



Sterile injectables
made with intelligent
collaboration

An altogether different approach to sterile injectables

Sterile injectables made with compelling science

Open dialogue. Successful delivery.

Welcome to Pfizer CentreOne. We strive to deliver on what we promise, which is surprisingly refreshing.

We're a global CDMO backed by Pfizer resources and a leader in sterile injectables. Working with our customers, we combine our technical and commercial knowledge with open dialogue to help solve your challenges, and scale with you every step of the journey.

An open and collaborative approach with Pfizer CentreOne

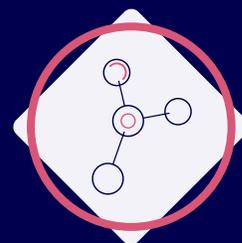
Our open and collaborative approach means we can offer you more efficient routes to market, high-quality sterile injectables and long-term supply assurance, so you always have what you need, when you need it. We've been helping our partners overcome many technical challenges for over 40 years. You can count on us to carefully guide your compound from development through to commercial manufacture. We're dedicated to being your dependable manufacturing partner, at the scale you need.

We're known for our expertise in:

- Complex biologics
- Controlled substances (II-IV)
- Lyophilization
- Sterile suspensions

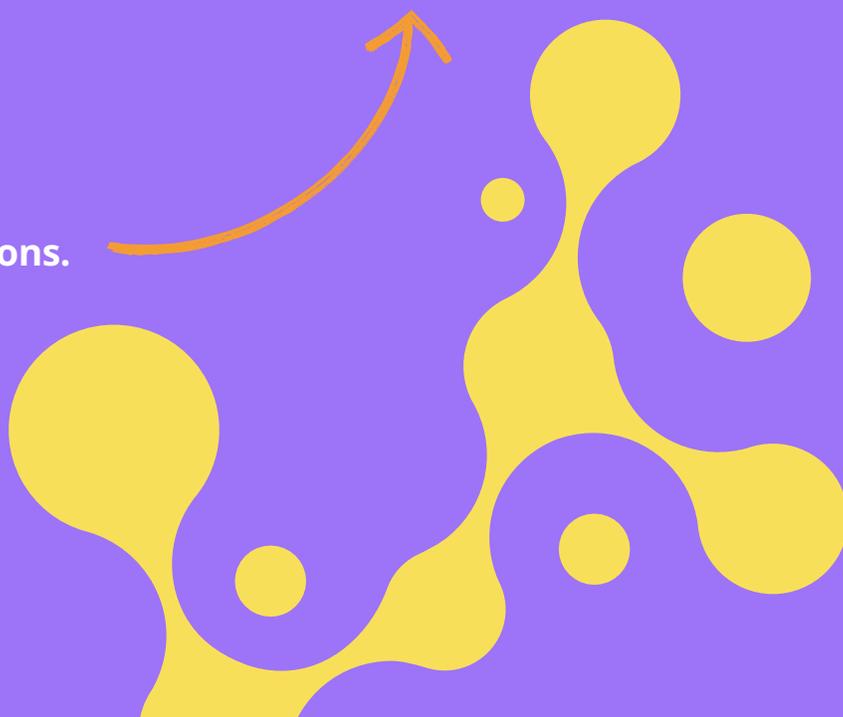
More collaboration, better solutions.

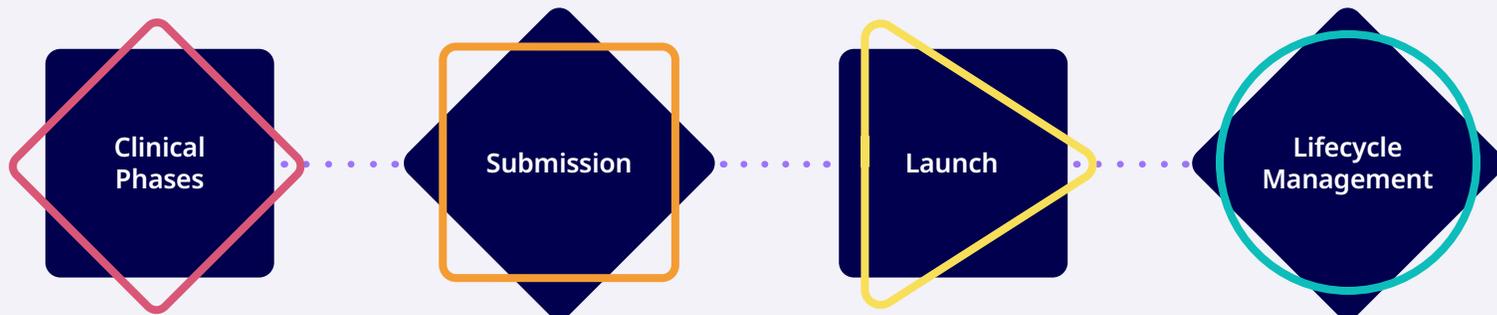
Our sterile injectables manufacturing network includes sites in:



- Australia (Melbourne)
- China (Wuxi)
- Croatia (Zagreb)
- Spain (Algete)
- United States (Kalamazoo, Michigan; McPherson, Kansas; Rocky Mount, North Carolina)

We offer comprehensive regulatory submission support that has established approvals around the globe, including FDA (United States), EMA (European Union), ANVISA (Brazil) and PMDA (Japan).





- Development & manufacturing
- Technical transfer
- Formulation
- Scale-up/validation

- CMC preparation
- Final package
- Pre-approval inspection

- Drug to market
- Production efficiency studies

- Cold-chain management
- Supply/distribution
- Drug delivery expansion

Capabilities at a glance:

Manufacturing

Clinical
Commercial

Services & processes

Aseptic fill-finish
Terminal sterilization
Lyophilization
Combination products

Compounds

Biologics
Small molecules
Controlled substances (II-IV)
Liposomal
Cytotoxics (liquid)
Vaccines (inactivated)
Monobactam
Sterile suspensions
Potent drugs
Hormones, steroids & prostaglandins

Other substances

Diluents

Container closure systems

Vials
Syringes
Ampoules
Cartridges

Secondary packaging and global supply chain services

- Packaging capabilities include: bulk (bright stock), single-/multi-unit cartons, kitting and multi-lingual labelling and package inserts
- Secondary packaging development, including customized kits
- Serialization (track and trace) programs
- Drug product storage and distribution: ambient (+15°C to +30°C), controlled room temperature (+15°C to +25°C), refrigerated (+2°C to +8°C), frozen (-15°C to -25°C)
- Cold chain logistics
- EU gateway services, including quality release support

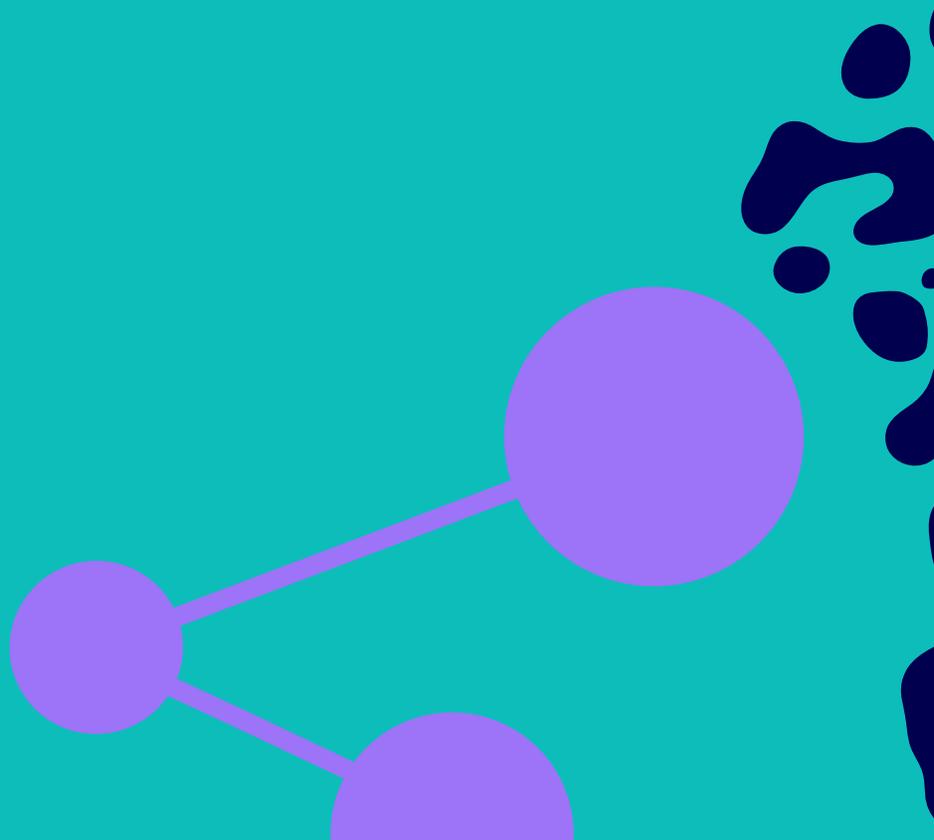
Regulatory overview cGMP inspections

FDA, EMA, ANVISA, GCC, GCC-DR, Health Canada, Korean FDA, MHRA, NMPA, PMDA, Taiwanese MOH, TGA, Turkish MoH, AIFA, COFEPRIS, EAEU, MOITRF, Kazakhstan, Belarus



**Discover how we're
altogether different**

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