



An experienced CDMO powered by Pfizer to support your biologic on its path to market

Ready to meet your biologic needs with expertise and experience

Welcome to Pfizer CentreOne, a global CDMO with decades of experience in taking your biologics from lab to patient. We leverage Pfizer's cutting-edge solutions to support your biologic drug substance and drug product needs with reliability and quality.

Our capabilities at a glance:

- Lab-scale upstream and downstream process development/process optimization capabilities
- Demonstrated success in product technology transfer and commercial-scale manufacture
- Full analytical capability in-house for in-process controls (IPC), release testing, and drug substance stability testing
- Analytical methods transfer and verification, comparability and stability studies, release testing
- Tech transfer acceleration capabilities at our Sanford facility
- Clinical, launch and commercial supply
- Single use facilities and equipment
- Cold chain handling and warehousing
- Outstanding safety performance
- A strong track record of technical transfer success and on-time in-full delivery

Development services and clinical to commercial manufacturing

From development to life-cycle management, we have the scientific, technical and regulatory expertise across our global network ready for your biologic manufacturing needs.



Achieving better biologics solutions together because for patients, **time is life**

At Pfizer, we can help in the development and manufacturing of a range of therapeutic proteins and antibodies using expression in recombinant organisms.

Designed with logic and delivered with care:

Gene and cell therapies (GCTs)

- 70+ experienced gene and cell therapy Pfizer scientists
- Several years of experience from Pfizer's internal research and pipeline optimization
- Expertise developing and manufacturing scalable viral vectors across multiple serotypes
- Industry-leading yield and productivity ratios
- Batches ranging from 200-2000 litres
- 40+ GMP batches and 100+ transfections
- Gene therapy regulatory expertise

Antibody-drug conjugates (ADCs)

- The world's first commercial approved ADC product (Mylotarg™)
- End-to-end capability from cytotoxic compounds and drug substance intermediates to sterile drug products
- Fermentation, recovery, chemical synthesis and purification capabilities
- High-value formulations in a wide range of vial sizes and doses
- Site designed for cytotoxic drug processing
- Bulk packing of vials in containment trays

Monoclonal antibodies (mAbs)

- Proven history in producing therapeutic proteins and antibodies using expression in recombinant organisms
- Extensive testing experience, bioassays and protein-specific techniques
- Partnering with customers to enable seamless integration across the entire lifecycle of your molecule
- Cell culture medium development and optimization
- Scale-up from lab to pilot to commercial
- Clinical manufacturing Ph 1-3
- Biosafety levels 1-2

Complex biologics

- Production of critical vaccine starting material and protein drug substance intermediate (DSI)
- Process characterization
- Yields optimization expertise
- Pneumo DSI and DS, and polysaccharides and toxoid DSI
- Multi-product trains for manufacturing vaccine intermediates and drug substances for both commercial vaccines and clinical trial materials
- Large-scale microbial fermentation, purification, conjugation, cell banking
- BSL 2+ facility design

The bio-logical choice for life-changing therapies

Discover how we can help accelerate your biologics' journey to market with reliability and quality

Our Pfizer biologics experts are with you every step of the way from a **global network of biologic sites:**



How can our Pfizer biologics experts **help you?**

As an experienced global CDMO partner with a range of biologics capabilities, we can help you skillfully maneuver through complexities, keeping pace with scientific advancements and regulatory requirements - because time is life.



Dave Merkooloff
Technical Services
Site Leader, ADC
Pearl River



Lisa Ann Thimmesch
QA directory of
documentation
and training



Chris Lawler
Business Development
Lead for Gene Therapy
Services



Scott Coury
Senior Manager of
Business Development,
Sanford

Get in touch with our **biologics experts**



Discover how we're
altogether different

Visit us at www.pfizercentreone.com