Intelligent collaboration with **Pfizer CentreOne**

Pfizer CentreOne

Listening. Solving. Guiding.

Welcome to Pfizer CentreOne. We're a global CDMO embedded within Pfizer and a leading supplier of specialty APIs. Working with our customers, we combine our technical and commercial knowledge with open dialogue to solve challenges – we call this intelligent collaboration.

More collaboration, better solutions.

Our collaborative approach means more efficient routes to market and high-quality APIs and drug products.

Backed by Pfizer resources, we have the experience, flexibility and scale to deliver technical expertise, global regulatory support and long-term supply.

Great science. Global reach. Genuine results.

We offer CDMO services focused on:

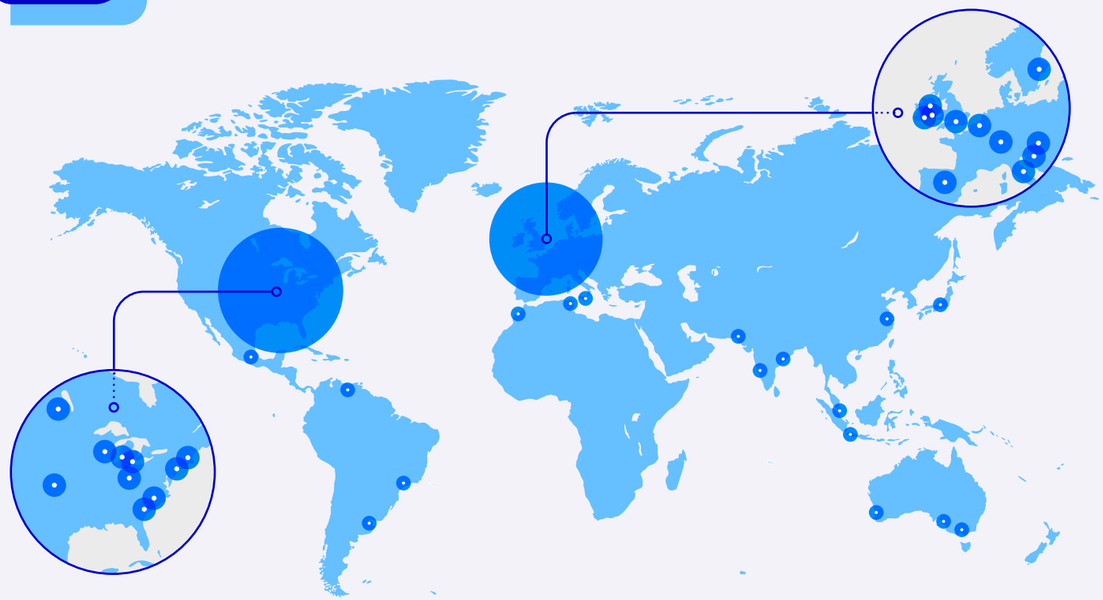
- Small molecule APIs
- Large molecule biologics
- Oral solids
- Sterile injectables

We sell APIs and intermediates manufactured in the U.S. under Pfizer quality standards:

- Steroids
- Hormones
- Antibiotics
- Prostaglandins

Our development and commercial offering

Our global manufacturing network includes 35+ sites:

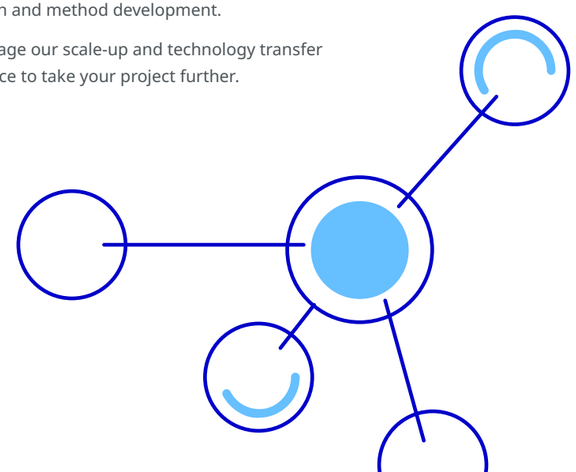


Development Services

Our global network delivers end-to-end development and manufacturing expertise. We will partner with you to take your molecule from early clinical phases through commercial manufacture and lifecycle management.

We offer full process development and optimization, including formulation, manufacturing, analytical testing, validation and method development.

We leverage our scale-up and technology transfer experience to take your project further.



Our capabilities at a glance:

- Clinical manufacturing
- Development of cell cultures and lab-based fermentation processes
- API synthesis
- Specialized lyophilization development and optimization technology
- Manufacturing process optimization
- Safety screening and hazard evaluations
- Chemical and analytical development
- Scale-up from pilot to commercial
- Plant scale fermentation development
- Regulatory support – pre and post-launch

Regulatory Affairs Services

- Dedicated regulatory resources protect your confidentiality
- Access to Pfizer's global regulatory expertise and support
- Knowledge of the regulatory impact of manufacturing changes in a given market
- Proactive approach to early engagement with regulators
- Flexible options that provide customized submission support

Development

Scope opportunities:
- Due diligence

Regulatory strategy:
- Clinical trial application author and support

Quality/supply agreement input and review

Commercial

Authoring/ review of the initial submission

Review Agency meetings:
- Serve as liaison with site CMC and QA
- Support for deficiency responses

Labeling development for drug products

Support for launch

Lifecycle Management

Post approval submission:
- Strategy development
- Documentation
- Authoring/review

Annual reports:
- Due date tracking
- Maintenance
- Compilation

International registration support

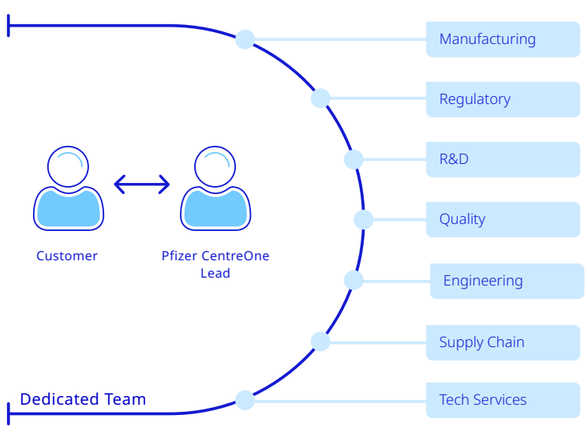
Review and assessment of change controls

Management of associated DMFs

Simplifying the Customer Journey

A dedicated commercial lead:

- Ensures cross-functional support from start to finish
- Creates effective lines of communication and coordination
- Integrates information to improve decision making
- Works with core team members to build strong relationships with customer counterparts fostering team accountability, ownership, and partnership
- Provides formal program management which guarantees continuity throughout the commercial manufacture process



Pfizer's global network allows access to commercial expertise in:

Small Molecule APIs

- Fermentation, biotransformations, complex multi-step synthesis, cryogenic chemistry, hydrogenation, chromatography, halogenations, milling and micronizing

Oral Solids

- Tablets, capsules, semi-solids, wet/dry granulation, blending, coating, extrusion, compression, printing, high containment and hormone manufacture

Large Molecule Biologics

- Microbial fermentation, mammalian cell culture, viral cell culture, vaccines, cytotoxin production, purification and pegylation

Sterile Injectables

- Aseptic and terminally sterilized filling of liquids, powder and suspensions, lyophilization, vials, ampoules, pre-filled syringes, IV bags/bottles, auto-injectors and surgical hemostatic devices

Investment Strategy

We are experiencing an exciting era in drug discovery and development with scientific advances promising future breakthroughs. To make this promise a reality, our manufacturing capabilities must keep pace and look ahead.

Pfizer invests more than $1B a year in our network of manufacturing sites, including state-of-the-art technologies, equipment and facilities.

Quality and Regulatory Expertise Across Pfizer's Global Network

Proven quality system

We assure quality for our customers' products through our proven enterprise-wide Pfizer Quality System approach and our decades of successful development expertise. Most Pfizer CentreOne staff have more than 15 years of experience managing customer programs across a wide range of biologics, complex small molecules and sophisticated dose forms.

Continuous improvement

Pfizer continually invests in its process technologies, analytical capabilities and manufacturing operations to sustain quality and reveal process efficiencies and economies.

Collaboration

Well-synchronized collaboration assures quality. Our dedicated method transfer teams deeply understand FDA and ICH validation guidelines, and work together with our customers to orchestrate smooth, compliant transfers into our sites. Our analytical chemists then collaborate to develop and trouble-shoot process methodology.

Right first-time processes

Focused on efficiency, our quality teams perform in-process testing and/or release with an emphasis on getting it right the first-time so programs can avoid issues that may trigger investigations, delays or batch failures.

Regulatory understanding

Managing regulatory filings and submissions for Chemistry, Manufacturing and Controls (CMC) for complex APIs requires extensive knowledge of the global regulatory landscape. This is especially true in early development stages when proactive regulatory engagement can minimize risks and potentially avoid delays.

We are well versed in global regulatory requirements and can help navigate customers' products through launch, wherever their drug strategies take them.

Let’s collaborate

Visit us at **www.pfizercentreone.com**

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