

Global Regulatory Services

# Delivering regulatory solutions throughout your product's lifecycle



Catalent™

## About Catalent Pharma Solutions

Catalent is one of the leading providers of advanced dosage forms and packaging technologies as well as development, manufacturing, and packaging services for pharmaceutical, biotechnology, and consumer healthcare companies in nearly 100 countries.

Taking the specific needs of a product or customer into account, we employ our scientific, regulatory, operational, and commercial resources to form a customized and integrated approach. Utilizing our decades of experience and constantly expanding knowledge, we can often help our customers streamline project plans, shorten timelines, and better manage risk.

With proven global, strategic expertise that extends from the US to European, Asian, Canadian, and South American markets, Catalent provides the regulatory solutions to move your compound efficiently through all phases of research and development and to help bring your product to market faster.

We offer an extensive global consulting portfolio that includes:

- Worldwide scientific and regulatory strategies
- Project management and general drug development
- Nonclinical and clinical development strategies
- Regulatory submissions at investigational and marketing stages
- Electronic regulatory publishing services

**Minimize your product's development time...  
maximize your product's time on the market.**



### Why partner with Catalent?

Catalent provides comprehensive global regulatory and clinical support services to drive successful, cost-effective, and timely approval for pharmaceutical and healthcare products.

Consider us first because of our:

- Track record of success with regulatory approvals
- Strategic, global approach to regulatory planning and product development
- Global network of regulatory experts
- Experience with established and novel pharmaceutical dosage forms
- Expertise in a wide range of therapeutic categories
- Continuity of service from the lab to the market

# Our goal is to help you achieve your regulatory objectives

Our capabilities include:

## Documentation

- Generation, compilation, and/or maintenance of all types of regulatory documentation
- Comprehensive, in-depth technical and medical writing
- Information-research findings and expert opinion reports

## Regulatory guidance

- How to prepare all phases of product development and document submissions
- Development and coordination of worldwide submission objectives
- Development strategies, responses to warning letters, inspections, and clinical events
- Product development, intellectual property, quality issues, line extensions, and generic development

## Liaison

- Communicate with regulatory authorities
- Long-term interactions with United States, European, Asian, Canadian, and South American health authorities



## Analysis

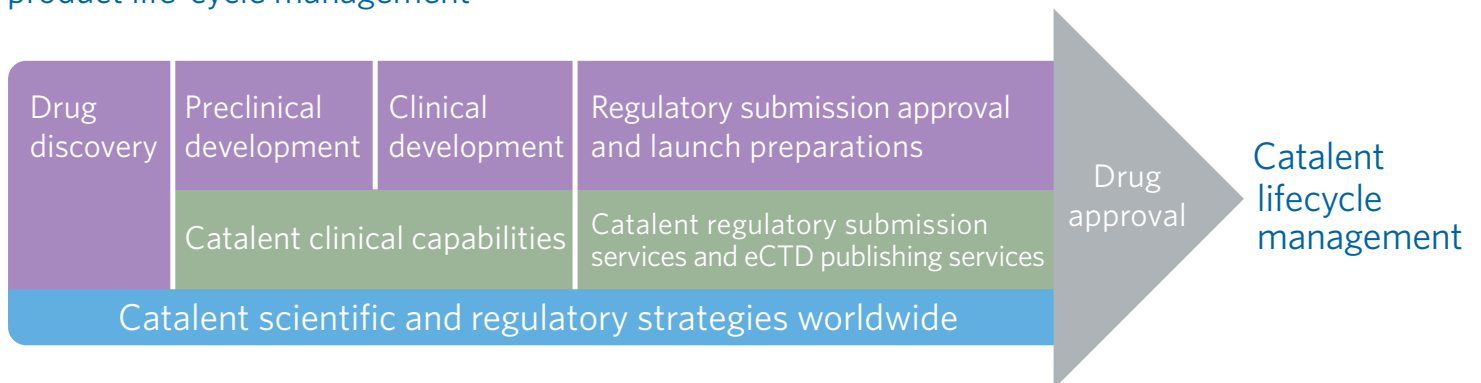
- Product potential analysis
- Product development planning

## Management services

- Product life-cycle management—providing compliance management and leading product-development advice on intellectual property, quality issues, line extensions, and generic development
- Access to broad network of in-house specialized regulatory and development experts

**We can meet the regulatory challenges to optimize your research investment and help expedite your product's regulatory approvals.**

## Strategic consulting and product life-cycle management



# Uninterrupted service from laboratory to market

## Clinical capabilities

Catalent maintains in-house clinical experts who ensure scientific integrity and cGCP compliance of all development data—a prerequisite for a commercially successful product.

We also provide:

- Program management
- Development plans
- Nonclinical and clinical study design, protocol development, and study report preparation
- Identification and coordination of development teams
- Selection, qualification, management, and monitoring of nonclinical study sites, clinical trial sites, and clinical research organizations (CROs)
- Preparation and evaluation of Investigator's Brochures, INDs, ANDAs, NDAs, postmarket safety reports, and informed consent forms
- Clinical supply management, including labeling and packaging
- Liaison activities with regulatory authorities
- Package inserts/leaflets:
  - Development
  - Readability



Catalent specializes in the management of regulatory submissions, ensuring the quality, consistency, and technical validity of all product-specific documentation.

Catalent provides preparation of chemistry, manufacturing, and controls (CMC) documentation for drug substances and finished formulations in the US, Europe, Asia, Canada, and South America for all dosage forms.

## Extended range of services to support your regulatory needs

### Compliance services

Catalent provides manufacturing, testing, and packaging audits as well as complete compliance/validation programs.

Our specialty services include:

- Worldwide cGMP plant audits (active pharmaceutical ingredients, drug products, biologics, medical devices)
- Contract laboratory audits
- Vendor qualification audits
- Design of cGMP compliance programs, including Standard Operating Procedure (SOP) development
- Preapproval Inspection (PAI) readiness and compliance programs
- Consultation regarding cGMP facility design
- Data integrity audits
- 21 CFR Part 11 compliance audits and programs

### Publishing capabilities

Catalent expertise encompasses paper and electronic regulatory submissions, study reports, and publications.

Key Catalent services include:

- Electronic submissions expertise
- Extensive Common Technical Document (CTD) experience
- Technical writing expertise, from highly comprehensive scientific reports to fundamental documentation for premarket and postmarket needs



### Training workshops

Catalent training workshops provide participants and their companies with the opportunity to benefit from our extensive range of experience in the pharmaceutical industry.

Why select Catalent for your staff training requirements?

**Experience**—Over the years, we have provided successful solutions to our customer's various regulatory challenges

**Expertise**—We have extensive dosage form and therapeutic expertise

**Staff development**—We can help your staff understand processes and procedures to optimize regulatory submission success

**Methodology**—Each module is focused on your particular learning objectives to ensure that the learning outcomes that support your strategic goals are fulfilled

**Customized workshops**—We can design a customized workshop to meet your particular requirements, or you may select from our extensive library of workshops that include regulatory, clinical, and compliance topics.

# What can we do for you?

Minimize your product's development time...  
maximize your product's time on the market.

From the time a drug or biologic is just someone's good idea, through the product's entire lifecycle, Catalent can help. Our scientific and regulatory consulting services can help minimize your product's development time and maximize your product's time on the market.

Contact us today. Let us show you how we can help you get your products to market faster, stay there longer, and be more successful.

In addition to our scientific and regulatory consulting services, Catalent provides the following resources that span the full product lifecycle:

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

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