

Clinical Supply Services

Clinical supply services that meet the demands of the global market



Catalent[™]

Integrated resources. Seamless support. Superior project management.



In today's challenging clinical environment, every project is different. Changes occur frequently during the development phase that require unique solutions and a high degree of flexibility. Catalent is a partner that not only offers creative solutions but provides the flexibility and integrated global resources necessary for clinical trial success.

It's critical to have a partner that can provide the full spectrum of support: global clinical supply services, an extensive logistics network, state-of-the-art data management and superior project management. Catalent provides the support that's easy and seamless to your organization, all with our unsurpassed dependability and experience.

During the clinical trial phase, reliable project management and the right resources can ensure that your product moves swiftly toward commercialization. Catalent can help you realize your product's promise and potential by delivering on our commitment to customers: to provide the highest-quality and most comprehensive clinical trial support on the market.

The Catalent commitment is backed by a number of distinct attributes:

- **Industry-leading experience and resources**—over 25 years in the clinical supplies industry and a proven track record in worldwide logistics management, project management and regulatory affairs.
- **Global infrastructure**—our facilities in the U.S., the U.K. and Germany are fully inspected and certified by the appropriate U.S. and European regulatory agencies, allowing us to support global studies from any site.
- **Unmatched capabilities**—manufacturing and packaging for all dosage forms plus proprietary compliance packaging solutions to help you improve study outcomes.

Rated by our customers in a third party loyalty survey^[1] as providing a **higher level of service on key project management attributes** than the leading competitors, Catalent Clinical Services has a demonstrated track record of excellence.

Catalent supplies clinical trial materials through an integrated network dedicated to accelerating your product's path to market. We offer a unique and complete solution:

...**the capacity** to provide advanced clinical manufacturing and analytical support

...**the expertise** to manage even the most complex clinical packaging requests

...**the insight** to handle all your regulatory challenges and distribution needs

...**the flexibility** to provide global capabilities with local service and best-in-class project management

^[1] 2006 Loyalty Research Center Survey with Respondents selecting a leading clinical supply services benchmark from a comprehensive list of competitors. Attributes rated include follow through, technical expertise, understanding your needs, being responsive, being flexible, having authority to handle all your issues, providing batch records and approvals in a timely manner.

Partnering the right science with the right systems

Catalent clinical supply teams—including expert resources in clinical manufacturing and analytical support—work together to deliver a seamless service continuum as your product moves towards commercialization.

Clinical Manufacturing

Our clinical manufacturing professionals employ innovative solutions and proven processes to ensure that your timelines are achieved.

We provide:

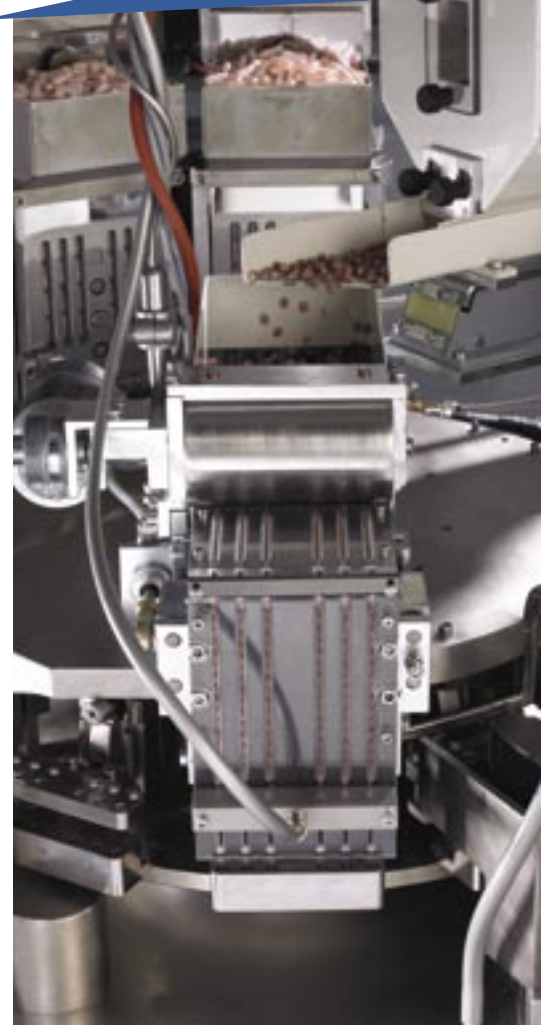
- Global procurement and deblistering of comparator drug products
- Fully automated over-encapsulation of tablets, capsules, pellets and other solid dosage forms in various combinations
- Multi-product over-encapsulation
- Blending and granulation capabilities
- High-speed active and placebo capsule manufacturing
- 100% check weighing of all capsules
- Customized fills
- Tablet manufacturing, including matching placebo tablets

Analytical Support

Our experienced analytical teams have the expertise and the systems to supply quality analytical services within your timelines.

Our services include:

- Microbiological testing
- Release testing
- Stability testing
- Incoming analysis and ID testing
- Method development/validation
- Preparation of technology transfer protocols



Delivering the total package

Clinical Packaging

The Catalent packaging network sets the industry standard for quality, capacity and speed. We have dedicated teams specializing in everything from package design to labeling and assembly. All activities are coordinated by strong project management teams with status updates communicated on a frequent basis. Our resources allow us to customize the ideal packaging solution in an innovative and efficient manner.

Package engineering and design

- Comprehensive in-house design and manufacturing
 - Tooling
 - Cards/wallets and kits
- Proprietary child-resistant/senior-friendly technologies
- Patented, patient-compliant delivery systems (including unit-dose)

Comparator/additional product services

- Global procurement of comparator medication
- Baseline therapies
- Rescue medication

Primary and secondary packaging

- Accurate filling of API into bottles or capsules for Phase I supplies
- Blister packaging
 - Thermoforming
 - Cold forming
 - Multiple-product primary packaging
 - In-line printing
 - Vision systems
- Flow wraps
- Bottle filling
 - Fully integrated lines
- Liquid and powder filling into sachet/pouch
- Card/wallet sealing
- Specialty-product capabilities
 - potent compounds, cytotoxics, hormones, cephalosporins
 - moisture-sensitive and oxygen-sensitive products
 - cold chain products including refrigerated, frozen and temperature-sensitive
 - controlled drug substances



Labeling and assembly services

- Multi-language labeling
- Randomization services
- In-house printing of labels plus code-breaking devices
- Open-label, double-blind labels and unblinding envelopes
- Manual and automated label applications
- Barcode labeling capabilities
- Patient kit assembly

QP release

- Multiple QPs at each site
- U.S. site approved as meeting EU GMP standards



Solutions without borders

Warehousing and Distribution

Site-to-site connectivity—coupled with storage, shipment and tracking resources—gives Catalent the ability to provide seamless supply chain management. From our warehouses to your investigational sites around the globe, we make sure the correct product gets to the right place on time.

Our material and logistics management capabilities include:

- cGMP warehousing and high-capacity storage
 - Storage and handling of DEA-registered Schedule II-V products
 - Cold-chain inventory management, including refrigerated and frozen capabilities
 - Customized inventory management systems
- Industry-leading distribution and return-drug services
 - International presence, experience and scale with facilities in the U.S., the U.K. and Germany
 - Cold-chain distribution management including refrigerated and frozen shipments
 - Global distribution and tracking with experience in shipping to over 75 countries
 - In-depth knowledge of worldwide regulatory and import/export guidelines
 - Return-drug reconciliation and management

The service continuum

Our facilities, extensive service portfolio and professional project management distinguish Catalent as a leader in clinical supply services. We're fully integrated from the laboratory to the production facility to the warehouse—and our sites and systems work together to ensure fast turnaround.

This integration also extends to our commercial operations. Catalent is one of the only providers that can supply:

- Seamless scale-up and technology transfer
- Access to a comprehensive continuum of services ranging from discovery support to launch
- Coordinated project management from the clinical stage to commercialization
- Full regulatory affairs assistance, including regulatory agency liaison, preparation of expert reports, clinical trial applications and compilation of dossiers



Solutions from start to finish

In addition to our clinical supply services, Catalent provides resources that span the full product life cycle.

- **Development**—from discovery support to advanced clinical testing
- **Drug Delivery**—patented and proprietary technologies for all dosage forms
- **Manufacturing**—for oral solids, softgels and topical, sterile and biologic drugs
- **Packaging**—clinical and commercial packaging and printing

Our global facilities

10381 Decatur Road
Philadelphia, PA 19114
USA

Wingates Industrial Park
Westhoughton, Bolton
Lancashire BL5 3XX
United Kingdom

Steinbeisstraße 2
D-73614 Schorndorf
Germany

About Catalent

Our technical expertise and global experience enable our customers to focus on their core strengths. In an industry where innovation, time-to-market, and supply chain reliability are critical, no other company helps overcome formulation hurdles, achieves approval milestones, and meets market needs more effectively than Catalent.

With experience in more than 100 countries, extensive knowledge of the pharmaceutical, biotechnology and consumer healthcare markets, and a global facility network that spans five continents, Catalent is well positioned to serve you, wherever you do business.

Catalent Pharma Solutions

14 Schoolhouse Road
Somerset, NJ 08873 USA

T (866) 720 3148

F (732) 537 6480

www.catalent.com

sales@catalent.com