Pfizer CentreOne

A leading global CDMO, powered by Pfizer

We are Pfizer CentreOne, Pfizer's **integrated CDMO**

An altogether different CDMO ready to meet your needs

As an award-winning global CDMO, Pfizer CentreOne uses Pfizer's extensive scientific and technical expertise to manufacture medicines for pharmaceutical and biotech companies like yours. We partner closely with you to help advance your drug development, clinical to commercial launch and ensure long term supply of your product, because for patients waiting, time is life.

Access to Pfizer's go to market experience

We make it easy for you to partner with our Pfizer global network of scientists and technical experts, providing CDMO services across more than 35 sites and six continents around the world.

Backed by Pfizer's resources we have decades of experience to help ensure you get the flexibility, technical expertise, quality assurance and global regulatory support you need.

A legacy of providing a steady supply of critical ingredients

Owning a legacy of quality and industrial safety, we offer APIs and intermediates manufactured in the U.S. under Pfizer quality standards:

- Steroids
- Hormones
- Antibiotics
- Prostaglandins

Leverage cutting-edge development and commercial manufacturing solutions

We offer CDMO services focused on:

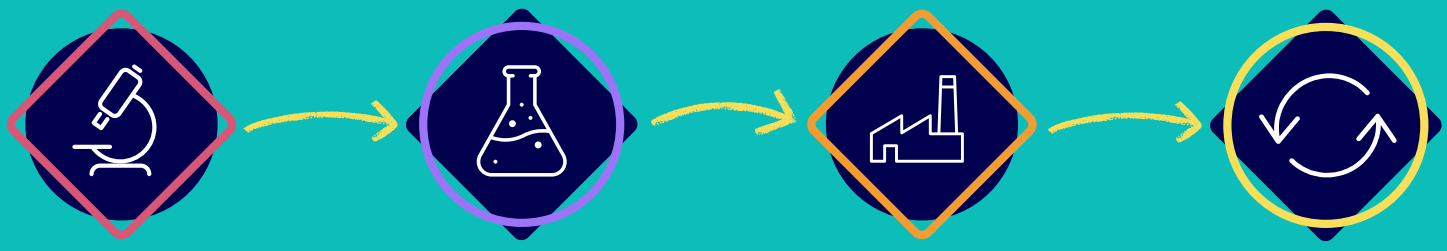
- Small molecules
- Biologics
- Oral solids
- Sterile injectables

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.

Expertise and a global network ready for your manufacturing needs



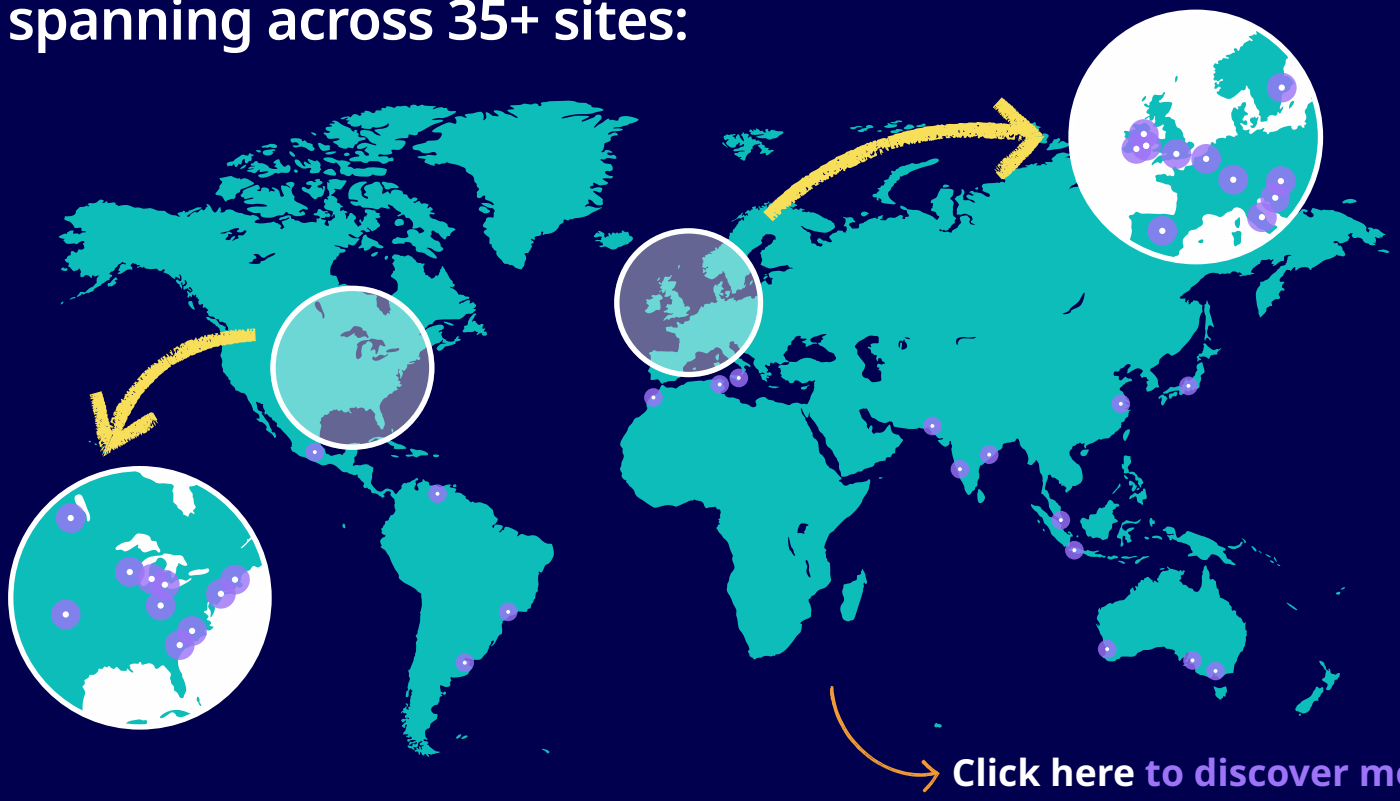
End-to-end development

Early clinical phases through to commercial manufacture

Secured capacity

Lifecycle management

A global manufacturing network spanning across 35+ sites:



Click here to discover more

Development services

We are ready to meet your drug substance and drug product needs with comprehensive development and optimization services encompassing:

- Formulation and scale up
- Method development
- Validation
- cGMP manufacturing
- Analytical and stability testing

We partner with you to take your drug substance and/or drug product from early clinical phases through commercial manufacture and lifecycle management.

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

A dedicated commercial lead helps ensure:

- Cross-functional support from start to finish
- Effective lines of communication and coordination
- Information integration to improve decision-making
- Team accountability, ownership, and partnership
- Continuity throughout the commercial manufacturing process

Our capabilities at a glance:

- Clinical manufacturing
- Scale-up from pilot to commercial
- Development of cell cultures and lab-based fermentation processes
- Plant scale fermentation development
- Manufacturing process optimization
- Specialized lyophilization development and optimization technology
- API synthesis, including organic synthesis, fermentation, purification and particle sizing
- Safety screening and hazard evaluations
- Chemical and analytical development
- Lab & pilot scale manufacturing
- Controlled Substances (II-IV)
- Full range of OEB 1-5
- Regulatory support – pre and post-launch
- Ensuring supply chain reliability; each company in our vast supply chain are evaluated carefully for risk with continuity tracked

Pfizer's global, technical and scientific expertise allows for commercial excellence in:

Small molecule APIs

- Fermentation
- Biotransformations
- Complex multi-step synthesis
- Cryogenic chemistry
- Hydrogenation
- Chromatography
- Halogenations
- Milling
- Micronizing

Biologics

- Microbial fermentation
- Mammalian cell culture
- Viral cell culture
- Vaccines
- Gene and cell
- Cytotoxin production
- Purification
- Pegylation

Oral solids

- Tablets
- Capsules
- Wet/dry granulation
- Blending
- Coating
- Extrusion
- Compression
- Printing
- High containment
- Hormone manufacture

Sterile injectables

- Aseptic and terminally sterilized filling of liquids
- Powder and suspensions
- Lyophilization
- Vials
- Ampoules
- Pre-filled syringes
- IV bags/bottles
- Auto-injectors
- Surgical hemostatic devices

These are our capabilities at glance, contact us here for more information

Discover Pfizer CentreOne Quality Standards

We operate to global quality standards and processes to help ensure the smooth and efficient delivery of your API or drug product.

Culture of integrity & accountability:

Seamlessly integrated into our operations, to help ensure patient safety, product quality and data integrity principles are maintained.

Leadership review:

Robust escalation pathways are established, ensuring Senior Quality Leader involvement of quality related events.

Risk identification & mitigation:

Diligently assess known and emerging risks, taking proactive measures to mitigate them.

Controlled management:

Rigorous control over processes, policies, and procedures, executed by highly skilled personnel.

Monitoring & investigation:

Robust monitoring programs and effective investigation protocols maintain a state of control.

Expertise & scalability:

Exceptional regulatory record across global markets ensures compliance and reliability as your product scales.

Regulatory affairs services

We support you around the globe with our team of regulatory affairs professionals who have access to regulatory requirements for more than 150 countries.

1) **Helping to guide you through development**

With experience handling CMC regulatory affairs issues, we can help you to find solutions that fit your needs.

2) **Keeping your intellectual property safe**

You're safe with us! We have well-established systems in place to help protect your information.

3) **Providing guidance on the quickest regulatory pathway**

If there is a way to expedite a regulatory pathway toward approval, we can partner with you to find it!

4) **Helping to get your asset registered in your selected global markets**

We have access to all the latest regulatory requirements to enable commercialization across the globe.

5) **Offering a fully published Module 3 section (CMC), just like Pfizer**

You will get a Module 3 section (CMC) that fits your needs - all you need to do is drop the CMC module into the rest of your application.

6) **An altogether different regulatory affairs experience**

Our comprehensive regulatory affairs support utilizing Pfizer systems and resources is something no other CDMO can offer.

Protecting your IP is at the core of what we do

We are dedicated to providing you with total peace of mind, protecting your intellectual property (IP) with a robust CARE system:

- **C** — **Controlled:** Your confidential information is stored in a controlled, isolated and secure location.
- **A** — **Agreements:** We define our agreements with you and follow their parameters to the letter.
- **R** — **Rules:** Our organization's policies and corporate guidance materials provide a defined framework for safeguarding your IP.
- **E** — **Education:** Our colleagues are trained to meet the highest regulatory standards when handling IP.

Gain access to Pfizer's global experts

Our global network of experts help ensure a timely, secure, and consistent supply of your product; facilitating early engagement with regulators and offering customized submission support. Meet some of our experts below:

Dave Merkooloff

Technical Services Site Lead | Pearl River, NY, USA

Responsible for technical transfer and validation of antibody-drug conjugates, and immunoconjugates, Dave has over 20 years of experience in commercial and clinical manufacturing to support you throughout your journey.

Rossella Bruni

Site Lead and AD Pfizer Italia | SrL, Ascoli, Italy

With over 23 years of experience at Pfizer, including in multiple leadership roles, Rossella applies her unique insight and expertise in oral solid dose to help meet your drug substance and drug product needs.

Kristof Van Praet

PC1 Site Lead | Puurs, Belgium

Leveraging 17 years of experience in supply chain and procurement and extensive commercial experience, Kristof supports new product introductions, account management and business development.

Edward Bloomberg

PC1 Site Lead | Kalamazoo, USA

Utilizing 26 years of experience at Pfizer, including multiple leadership roles. Ed provides a range of key skills across injectable methodology, warehousing, and logistics operations, ready to support you throughout your manufacturing journey.

We are ready to be your strategic partner to help you change patients' lives - because Time is Life.

Get in touch with our Pfizer experts and start your journey today.

Pfizer CentreOne

www.pfizercentreone.com

Discover how we're altogether different

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