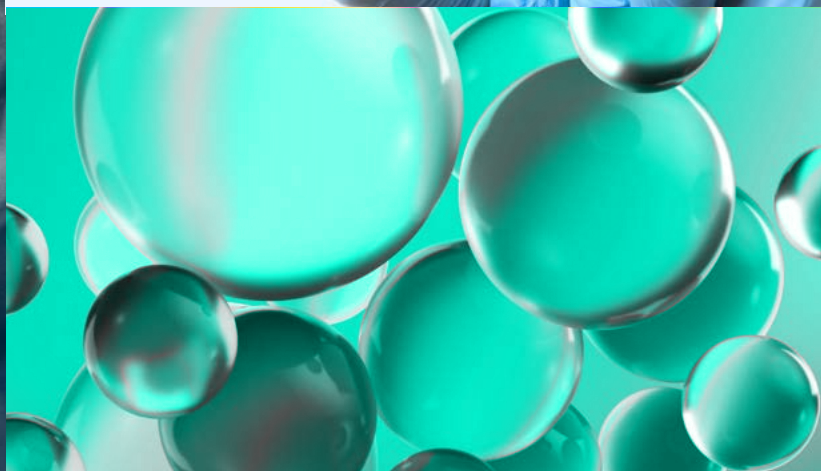
Pfizer CentreOne

Delivering excellence in every sterile injectable



From novel therapeutics like GLP-1 receptor agonists to biologics such as monoclonal antibodies (mAbs) and antibody-drug conjugates (ADCs), the clinical success of sterile injectable products is driving unprecedented demand. However, meeting this demand presents significant manufacturing challenges, including maintaining stringent sterility across processing workflows and ensuring consistent product quality and purity when scaling production.

Here, we examine the key offerings a reliable contract manufacturing organization (CMO) partner must provide to successfully help support your sterile injectable on its journey to patients, and how your sterile injectable project can benefit from the support of a CMO for therapies that define legacies.

The growing potential of sterile injectables

Biopharmaceuticals are most often administered via sterile injection due to their delicate nature. In part driven by the growth of the biologics market — which is anticipated to reach $596.65 billion by 2029[1] — the sterile injectables market is growing rapidly. By 2028, the global sterile injectable drug market is expected to be valued at $762.48 billion[2].

With a growing number of innovative modalities like novel vaccines, ADCs and GLP-1 receptor agonists entering the pipeline, sterile injectable therapeutics are becoming increasingly complex. In addition to navigating the unfamiliar challenges of working with relatively new therapeutic compounds, pharmaceutical innovators must ensure their sterility and quality while delivering at speed. Although advances in technologies like DDS platforms are helping to improve the stability and specificity of sterile injectable therapeutics, they are also adding to the complexity of drug development and manufacturing. This is particularly true when it comes to deciding between liquid formulation or lyophilization.

Helping you build your lasting sterile injectable legacy

Powered by Pfizer's global network, our sterile injectable experts guide your drug substance from late stage clinical to commercial manufacture, with services supporting aseptic fill-finish, terminal sterilization, lyophilization, DDS platforms and combination products.

With specialized facilities designed to help ensure fill finish precision in every dose for your sterile injectable — including GLP-1 products, ADCs and highly potent oncology drugs — we help you navigate complexities, keep pace with scientific and regulatory advancements, and deliver life-saving treatments to patients worldwide.

Supporting a wide variety of complex sterile injectable compounds, including:

- ADCs
- Controlled substances (II-IV)
- Vaccines (inactivated)
- Monobactam
- Hormones, steroids and prostaglandins
- Innovative vaccine technologies
- Highly potent and cytotoxic oncology therapies
- GLP-1 receptor agonists

Sterile injectable formats

With uncompromising reliability and quality, we're here to support your sterile injectable needs every step of the way, from clinical to commercial, providing flexibility across a broad range of sterile injectable container closure systems.

Vials from 2.0 mL to 100.0 mL

- Glass
- Plastic
- ACT-O-VIAL system
- ONCOTAIN glass flip-top vial

Pre-filled syringes (PFS) from 0.25 mL to 1.0 mL

- NEXTJECT syringe
- ABBOJECT syringe

Cartridges from 1.5 mL to 5.0 mL

- EPI cartridges
- CARPUJECT syringe system with SLIM PAK cartridges

Ampoules from 2.0 mL to 10.0 mL

- Glass

Delivering complex therapeutic compounds to their target with precision in every dose

To create a competitive edge, many sterile injectable developers are looking to innovate and improve drug presentations and formulations to differentiate their products from those of their competitors. As a result, biotechs and pharma are increasingly relying on DDS platforms to help improve the selectivity, effectiveness and safety of their sterile injectable. Many highly potent compounds and cytotoxic small molecule therapeutics benefit from encapsulation in DDSs, providing more secure handling and delivery, increasing bioavailability and reducing deleterious effects.

Advantages of drug delivery systems

- Improving safety
- Extending bioavailability
- Providing more control over the location, rate and time of release
- Improving stability upon delivery
- Enabling greater specificity
- Improving efficacy

Drug delivery system	Description	Applications	Benefits
Liposomes	Spherical-shaped carriers created from cholesterol and natural non-toxic phospholipids	Can be used to carry small molecule compounds and are a leading DDS platform for a variety of biologics, including innovative vaccines and gene delivery technology[3]	• Improved site targeting • Protect drugs from chemical degradation and clearance • Improved sustained or controlled release • Can provide superior therapeutic effects • Can lower toxic side effects[4] • Biocompatible
Microspheres	Polymer microspheres consisting of natural (e.g., proteins, polysaccharides) or synthetic (e.g., polyesters) polymeric materials	Can be used as both small molecule and biologic carriers and have been explored to target the lungs due to their small size and potential for surface modifications[5]	• Can enhance solubility and improve absorption and bioavailability • Protect drugs from enzymatic and photolytic degradation for prolonged therapeutic effect • Can decrease dosage frequency • Enable controlled release profiles • Can reduce dose and drug toxicities[5] • Easily injected • Greater biocompatibility
Lipid emulsions	A kinetically stable clear dispersion of two immiscible phases — oil phase and water phase — in combination with surfactant molecules	Are commonly used as carriers for poorly water-soluble small molecule drugs[6]	• Can improve the bioavailability of hydrophobic drugs • Can reduce severe adverse effects[6]
Nanocrystals	Nanosized drug particles that are typically in the form of nanosuspensions	Due to the advantages of high drug loading, platform stability and ease of scaling up, nanocrystals have been widely used to deliver poorly water-soluble small molecule drugs[7]	• Can increase saturation and dissolution rate • Can improve the solubility of high molecular weight and high lipophilicity drugs[8]
Albumin nanoparticles	Nanoparticles made of albumin	Can be used as carriers for small and large molecules. Possess an intrinsic ability to target tumor cells potentially circumventing cancer drug resistance[9]	• Nontoxic • Non-immunogenic • Biocompatible and biodegradable • Easily prepared under soft conditions[9] • Improves stability of various therapeutic cargos
Micelles	Self-organized molecular assemblies of amphiphilic molecules that comprise a hydrophobic core and a hydrophilic shell	Micelles have been widely used as a DDS platform for low molecular mass hydrophobic drugs, proteins and genes[10]	• Relatively small size, usually less than 50 nm, making them favorable for drugs entering the blood circulation • Simple assembly and feasibility of large-scale manufacture[10] • Storage stability and resistance toward dilution • Selective targeting to specific tissues

However, realizing the potential of these delivery systems requires extensive expertise. DDS platforms add to the complexity of drug manufacturing, requiring segregation strategies and specialized processing equipment. As a result, there are many hurdles drug producers must navigate:

1. The need for advanced analytical technologies

As compared with therapeutics lacking a DDS, more advanced analytical techniques are commonly needed to understand and assess the drug product's (DP) physicochemical properties and to characterize the advantages the delivery system provides. This could include analyzing the impact of the carrier on the extended-release, bioavailability, potency and target specificity of the DP. Developing specific assays to assess DP stability, formulation and process development outcomes is paramount.

2. A requirement for more specialized manufacturing equipment

Implementing some drug delivery technologies like liposomes requires specialized equipment that is not commonly found in traditional manufacturing settings. This could include compounding suites and specialized fill-finish lines.

3. Efforts involved in implementing new DDS technology

The implementation of new DDS requires extensive upfront work, usually carried out during process development and scale-up activities. To ensure the physicochemical and quality attributes are preserved throughout manufacturing, it is important to assess whether process stressors, such as mixing, hold times and lyophilization, are detrimental to the final DP.

Trusted quality and proven expertise for your sterile injectable

With decades of experience, our dedicated experts understand the intricacies of sterile injectable manufacturing, as well as the complexities that can arise when using DDS platforms. Leveraging our global network of Pfizer experts, specialized manufacturing suites and state-of-the-art technologies, we can help to identify the ideal DDS for your drug.

Committed to transparent communication, we work together with you to implement a holistic approach, helping to navigate DDS complexities to help you build your lasting sterile injectable legacy. With robust analytical techniques and validation strategies, we provide batch release and solid regulatory filing support — both key components to successfully completing a program.

We are with you through every stage of your manufacturing journey, carefully considering the need for creative solutions to help get things right first-time and prevent delays.

Liquid formulation or lyophilization?

Although liquid formulation is often the default for sterile injectable products, depending on the properties of your sterile injectable drug, it may be better suited to lyophilization. This can significantly impact product manufacturing in multiple ways.

Weighing up liquid formulation and lyophilization

Liquid formulation

- Easier to handle and move through the manufacturing process
- Yields larger outputs
- Lower cost
- Small molecules are generally more stable and easier to handle in liquid formula
- Lipid-based DDS like liposomes, fat emulsions and micelles will be rendered ineffective with lyophilization

Lyophilization

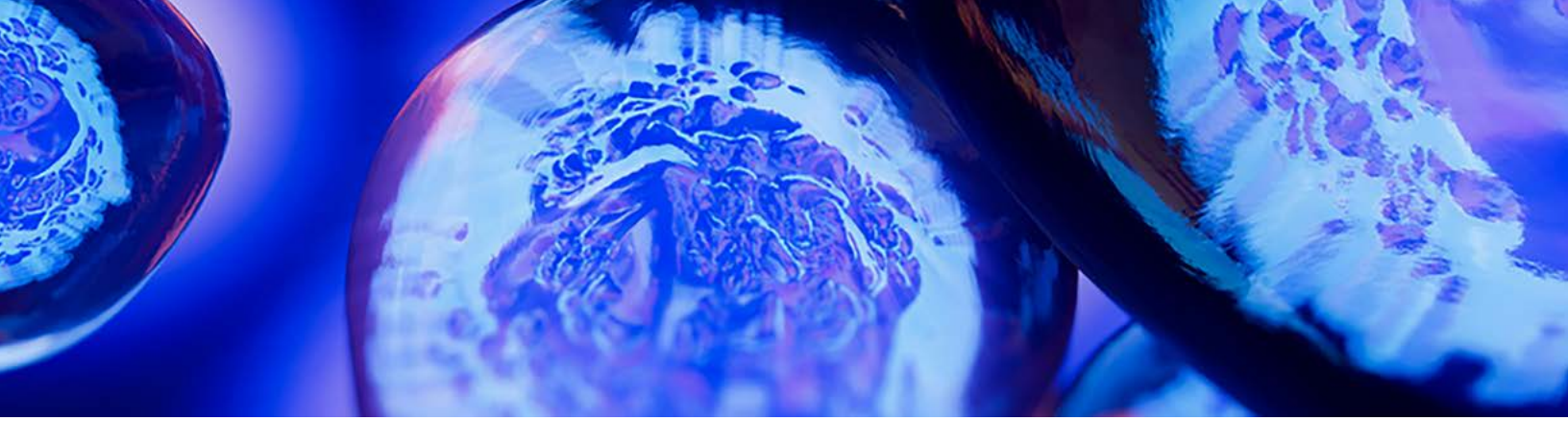
- Many biologics require lyophilization to preserve their integrity
- Can help to extend the stability of some compounds
- Prevents conformational changes, protein aggregation and other issues resulting from temperature changes, freeze-thaw cycles
- More complex than liquid formulation

With in-depth knowledge and capacity throughout our expansive global sterile injectable manufacturing network, we work closely with you to help ensure the success of your drug product, whether in liquid formulation or lyophilized.

Our lyophilization and liquid formulation capabilities

Across our global sites, we have a wide range of lyophilization and liquid capabilities to help meet the unique needs of your sterile injectable drug, including but not limited to:

- Lyophilization cycle optimization
- Multiple vial, cartridge and pre-filled syringe filling lines
- Compounding suites and tanks of different sizes (stainless steel and glass-lined)
- A wide variety of liquid filler pump technologies (peristaltic, TPO, rotary diaphragm, piston)
- Barrier technologies (restricted access barrier systems (RABS), isolators)
- Controls and equipment to support controlled substances
- Automated lines with integrated lyophilizer and fill lines
- Interlocks to minimize operator error and safeguard compliance
- Lyophilization units with automated loading systems
- Testing of non-commercial batches for both small molecule and biologic drugs



Our capabilities

Global expertise. Specialized capabilities.

Time is life, so in the rapidly evolving sterile injectable space, quality and expertise is key to helping ensure the safe, successful delivery of your breakthrough therapeutic to the patients who need it.

Backed by Pfizer's global network, our scientific and manufacturing experts leverage decades of experience to help meet your complex fill finish needs – including those for oncology medicines, novel vaccines, mAbs and beyond.

Our broad capabilities are here to support liquid formulation and lyophilization, pre-filled syringes, vials and cartridges. Alongside our specialized facilities, our Pfizer experts leverage their knowledge and extensive experience help deliver excellence in every injection.

As an experienced partner with broad capabilities, we can help you skillfully maneuver through complexities, keeping pace with both scientific advancements and regulatory requirements.

Cutting-edge facilities and specialized expertise

- Global scale with sites around the world with regulatory intelligence for more than 150 countries
- Sites specifically designed to support complex sterile injectable production, from small to large volumes
- Formulation of complex products
- Liquid and lyophilized filling with automated loading and unloading
- Automated lines with integrated lyophilizer and fill lines
- Lyophilization cycle optimization
- Conventional filling, isolator, RABS and true barrier systems
- Single-use technology platforms
- Analytical and microbiological services across the entire drug lifecycle

Efficiently delivering reliability and quality

Speed matters in getting your product to patients, but not at the expense of quality. Our dedicated quality and analytical teams are here to support you. From late stage clinical to commercial, we use cutting-edge technologies like automated fill lines with digitized infrastructure to safeguard data integrity, sterility and safety.

Powered by Pfizer's global reputation of reliability, we aim to provide supply chain reliability by carefully evaluating each of the companies in our vast supply chain for risk and business continuity. We'll also be your guide through the regulatory landscape, helping you clear a path to approval and support you in reaching your critical milestones in markets around the world.

Flexible and transparent support you can rely on

Our global Pfizer experts stand beside you, dedicated to unlocking innovative solutions and helping advance your sterile injectable to patients. We leverage our lightspeed principles to help optimize lead-times, meet your evolving expectations and overcome roadblocks your supply chain – because patients are waiting.

With a "right first time" approach, we work to keep you updated with real time data sharing throughout your project. Our multiple filling lines and flexible packaging across a wide range of vial and syringe sizes allow us to react quickly to changes in demand, while our continual investment in our global sites and SI technologies enable us to proactively prepare for the future of drug modalities.

Ready to build your lasting legacy?

From liquid and lyo to pre-filled syringes, vials and cartridges – we harness Pfizer's global network and expertise to help you with excellence in every injection – because time is life.

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