, 1998
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.

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- Monograph Testing (USP, EP, BP and JP)
- CMC Method Development & Validation
- Degradation 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
Coating Place, Inc.

Corporate Description
Coating Place is the leading Wurster fluid bed coating services supplier in the industry with over 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. All products at Coating Place are developed and manufactured with an integrated total quality management philosophy and will be handled in a confidential manner.

Technical Services
Formulation Development
- Technology transfer
- Feasibility studies
- Linear scale-up
- Moisture or oxygen barrier
- Organic or aqueous solvent coatings
- Taste masking

Oradel® Platform
- Multilayer bead coating
- Enteric release

Quality Control
- Full analytical support
- Method development and transfer

Facilities
Our 200,000-sq.ft. FDA-registered pharmaceutical facility is located in Verona, Wisconsin. Coating Place also operates a 190,000-sq.ft. specialty chemical facility in Sauk City, Wisconsin. 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.

Markets Served
Coating Place provides contract Wurster coating of pharmaceutical, nutraceutical, and specialty chemical products from development through commercial manufacturing, including:
- Rx, Branded, and Generic
- OTC
- Controlled Substance (Schedule II-V)
At Coating Place, every coating formulation is customized based on the unique characteristics of the project. Using our Oradel® oral delivery techniques, we can achieve a wide variety of release profiles. With over 40 years of experience in the CDMO industry, Coating Place offers technologically advanced Wurster fluid bed coating, high quality coating, linear scalability and superior customer service.

Innovative Development. Experienced Manufacturing.

Coating Place, Inc., 200 Paoli St. • PO Box 930310, Verona, Wisconsin 53593 U.S.A. • +1 (608) 845-9521 • www.coatingplace.com • info@coatingplace.com
Outsourcing and Consulting Services

Eurofins PSS Insourcing Solutions®

Corporate Description

Eurofins PSS Insourcing Solutions® (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 nearly 60-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 PSS Insourcing Solutions 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 is not staff augmentation, so it solves the challenges associated with the EU Temporary Agency’s Workers Directive 2008/104.

Facilities

With more than 2000 employees worldwide, Eurofins PSS Insourcing Solutions provides services at more than 70 sites in nearly 20 countries throughout North America, Europe, and Asia Pacific and is part of Eurofins BioPharma Product Testing, which operates 35 laboratory locations, totaling more than 1,600,000 ft² across 17 countries worldwide.

Major Products/Services

Our PSS Insourcing Solution® provides services for clients who require lab services at their facility. We have proven success providing dedicated teams 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 and molecular biology
- Immunochemistry
- Sample management
- Medical device testing
- Engineering
- Project management
- Bioassay characterization.

Markets Served

With more than 70 client sites worldwide, our PSS Insourcing Solution® provides the optimal external service provider in house for pharmaceutical and biopharmaceutical companies around the world.
Expanding across the globe and managing the largest bio/pharmaceutical clients’ drug development programs at over 70 client sites and approaching 20 countries, Eurofins PSS Insourcing Solutions® hires, trains and manages our employees to perform your defined scope of testing wherever you choose to take us.

Bringing nearly 60 years of GMP quality testing and in-house laboratory management expertise to your global sites, award-winning PSS delivers compliant, co-employment free, and cost-effective services and gives you the security of keeping your projects safely tucked away at your site.

Enjoy the best of both worlds; pocket the power of PSS.

Take Eurofins PSS Insourcing teams home with you anywhere in the world.

www.Eurofins.com/PSS
OUTSOURCING and Consulting Services

KCAS Bioanalytical & Biomarker Services

12400 Shawnee Mission Parkway Shawnee, KS 66216 USA

TELEPHONE 913.248.3000

E-MAIL info@kcasbio.com

WEBSITE kcasbio.com

NUMBER OF EMPLOYEES 135

DATE FOUNDED 1979

Corporate Description
KCAS is a progressive growing contract research organization of well over 100 talented and dedicated individuals committed to serving our clients and improving health worldwide. Our experienced scientists provide stand-alone bioanalytical services to the pharmaceutical, biopharmaceutical, animal health, and medical device industries. KCAS’ expert scientific management has a combined 135+ years of bioanalytical testing and laboratory expertise. Our depth and breadth of experience comes from more than 4600 proprietary and more than 900 non-proprietary assays developed to date.

Technical Services
Quantitative bioanalysis:
• Bioanalytical discovery support
• LC-MS/MS
• Ligand binding assays
• Immunoaffinity LC-MS/MS
• Immunogenicity

Biomarkers:
• Flow cytometry
• Cell-based assays

• Multiplex and single analyte
• Biomarker quantitation

Clinical Sample Kits

Facility
A 33,000-sq-ft. laboratory centrally located in Kansas City, KS

Markets Served
Led by strong, recognized pharmaceutical and biopharmaceutical experts and pioneers in bioanalytical and biomarker services, KCAS has proven success with more than 40 years of stable, secure growth and 17 successful FDA audits. The main drivers of our client’s success are communication, consistency, reliability, and our ability to find creative solutions.
EVENT OVERVIEW:
In this webcast, learn how the FDA Bioanalytical Method Validation Guidance (May 2018), the FDA Immunogenicity Testing of Therapeutic Protein Products (January 2019), and the February 2019 draft International Conference on Harmonisation (ICH) Bioanalytical Method Validation M10 guidelines have changed or are poised to change the landscape of outsourcing bioanalysis to support drug development. Additionally, the webinar will cover gaps in bioanalytical method validation guidance to support drug development most notably flow cytometry support of gene therapies.

The webcast will highlight the areas of each guidance that indicate a change of thinking from previous documentation provided by the agency. Experts will discuss the practical side of execution of these updated parameters, where appropriate, and the impact the documents will have on the scope and time line for outsourcing of bioanalytical analysis.

Key Learning Objectives
- What is new in FDA’s May 2018 Bioanalytical Method Validation Guidance?
- What is new in FDA’s January of 2019 Immunogenicity Testing of Therapeutic Protein Products?
- What is new in the February 2019 draft of the ICH Bioanalytical Method Validation M10 guidelines?
- What actions should bioanalytical testing labs take to adapt to these new guidelines?

Who Should Attend
- Pharmaceutical and biopharmaceutical industry CEOs, directors, and scientists who are decision makers within their companies and individuals who outsource bioanalytical to CROs

Presenters
- Franklin Spriggs
  Director, Biopharmaceutical Services
  KCAS Bioanalytical and Biomarker Services
- Marsha Luna
  Director, Pharmaceutical Services
  KCAS Bioanalytical and Biomarker Services
- Stephanie Bull, RQAP-GLP
  Quality Assurance Team Lead
  KCAS Bioanalytical and Biomarker Services

Moderator
- Rita Peters
  Editorial Director
  Pharmaceutical Technology

For questions contact Martha Devia at MDevia@mmhgroup.com
Company Description
At Lonza Pharma & Biotech, we provide contract development and manufacturing services that enable biotech and pharma companies to bring large- and small-molecule medicines to patients in need. From drug substance to the final drug product, our solutions feature concept to commercial capabilities to simplify your outsourcing experience and to provide a reliable outcome when you expect it. Our extensive track record includes development and manufacture of a wide variety of biological and chemical dosage forms including oral solid, parenteral, and inhaled delivery routes. We continuously invest to solve not just current, but also future challenges that support commercialization of pioneering therapies. Together, we can bring your next medicine to life.

Services Overview
We manage projects from pre-clinical development stage through to commercialization across mammalian and microbial produced biologics, small molecules, bioconjugates, and cell and gene therapies. Our extensive service portfolio covers both drug substance and drug product. We have strengthened our drug product and particle engineering capabilities and, with the recent acquisition of the former Novartis Stein facility, sterile injectables are also included in our service offering. Our integrated capacity enables you to collaborate with a single service provider for a wide variety of service needs, decreasing the amount of coordination required and saving you time and money.

Technical Services
Our service portfolio is comprehensive, which enables tailoring of a cost-effective and phase-appropriate package that suits your business needs. The following services serve as examples:

• SimpliFiH Solutions™ – Integrated First-in Human Service Package
• Drug substance development and production
• Oral, parenteral, and inhalation formulation development
• Production of drug substance and drug product intermediates
• High potency drug substance and drug product manufacturing
• Analytical method development and validation
• Regulatory consulting
• Lifecycle management
• Scale-up and tech transfer.

Facilities
We have contract development and manufacturing services around the globe. Our major development and manufacturing sites are located in Switzerland, USA, United Kingdom, Singapore, China, France, Spain, the Netherlands, Germany, Belgium, Mexico, India, Indonesia, and Japan. In addition, we have local sales offices in other countries to enable close communication with you.

Markets Served
We serve pharmaceutical and biopharmaceutical companies globally, striving to help reduce capital risk and increase chances of business success. Our customers range in size from small, even virtual companies, to some of the world’s largest drug manufacturers. The motivations for seeking an outsourcing partner will differ depending on company and business strategy. We work in close collaboration with you to ensure that we meet your specific requirements in each specific project.
As a leader for contract development and manufacturing, we at Lonza Pharma & Biotech are recognized for our reliable, high-quality services, global capacity, innovative technology platforms, and extensive experience. Our broad capabilities span across biologics, small molecules, bioconjugates, and cell and gene therapies.

We manage projects from pre-clinical stage through commercialization, and our expertise covers both drug substance and drug product. We believe that the best outcome – for you and for your patients – can only come as a result of a successful collaboration. Together, we can solve the next challenge and bring your next medicine to life.

Visit pharma.lonza.com
Email pharma@lonza.com
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the next medicine...
We’ll develop it together.
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MORE WHERE YOU WANT TO GO.

For those who demand more from their supply chain, only Marken provides a best-in-class Quality System, a global network of pharmaceutical supply chain centers in key regions, direct to/from patient home health care nursing services and industry-leading expertise. From orchestrating a more secure, patient-centered cell and gene supply chain to arming you with superior in-bound and out-bound services, Marken is helping you take your clinical program wherever you want it to go.

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WHERE YOU WANT TO GO.
LESS STATUS QUO.  
MORE WHERE YOU WANT TO GO.

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

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

Analytical Services
With more than 150 chemists on staff, Metrics analyzes the physical and chemical characteristics of drug substances and drug products through development and validation of methods, release, and stability testing. We perform this work in compliance with industry standards and international regulatory guidelines.

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

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

Concept to Commercialization
The parent company of Metrics Contract Services, Mayne Pharma, recently invested $80 million to significantly expand facilities and equipment at its site in Greenville, NC. Construction of the new 126,000 sq-ft. oral dose commercial manufacturing facility is now complete. The facility quadruples the company’s US manufacturing capacity, and the repurposing of existing space creates 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.
Increased capacity. Expanded formulation and analytical teams. Enhanced flexibility. At Metrics Contract Services, we’re better prepared than ever to take on your project... and see it through from concept to commercialization and everything in between.

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

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

Visit metricscontractservices.com to learn more about why we’re stronger by any metric.
Pharmaceutics International, Inc.

10819 Gilroy Road, Hunt Valley, MD 21031

TELEPHONE 410.584.0001

E-MAIL bd@pharm-int.com

WEBSITE www.pharm-int.com

NUMBER OF EMPLOYEES 350

DATE FOUNDED 1994

Corporate Description
Pharmaceutics International, Inc. (Pii) is a premier contract development and manufacturing organization (CDMO) offering unparalleled scientific insight and depth of product knowledge, while supplying high-quality dosage forms that enhance the lives of patients worldwide. Pii provides customized and flexible solutions, across several dosage forms and has experience with a broad range of compounds. For over 25 years, Pii has been supporting its pharmaceutical partners (from virtual to multinational) with extensive technical capabilities, know how, and the highest level of customer service. With more than 400 development programs completed, Pii’s scientific team has extensive experience working with drug substances representing a range of physicochemical characteristics (and challenges). Our specialized capabilities, multi-product facilities, and knowledge-base allow us to work with potent compounds and hormones, develop complex dosage forms, and support varied manufacturing processes. Pii operates over 360,000 square feet of state-of-the-art pharmaceutical development and manufacturing space, all located on one campus in Hunt Valley, MD. This includes over 70 flexible, manufacturing suites, several with the required containment controls for handling potent compounds and hormones, as well as a dedicated suite for the production of soft gel capsules. Licensed to manufacture DEA Schedule I-V products, with capabilities for both oral delivery and parenteral dosage forms, Pii has the depth to support development, clinical, and commercial requirements. Facilities are cGMP qualified and include dedicated formulation development centers for solid oral, liquid, and sterile products.

Services
- Preformulation studies
- Dosage form development and manufacturing
- Analytical development and testing
- CTM manufacturing
- Commercial manufacturing
- Stability storage and testing
- Serialization
- Clinical packaging
- Regulatory support
- Quality management
- Commercial packaging

Capabilities
- Sterile (vials, syringes, lyophilized, cartridges)
- Injectables (aqueous and non-aqueous)
- Oral solids (soft gels, tablets, capsules)
- Oral liquids (suspensions, syrups, solutions)
- Topicals
- Potent compounds, hormones, cytotoxics
- Solid dispersions
- Controlled release formulations
- Fluid-bed processing (solvent and aqueous)
- Micro and Nanotechnologies
- Coating (aqueous and solvent)
Pii provides customized and flexible solutions, across several dosage forms, and has experience with a broad range of compounds. For over twenty-five years Pii has been supporting its pharmaceutical partners with technical capabilities, know-how, and the highest level of customer service. With more than 400 development programs completed, Pii’s scientific team has extensive experience working with drug substances representing a range of physicochemical characteristics (and challenges). Our specialized capabilities, multi-product facilities and knowledge-base, allow us to work with potent compounds and hormones, develop complex dosage forms, and support varied manufacturing processes.

**CAPABILITIES**
- Sterile (vials, syringes, lyophilized)
- Injectables (including viscous)
- Oral solids (soft gels, tablets, capsules)
- Oral liquids (suspensions, syrups, solutions)
- Topicals
- Potent compounds, hormones, cytotoxics
- Solid dispersions (HME and spray drying)
- Controlled release formulations
- Fluid-bed processing (solvent and aqueous)
- Micro & Nanotechnologies

**SERVICES**
- Preformulation Testing
- Dosage Form Development
- Analytical Development & Testing
- CTM Manufacturing
- Commercial Manufacturing
- Clinical Packaging and Distribution
- Regulatory Support

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FOR PERSONAL NON-COMMERICAL USE
PTI provides inspection equipment for the following applications:

- Parenteral/injectibles:
  - Vial/ampoule
  - Syringe/cartridge/auto-injector
- Blister packaging and other low headspace packaging (transdermal patch)
- Medical device packaging
- Tyvek®/porous packaging
- Rigid containers (bottles, cups, trays)
- Pouches and other flexible packaging formats (stick packs and sachets)
- Ophthalmic

Our Mission
PTI's mission to provide complete package integrity test solutions begins with a client's problem statement and concludes with a definitive path to package integrity assurance. Our non-destructive deterministic inspection technologies bring clarity and actionable information to package testing requirements.

Major markets include
- Pharmaceutical
- Biological
- Medical Device
- Nutrition/oral Dose
- Food & Beverage

Facilities
PTI's headquarters is located in Hawthorne, New York, just outside New York City. PTI also has an affiliate office in Europe, CCIT s.a.
Proven Innovation for Non-destructive Leak Testing of Pharmaceutical Packaging

Leading Edge Container Closure Integrity Test Equipment

PTI • Packaging Technologies and Inspection
# Ad Index

<table>
<thead>
<tr>
<th>COMPANY</th>
<th>PAGE</th>
<th>COMPANY</th>
<th>PAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>AbbVie</td>
<td>44–45</td>
<td>GEMÜ</td>
<td>30–31</td>
</tr>
<tr>
<td>Adare Pharmaceuticals</td>
<td>46–47</td>
<td>KCAS</td>
<td>64–65</td>
</tr>
<tr>
<td>Ashland Specialty Ingredients</td>
<td>18–19</td>
<td>Lonza</td>
<td>66–67</td>
</tr>
<tr>
<td>AMRI</td>
<td>48–49</td>
<td>Marken</td>
<td>68–69</td>
</tr>
<tr>
<td>Associates of Cape Cod</td>
<td>50–51</td>
<td>Medical Countermeasure Systems</td>
<td>3</td>
</tr>
<tr>
<td>Baxter BioPharma Solutions</td>
<td>52–53</td>
<td>Metrics</td>
<td>70–71</td>
</tr>
<tr>
<td>Cambrex</td>
<td>54–55</td>
<td>MFG Tray Company</td>
<td>32–33</td>
</tr>
<tr>
<td>Catalent</td>
<td>56–57, 80</td>
<td>MG America</td>
<td>34–35</td>
</tr>
<tr>
<td>Chemic</td>
<td>58–59</td>
<td>Natoli Engineering Company</td>
<td>36–37</td>
</tr>
<tr>
<td>Contec</td>
<td>10–11</td>
<td>Patheon</td>
<td>79</td>
</tr>
<tr>
<td>Coating Place</td>
<td>60–61</td>
<td>PDA</td>
<td>38–39</td>
</tr>
<tr>
<td>Colorcon</td>
<td>74</td>
<td>Perfex</td>
<td>12–13</td>
</tr>
<tr>
<td>CordenPharma</td>
<td>20–21</td>
<td>Pharmaceuticals International, Inc. (Pii)</td>
<td>72–73</td>
</tr>
<tr>
<td>Elizabeth Companies</td>
<td>28–29</td>
<td>PTI Inspection Systems</td>
<td>76–77</td>
</tr>
<tr>
<td>Emergent</td>
<td>7</td>
<td>Tedor Pharma</td>
<td>5</td>
</tr>
<tr>
<td>Eppendorf</td>
<td>24–25</td>
<td>Vac-U-Max</td>
<td>40–41</td>
</tr>
<tr>
<td>Eurofins</td>
<td>62–63</td>
<td>Veltek</td>
<td>14–15</td>
</tr>
</tbody>
</table>
While observing the API manufacturing process for a client, Michael wasn’t happy with what he saw. The purification process was inefficient, unnecessarily driving up costs. So, he got to work analyzing the entire process and his ideas were tested in the lab. The improvements discovered were so impressive that the client agreed to test the process at a larger scale. After another successful outcome, they decided to implement the refinements across the entire manufacturing process. The result not only reduced impurities and cut costs, it enabled capacity improvements which allowed greater control to manage larger volumes of material.

Michael Stanek, Ph.D.
VP Business Management,
Pharma Services,
Linz, Austria

Find out more at thermofisher.com/patheon
With 3 NEW facilities, Catalent has expanded its European solutions and expertise by adding two sites in the U.K. focused on oral drug development and spray dry technology, and one in Italy providing clinical and commercial manufacturing, fill finish and packaging for tech transfers and new launches of oral dose and biologics. These new sites complement 11 existing Catalent manufacturing facilities that provide clinical logistics and supply, softgel and oral technologies, and drug product manufacturing of injectables, with the flexibility to offer individual services and integrated solutions. The leading European development, delivery and supply network.