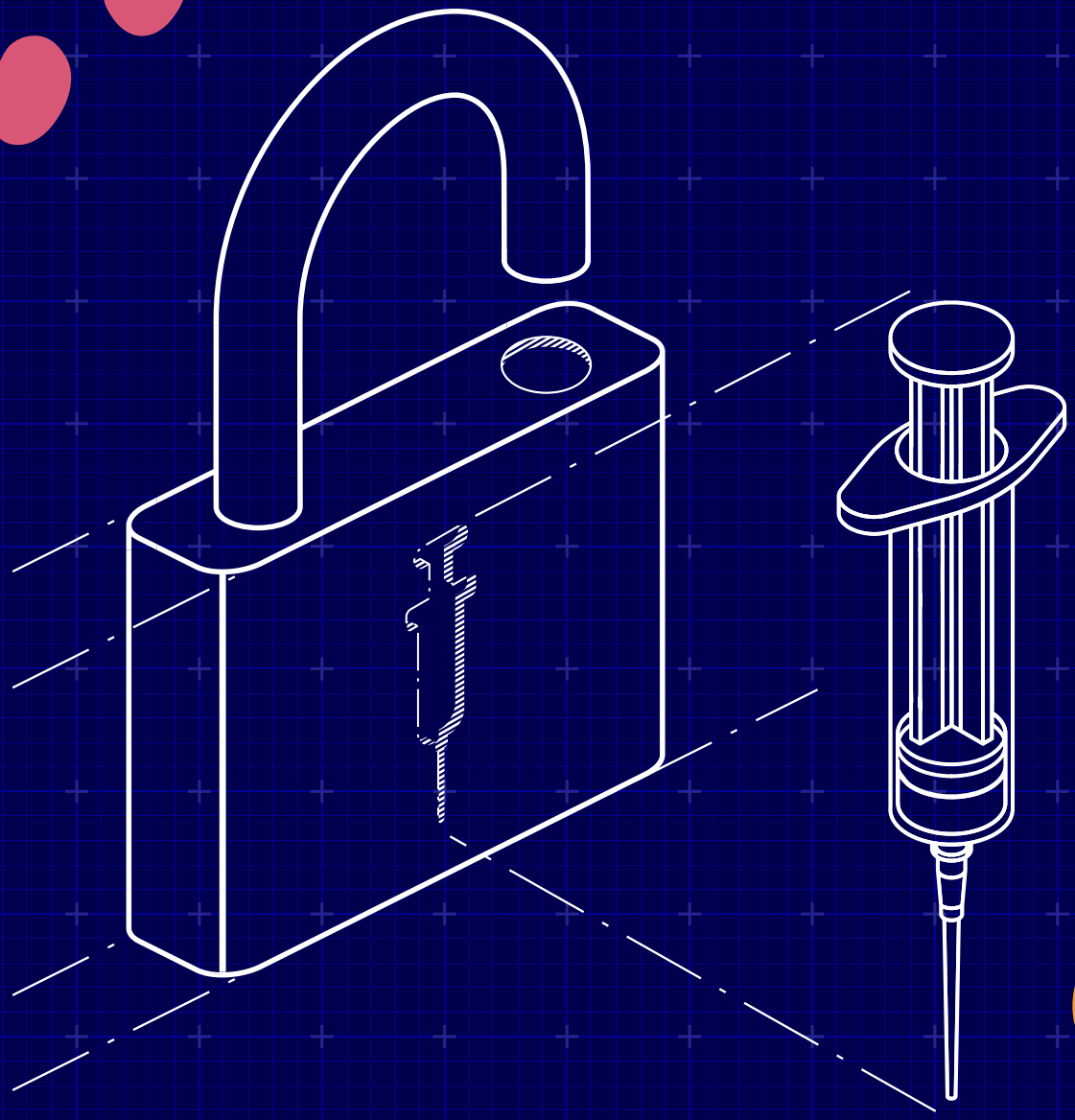
Pfizer CentreOne



Unlocking the potential of your sterile injectable

Pfizer CentreOne

Exact SI-ence

Supporting the unique needs of your sterile injectable, as a leading global CDMO

Expansive expertise and specialized capabilities

Time is life, so in the rapidly evolving sterile injectable space, expertise is key to ensuring the safe, successful delivery of your innovative therapeutic to the patients who need it. Around the world, our Pfizer scientists and manufacturing experts leverage their decades of experience alongside our specialized facilities to unlock the potential of your sterile injectable drug substance (liquid or lyophilized) and product (PFS, vials, cartridges).

Uncompromising quality and reliability

To help ensure speed while maintaining consistently high quality of your product, robust processes are in place developed and optimized by our global experts. With dedicated quality and analytical teams, we are here to support your needs as your project progresses from clinical to commercial. Specialized technologies like automated fill lines with digitized technology help to ensure integrity in data, safeguard sterility and secure safety.

At Pfizer CentreOne we aim to provide supply chain reliability by carefully evaluating each of the companies in our vast supply chain for risk and business continuity track record.

A flexible & transparent global partner

Our global Pfizer experts are dedicated to unlocking creative solutions to meet your needs using our light-speed principles: from identifying lead-time efficiencies to meeting your evolving expectations and overcoming roadblocks in supply. With a "right first time" approach, we work to keep you up to date in real time, leveraging protocols for data sharing.

We're at the forefront of complex SI:

- Expertise with complex therapeutics such as ADCs, novel vaccines and gene and cell therapies
- Including the capability to meet your needs across various delivery mechanisms
- With extensive capabilities for both liquid and lyophilized filled pre-filled syringes and vials

We continually improve and invest in our global sites:

- Australia (Melbourne)
- Belgium (Purrs)
- China (Wuxi)
- Croatia (Zagreb)
- Spain (Algete)
- United States (Kalamazoo, McPherson, Rocky Mount, Pearl River, Andover, Sanford)

Clinical phases

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

Submission

- CMC preparation
- Final package
- Pre-approval inspection

Launch

- Drug to market
- Production efficiency studies

Lifecycle management

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

Regulatory experience for more than 150 countries, supporting you around the globe

Capabilities at a glance:

Manufacturing

- Clinical
- Commercial

Services and processes

- Aseptic fill-finish
- Terminal sterilization
- Lyophilization
- Combination products

Compounds

- Biologics (ADC, gene and cell therapy, mAbs, other complex)
- Vaccines (inactivated and novel technologies)
- Small molecules
- Controlled substances (II-IV)
- Cytotoxics (liquid)
- Monobactam
- Sterile suspensions
- Hormones, steroids and prostaglandins
- Capability across various delivery mechanisms

Other substances

- Diluents

Container closure systems

- Vials
- Pre-filled syringes
- Ampoules
- Cartridges

Secondary packaging and global supply chain services

- Packaging capabilities include: bulk (bright stock), single-/multi-unit cartons, kitting, 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

From liquid and lyopholization to pre-filled syringes, vials and cartridges – helping you unlock the potential of your sterile injectable.

Ready to unlock the potential of your sterile injection?

With a strong reputation for reliability & quality while delivering at speed, click here to learn how we can support your entire path to commercialization.

As an experienced global partner with broad SI capabilities, we can help you skilfully maneuver through complexities, keeping pace with both scientific advancements and regulatory requirements - because time is life.

Kristof Van Praet
Pfizer CentreOne site lead, Puurs

Eva Sanchez
Business development manager and Pfizer CentreOne site lead, Algete

David McAllister
Business development manager and Pfizer CentreOne site lead, Melbourne

Lisa Ann Thimmesch
QA director of documentation and training, McPherson

Get in touch with our SI experts

Click here to learn how we can help meet your needs from clinical development to commercialization.

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www.pfizercentreone.com

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