

# The most complete source for your pulmonary and nasal product challenges



## Effective solutions. Every step of the way.

Our global expertise and integrated capabilities make us the world's leading provider of pulmonary and nasal product development, manufacturing and packaging.



Our comprehensive pulmonary and nasal development services can help expedite your product from concept and feasibility studies through all stages of the product life cycle. We provide the expertise you need for:

- Dosage form selection and technology assessment
- Formulation development and analytical testing
- Supplying toxicological and clinical trial materials
- Commercial-scale manufacturing
- Packaging services

Our team has extensive experience with all pulmonary and nasal dosage forms:

- Pressurized metered-dose inhalers (pMDIs)
- Dry powder inhalers (DPIs)
- Nasal sprays and solutions/suspensions for inhalation
- Nebulizers and liquid inhalers

Our outstanding scientific staff has in-depth experience in the inhalation arena. We have been involved in numerous product approvals. Catalent has made significant investments in top scientific talent, technologies, resources and capacity to lead the way into the future.



## Our customized solutions can resolve your unique challenges

Our project managers will collaborate with your team to ensure effectiveness and efficiency. Whether you require only a single service or a comprehensive plan to expedite your product on the path to commercialization, our best-in-class solutions are your best choice for long-term success.

## A full continuum of services

We offer the widest range of capabilities available from a single source including:

- In-depth expertise and experience in pulmonary and nasal sciences
- Thorough understanding of U.S. and European regulatory requirements and submission protocol
- Our track record working with regulatory agencies and industry groups is exemplary
- Our experience includes handling potent compounds and all controlled substances in Schedules I-IV
- Assistance in defining submission strategies on Chemistry, Manufacturing and Controls (CMC) to avert potential issues by using the best possible solutions
- Knowledge and insight gained through supporting industry expert groups (EPAG, ITFG, PQRI)

We work with 46 of the top 50 global pharmaceutical companies, 28 of the top 50 global biotech companies and many of the most promising emerging firms.



## Catalent offers:

- A combination of global reach plus a breadth of capabilities and expertise unparalleled in the industry
- Customized solutions to accelerate your product's development
- A strong project management network and approach that results in productive, collaborative relationships

# A full range of offerings... focused on your success

## Preformulation

Our capabilities can benefit your product right from the conceptual stage. Beginning with our formulation feasibility team, we will help you address issues and situations with your products before they become problems.

Our preformulation services include:

- Drug candidate screening, salt selection and lead optimization
- Solubility in propellant and cosolvent systems
- Drug-excipient compatibility
- Formulation-container closure system compatibility
- Micrometric properties - particle size, density, flow and more
- Solution/solid-state stability and characterization studies
- Method evaluation, optimization, development and validation
- Method transfer
- Particle size reduction (e.g., sub-contrast micronization, spray drying)
- Physico-chemical properties evaluation

## Dosage form development

Technical requirements...characterization of aerosols...device performance... cGMP compliance...and more. We have a unique understanding of the dosage form development challenges you are up against, and we are here to help by offering expertise in:

### Pressurized metered-dose inhalers

- Formulation selection and optimization
- Canister, valve and actuator selection
- Spacer and add-on device testing



### Dry powder inhalers

- Powder evaluation and characterization
- Formulation of low- and high-dose powder systems
- Formulation of carrier-based or pure drug aggregated systems
- Evaluation of moisture effects on powder properties, formulation stability and aerosol performance
- Device evaluation and selection

### Nasal sprays

- Formulation selection and optimization
- Pump and container selection
- In-vitro bioequivalence testing
- Both sterile and preserved production capabilities

### Solutions and suspensions for inhalation

- Formulation selection and optimization
- Manufacturing of Blow/Fill/Seal nebulizer solutions
- Container selection
- Aerosol characterization of formulation/nebulizer system combinations



## Product testing

Our analytical teams have faced many of the very same challenges you face today. We offer an insider's knowledge of complex testing processes and procedures. This complements our product development and aids our understanding of test methods versus product-specific troubleshooting. Our testing services include:

- A wide range of laboratory space featuring flexible configurations
- Controlled temperature and humidity laboratories
- Manufacturing validation support (process and cleaning validation)
- Release and finished product testing
- Particle sizing and spray analysis
- Drug and delivery assays
- Stability studies (ICH and custom conditions)
- Structural elucidation of drug-related impurities and degradation products
- Extractables and leachables studies - world-renowned scientific staff

## Clinical and commercial manufacturing

We offer complete clinical trials materials preparation in support of Phase I-IV studies for all pulmonary and nasal dosage forms and provide seamless technology transfer to our commercial manufacturing facilities, including:

- MDI, DPI, nasal sprays and nebulizer production capabilities
- Fully automated MDI production lines
- Class 10,000 space
- Potent compound handling capabilities
- DEA-controlled substances licenses
- Flexible manufacturing and warehouse space
- Build to suit
- "Roll in - roll out" equipment and processes
- Warehousing
- Vendor qualifications



Catalent has made significant investments in top scientific talent, technologies, resources and capacity to lead the way into the future.

## Focused on your success

From drug formulation and development, through commercialization and distribution, Catalent is the most complete source for best-in-class solutions that help products perform at their full potential. Find out for yourself why so many manufacturers—large and small—trust their products to us.

## 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, sterile and biologic drugs
- **Packaging**—clinical and commercial packaging and printing

## 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.

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