Your scalable sterile manufacturing destination.
Our world.

Scalable Manufacturing of Sterile Drug Products

At PCI, ensuring life-changing medicines reach those who need it most is our highest priority. As a truly integrated global CDMO, we are manufacturing, packaging and supply chain experts, harnessing our experience and expertise to deliver you a seamless solution with the ultimate aim of improving the lives of patients.

At PCI, we provide comprehensive clinical to commercial scale manufacturing services delivering true life-cycle management for sterile drug products.

Sterile Manufacturing Overview

Our global manufacturing capabilities in complex formulations cover a broad range of injectables including nanoparticles, mRNA, mABs, proteins, oligonucleotides, and other biologics across multiple delivery formats from vials and bottles to pre-filled syringes and autoinjectors.

We provide integrated large and small molecule solutions for clinical and commercial projects, and with over 20 years in the sterile fill-finish manufacturing space, we are dedicated to your success in bringing life-changing therapies to patients.

Sterile Development Services

We focus on developing sterile manufacturing processes that are scalable, reproducible, and commercially robust. We utilize a Quality by Design (QbD) approach to provide you with a product that meets your Critical Quality Attributes (CQAs). Whether you are facing solubility or stability challenges, we can develop and optimize your formulation for any parenteral route of administration. If lyophilization is required to support the long-term stability of your product, PCI is able to develop a lyophilization cycle to provide you with a commercially elegant presentation of your product.

Based on the results of an in-depth Process Risk Assessment (PRA) of your current manufacturing process, we will work with you to determine the Critical Process Parameters (CPPs). We will design an experimental plan to investigate and characterize the CPPs. Using the Quality by Design (QbD) approach, we can develop a formulation that will increase product solubility. If an aqueous formulation does not yield the desired concentration, we can use complexing agents such as cyclodextrins or an organic solvent formulation, to develop an emulsion or suspension.

Overview

Sterile Manufacturing Services

Over the years, we have built our reputation as the go-to, full-service CDMO that our clients trust with their sterile manufacturing needs. Our reputation has been earned by providing insightful guidance and a robust infrastructure to deliver on the most challenging products on time and on budget.

We provide comprehensive sterile fill-finish services for clinical and commercial supply. Our aseptic contract manufacturing capabilities include filling solutions, emulsions, and suspensions in vials, pre-filled syringes and dropper bottles, and our aseptic freeze-dryers are designed with redundancy in mind, increasing manufacturing reliability.

Bulk Lyophilization

With more than 20 years of experience in freeze-drying bulk products, we are able to handle small and large-scale bulk lyophilization, harvesting, and packaging of your medical device, drug intermediate or API.

Complex Formulations

If your product cannot be sterile filtered or terminally sterilized, our dedicated ISO 5 and Grade A aseptic formulation suites may be a solution for your challenging formulation process. Our highly skilled engineers will work diligently to fully understand your complex parenteral formulation, critical timelines, developing a unique program and scale-up process for you to take your customized formulation from the bench to GMP.

Analytical Services for Sterile Products

PCI delivers unmatched quality to our clients globally. We perform rigorous analytical testing services for sterile products to support in-process, release, and ICH stability testing. We can perform analytical method development, support efficient method transfers, and phase-appropriate validation to further support your testing needs.