An altogether different kind of CDMO
An altogether different approach to specialty API supply

Open dialogue. Successful delivery.

We’re Pfizer CentreOne, an altogether different kind of CDMO. As a part of Pfizer and backed by its expert capabilities, we strive to advance customers’ drug development, market launch and commercial supply; helping to deliver breakthroughs that change patients’ lives. Working closely with our partners, we combine our technical and commercial expertise with open dialogue to help lead you to your next breakthrough. Our technical and commercial knowledge with open dialogue to solve challenges – we call this intelligent collaboration.

More collaboration, better solutions.

Our open and collaborative approach to our partnerships 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.


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

Development Services  Clinical & Commercial Manufacturing  Lifecycle Management
A global manufacturing network spanning across 35+ sites:

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.

By drawing upon the scientific power of Pfizer, we help shape your development masterpiece.

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**

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**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
**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.
Discover how we’re altogether different
Visit us at www.pfizercentreone.com