



Contract Pharma Services





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With Alkermes Contract Pharma Services, you have the opportunity to outsource your development, scale-up and manufacturing requirements to a trusted, experienced and dedicated expert in outsourcing services.

Four decades delivering contract pharma solutions for our partners

Alkermes Contract Pharma Services provides solid dosage form product development, formulation solutions and manufacturing services for the pharmaceutical market.

We have a long and successful history in the development and manufacture of pharmaceutical dosage forms for pharmaceutical markets worldwide. Since our founding in 1969, we have focused on assisting companies in drug product process design and development, process improvement as well as sharing our significant experience with difficult to make products. We have a blue chip list of partners and have assisted in the successful launch of multiple products in more than 100 countries in North America, Europe and Asia.

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We recognize that pharmaceutical companies can reap significant benefits from implementing an outsourcing strategy – achieving it just got easier

Alkermes Contract Pharma Services is a leading provider of solid dosage form product development and manufacturing services for the pharmaceutical market. All the services we offer to our partners are provided with the greatest attention to quality and customer service.

Product Development and Optimization

We have a wide range of development and optimization services to offer our partners including one of the most commercially successful drug technology portfolios in the industry. Our streamlined pathway to pharmaceutical dosage form development includes a Quality by Design (QbD) approach which allows our teams to make intelligent decisions from analytical method development right through to manufacturing process characterization.

Product Scale-up and Manufacturing

Our manufacturing group provides world-class current Good Manufacturing Practices (cGMP) scale-up and manufacturing services for solid oral dosage forms. Highly trained and experienced staff operate on a flexible manufacturing schedule - up to 24 hours a day, 7 days a week in order to meet demands.

Alkermes Contract Pharma Services is driven by 'excellence in everything we do', which, through our integrated Operational Excellence program, gives you the reassurance that your product will be guided through our facilities to exacting specifications.





Key Benefits

Experience and expertise:

- 40+ year history in business with strong track record

The industry trusts us:

- 30+ leading pharma companies are customers of ours

Proven drug optimization capabilities:

- 12 products developed and/or manufactured and, launched since 2001

FDA/EMA-licensed sites in both Europe and U.S. (including supply of product to Brazil, China and India)

Wide range of services:

- Effective, robust and swift technical (tech) transfers
- Full selection of proven and validated technology and process improvement solutions
- Modern facilities with best in class systems
- Competitive pricing
- On-time delivery record
- Exceptional compliance track record
- Excellent environmental, health and safety record.

Our partners are unique



As each of our partners is unique, we tailor our services according to their specific project requirements.

Speed to Market:

- Proven efficiency with on-site technical, development and manufacturing services and registration support to provide a fast efficient service
- Capacity to design, build, commission, qualify and commercialize any solid oral process on-site

Compliant, Reliable and Cost Efficient Supplier:

- Excellent compliance record in the U.S. and Europe with experienced and motivated staff
- Flexible infrastructure and efficient operations with mature Lean 6 Sigma/Operational Excellence programs

Effectiveness of Transfer:

- We leverage through process and product understanding, honed risk assessment (RA), process modelling and optimized experimental approaches, to maximize transfer effectiveness
- We work to ensure transferred processes are robust and capable.
- Process documentation, QA systems, calibration and maintenance activities that are targeted towards key process variables/steps (i.e. waste elimination and error proofing by design)

Dedicated Customer Service:

- We believe in the importance of open communication
- A dedicated project management resource will keep you informed at all stages in the project/commercial supply arrangement

Access to Full Capabilities of Our Sites:

- Capacity of 2.5 billion solid dosage units, process and analytical equipment, Drug Enforcement Administration (DEA) controlled site, packaging facilities for U.S. and EU

Opportunity to Examine Tax Options:

- Facility located in a Low Tax Jurisdiction (LTJ)

Process Optimization Post-Launch:

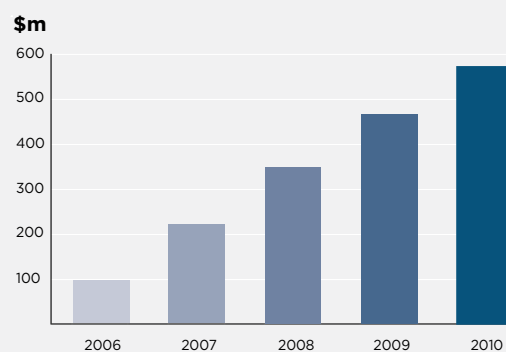
- Small scale, reduced Active Pharmaceutical Ingredients (API) cost, material changes, additional strengths.



Our Financial Stability and Revenue Growth

Alkermes Contract Pharma Services is well established with a strong record of profitability.

Cumulative 5yr Earnings Before Interest, Taxes, Depreciation and Amortization (EBITDA) Contribution.



Our Promise to Our Partners

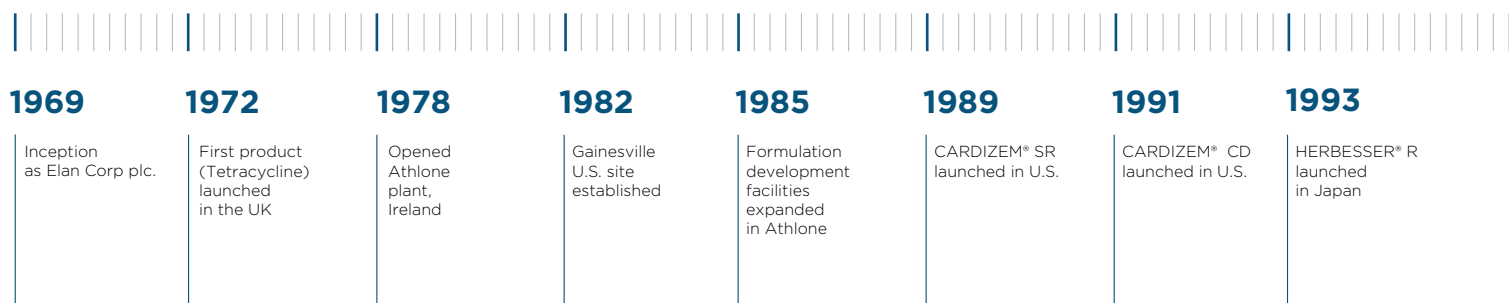
Now your company can access the proven performance of Alkermes Contract Pharma Services

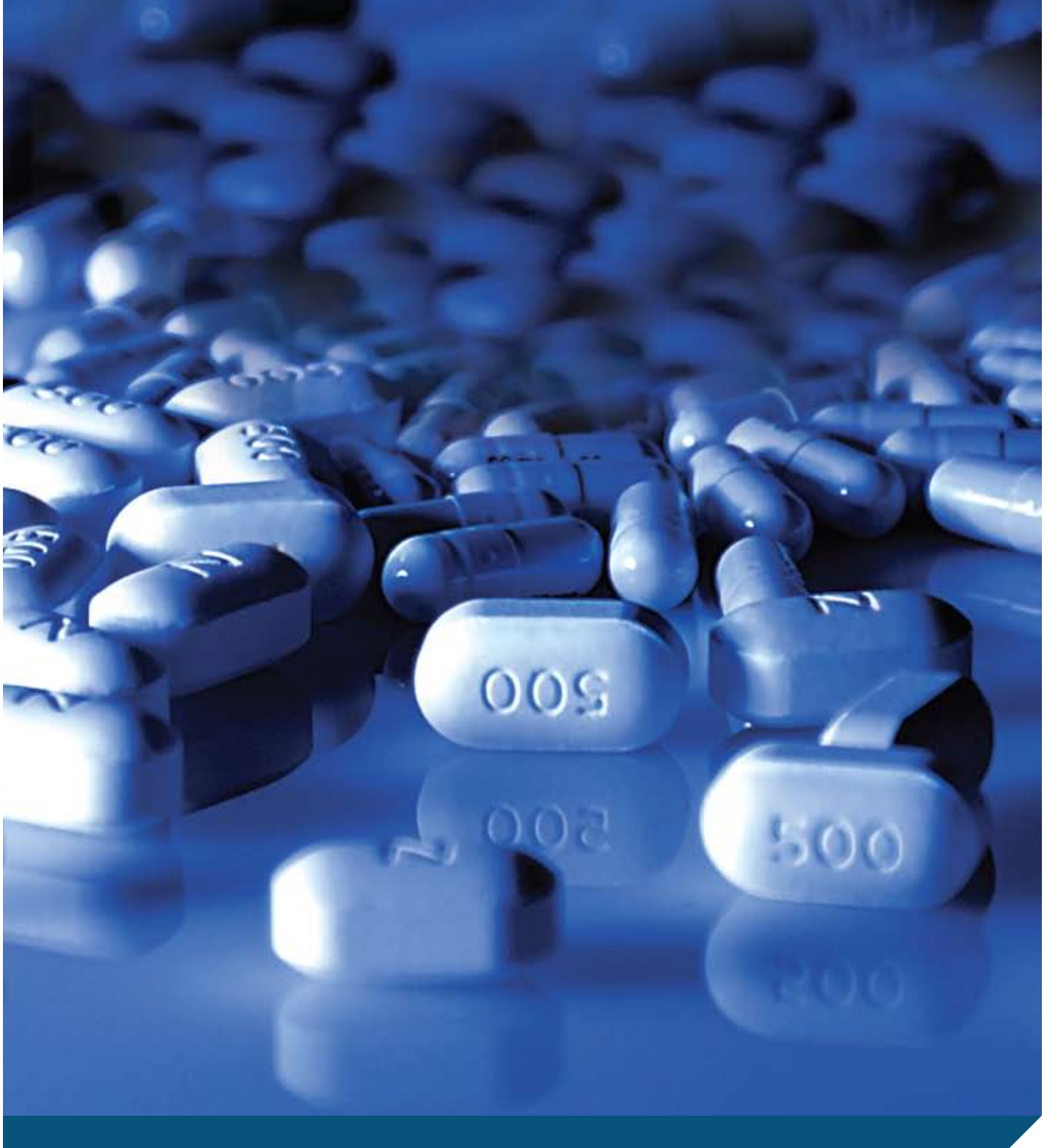
Our Partners Represent Many of the World's Leading Pharmaceutical Companies, Including:



Company logos here are trademarks of their respective companies

A Long History Built on Success





1994

THEODUR
launched
in Japan

1996

NAPRELAN®
launched
in U.S.

1998

Acquired
NanoCrystal®
technology

2003-2005

Major expansion
of Athlone, Ireland
and Gainesville sites
- \$200M+ investment

2000-2009

Key product launches:
INVEGA® SUSTENNA®, LUVOX CR®,
EMEND®, TRICOR® 145/LIPANTHYL®,
RITALIN LA®, FOCALIN XR®,
AVINZA®, MEGACE® ES and
ZANAFLEX CAPSULES®,
RAPAMUNE® manufacture

2010

AMPYRA®
launched

2011

Elan Drug
Technologies
merged with
Alkermes, Inc to
become
Alkermes plc.

Our wide range of services sets us apart

Commercially validated approaches, expertise and creativity together with clear and well defined communication procedures, are key to achieving optimum solutions to meet your product requirements.

Development Capacity

Our development capabilities comprise of highly experienced and accomplished scientists and support staff that participate in an open and team-focused environment in the development of your products. We actively encourage partner participation throughout the development, tech transfer and scale-up stages to successfully achieve your project goals.

Specialized Development Services

We are a leader in specialized development services with a broad platform of patented drug optimization technologies and strategies.

Registration Support

Our Regulatory Department has successfully assisted a number of companies with various applications to the regulatory authorities in the U.S., Europe and Japan. We provide assistance to our partners with the preparation of New Drug Applications and updates, Investigational New Drug Applications, Drug Master files and post-marketing supplements. We maintain site reference files and authorized access to drug master files as needed. Our quality group holds the responsibility of releasing our partners' batch records and undertakes this according to internal standard operating procedures and cGMPs.

Analytical Services

At Alkermes Contract Pharma Services we offer a complete range of analytical capabilities to support your requirements – be that technology transfer, scale-up, clinical trial supplies or full scale commercial manufacturing. We have over 72,000 square feet of laboratory space.

Our highly qualified chemists and scientific staff operate in fully equipped, best in class facilities that include:

- Raw Material, In-Process and Finished Product release testing laboratories
- Microbiology laboratories
- Bioanalytical laboratories
- Stability incubators and testing facilities
- Method Development laboratories
- Method Validation laboratories.

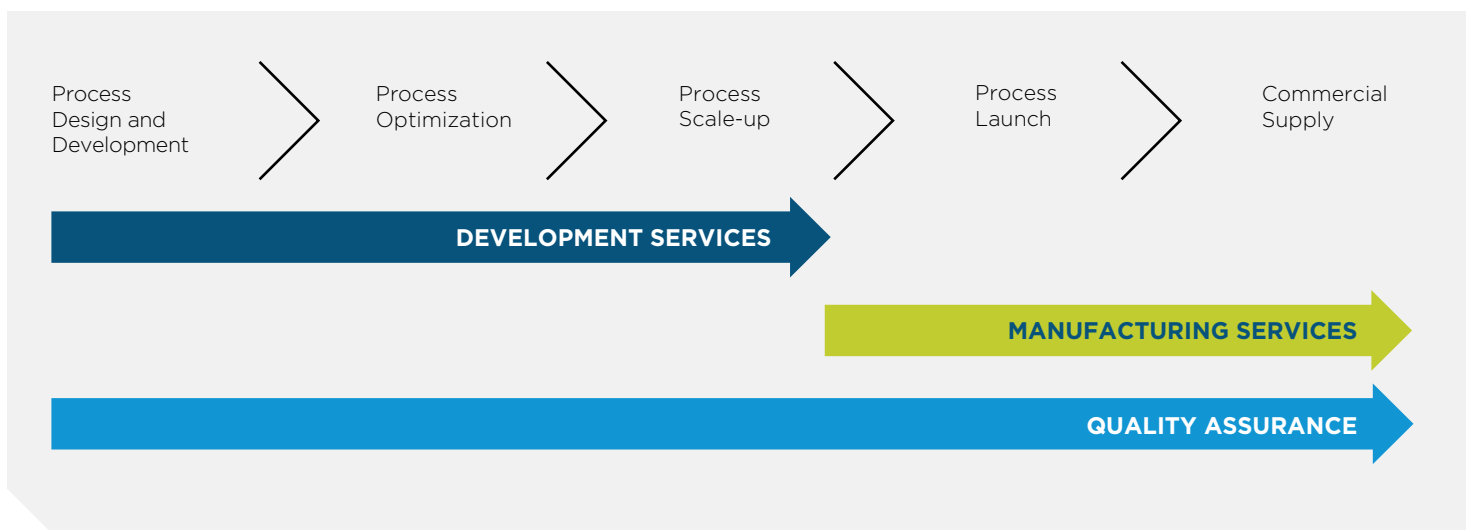
Manufacturing Services

We offer a complete range of pharmaceutical manufacturing capabilities to support your requirements including effective, robust and swift tech transfer, full selection of proven and validated technology and process improvement solutions, competitive pricing, on time delivery and exceptional compliance track record in FDA/EMA licensed sites in the U.S. and EU.





Our Wide Range of Services Sets Us Apart



For seamless tech transfer you can take advantage of our integrated facilities

Scale-up and manufacturing capabilities in U.S. and Europe

Since 2001 we have developed 12 products which have been launched in the U.S. and international markets. The majority of our 500+ staff have 10+ years pharmaceutical experience.

Athlone, Ireland Facility



- Located on 40 acres site, the facility has approximately 505,000 square feet of space
- FDA/EMA-licensed
- The facility has an equipped capacity of 2 billion unit solid oral doses

Gainesville, GA, U.S. Facility



- Located on 148 acres of land, the facility has approximately 87,000 square feet of space
- Includes 288 pallet vault built in accordance with DEA specifications
- FDA/EMA/DEA-licensed
- The facility has an equipped capacity of 500 million unit solid oral doses

Capabilities and Facilities

- Dedicated research, development, scale-up and commercial manufacturing
- Modern facilities in Europe and U.S.
- Development and tech transfer capabilities
- Formulation through scale-up and full scale manufacturing
- 2.5 billion units annually in solid oral dosage form manufacturing capacity
- 270,000 square feet of cGMP manufacturing facilities
- Excellent compliance record
- Packaging facilities U.S. and Ireland
- Mature infrastructure
- DEA approved controlled substance manufacturing plant in U.S.
- Product manufacture for U.S., European and Japanese markets as well as the emerging markets of India, China and Brazil.

Capabilities in detail

Modern Solid Oral Dose Facilities to fit your Precise Product Requirements

We offer a significant advantage in outsourcing – a broad range of services and expertise integrated to one company – based in the U.S. and Europe. This approach reduces the need for technical transfers from product development and clinical trial suppliers to commercial manufacturing sites, enabling efficient scale-up from formulation to commercial production. By providing the whole process in this integrated manner, we have been able to recommend ways to improve production methods – reducing partner risk and also improving efficiencies.

Process and Equipment List

Modern processes and equipment for fit your precise product requirements including:

- Milling
- Screening
- Blending
- Wet granulation (high shear and fluid bed) for solvent and aqueous processing
- Bead coating (organic solvent and aqueous based) using Wurster FBP, CF granulation and pans
- Tableting
- Film coating and sugar coating
- Encapsulation (powder, bead, dual fill)
- Finished product packaging (bottle/blister/vial) including cold chain capability
- Controlled Substance manufacture
- Release testing – EU QP Service available for U.S. clients doing business in Europe

Packaging Facilities and Capabilities

Experienced staff skilled in areas of package engineering and testing, focus on specific packaging requirements, industry regulations and guidelines to meet your product needs and timelines. We also have expertise in the handling of Schedule II compounds.

Service offerings:

- Bottle filling and packaging
- Blister packaging – PVC, Foil
- Modern defect detection and rejection systems
- Access to hand packaging area for ‘special’ presentations
- Artwork management

Warehouse Capabilities

- Fully Automated Movement Control System (MCS)
- MCS fully integrated with SAP inventory management
- Storage Capacity of >4,000 pallets and 100 Intermediate Bulk Containers (IBCs)
- Cold storage facility

Best in Class Systems

Our dedication to best-in-class systems underlies our commitment to providing the highest quality service to our partners.

Enterprise Systems:

- SAP BW SEM
- Business Objects Reporting
- Core Pay and Time/ADP eTime
- Performance & Compensation Management System

Networks:

- Microsoft Active Directory
- MS Outlook 2007
- Oracle / MS SQL Databases
- Nortel / Cisco LAN / WAN
- Intranet

Laboratory Systems:

- Sample Manager LIMS
- Chromatographic network system - Empower
- Dissolution - ICALIS

Maintenance Management:

- PEMAC/Maximo (PMs, Work Orders)
- Compucal (Calibration Management)

Manufacturing:

- Highly automated manufacturing equipment utilizing SCADA and iFix control Systems
- Building Management System controlling temperature, pressure and humidity
- Fully automated lights out warehouse, integrated with SAP

Packaging:

- Vial labelling and cartoning
- Blister
- Bottle.

From initial development through clinical scale up and manufacturing with ongoing customer support

Alkermes Contract Pharma Services is a scalable solution that keeps up with your product and business as it grows.

	DEVELOPMENT SERVICES	
	Phase 2	Phase 3
Integrated approach from initial development through to scale up and manufacturing with on-going customer support		
Formulation Development		
Drug Optimization Technology Platforms		
Analytical Methodologies		
Quality By Design		
Clinical Batch Manufacture		
Stability Services		
Regulatory Support		
GMP/EHS Compliance		
Quality Testing		
Operational Excellence		
Process Design		
Pilot Scale Process Optimization		
Process Validation		
Project Management		
Facility Design and Build		
Customer Relationship Management		

Our legacy of quality and environmental health & safety

In the global pharmaceutical marketplace your reputation is built on quality. When you partner with Alkermes Contract Pharma Services we provide you with the confidence to ensure your product will stand up to its promise of quality.

A number of Operational Excellence (OE) initiatives have been developed and executed to embed a process improvement culture within our manufacturing facilities, with a focus on reducing variability and eliminating waste. Problem solving throughout the organization is approached in a collaborative and mature manner by focusing on the needs of the customer, empowering employees, and optimizing existing activities in our manufacturing, scale-up and development processes.

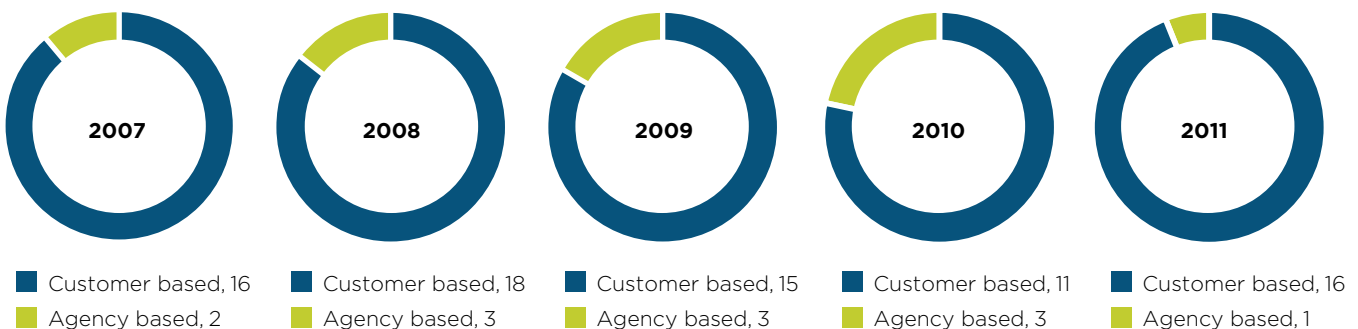
A systematic training program over the past five years has meant trained problem solvers (black belts, green belts and yellow belts) can anticipate, overcome and improve workflow challenges.

Extensive Laboratory Systems in place including: a SAP based ERP system with full adaptation of the associated Quality Module; Sample Manager LIMS; Chromatographic network system - Empower; Dissolution - ICALIS and an extensive array of stand-alone analytical techniques.

Our Legacy of Quality

We have a proud history of quality with multiple regulatory authorities. There is a culture of 'Building Quality' into all we do and this message is continually reinforced at all levels in the organization. We have an excellent compliance record with regulatory agencies including EMA and FDA where, for example, the Gainesville plant has enjoyed zero 483's in its last three successive inspections.

2007-2011 Audit History



Environmental Health and Safety Programs

For the protection of our employees and our environment, we operate an integrated Environmental Health and Safety (EHS) management system, managed by our dedicated Health and Safety Department. We strive to conserve resources and eliminate environment, health, safety effects and risks that may be associated with our products, services and operations.

Speed to Market

At our Athlone site, we received zero non-conformances in our last audit. We are committed to responsible environmental stewardship practices at all of our sites. As part of our Environmental Management System we operate in full compliance with all relevant environmental regulatory requirements meeting established objectives and targets.

Demonstrated Successful inspections From:

- Food & Drug Administration
- Irish Medicines Board
- Environmental Protection Agency
- Health & Safety Authority
- Client and Consultant Audits.

Inspection Ready Status and Continuous Quality Improvement is reinforced by our extensive self-inspection program and corrective and preventative action database.

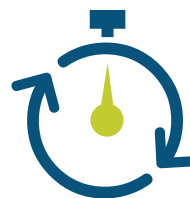
A Suite of Performance Metrics Measured and Available for Our Partners including:



Right First Time



OTIF



Cycle Times

Locations and Contact Details



Wilmington
Scale-up and
Manufacturing facility

Gainesville
Development, Scale-up
and Manufacturing facility

Dublin
Administration office
and HQ for Alkermes plc

Athlone
Development, Scale-up
and Manufacturing facility

If you would like further information on how we can be your outsourcing partner of choice, contact us on:

Alkermes Contract Pharma Services

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Cell/Mobile: +353 86 023 2273

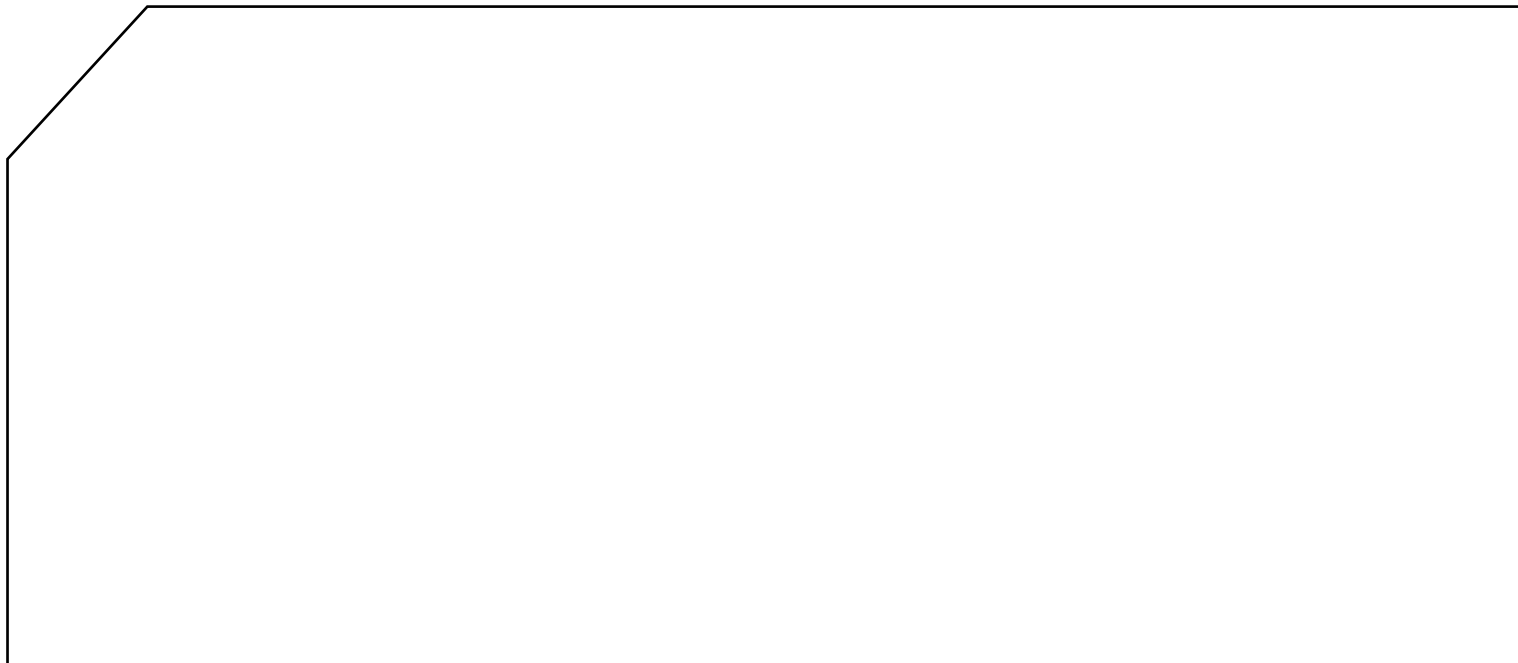
contract@alkermes.com



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