Your scalable non-sterile manufacturing destination.
Our world.

Scalable Manufacturing Services for Non-Sterile Drug Products including Highly Potent Molecules

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.

Our clinical to commercial scale manufacturing capabilities using geometrically similar equipment trains provides true life-cycle management for potent and non-potent drug products.

Clinical Trial Manufacturing

PCI provides a comprehensive service at each stage of the product life-cycle for a wide range of dosage forms, in full compliance with GMP regulatory standards for both highly potent and non-potent drug products.

Our strength lies in the integrated nature of our services, combining formulation and analytical development with GMP clinical manufacturing and packaging through a fully cross-functional project team, coordinated by an experienced team of project managers.

Utilizing our state-of-the-art facilities, we offer unrivalled capabilities and a true focus on customer need. We provide clinical manufacturing and packaging of multiple dosage forms for investigational use including solid oral dose, liquids, and semi-solids.

All clinical manufacturing services are fully supported by a dedicated and experienced team of Qualified Persons, a full analytical laboratory and a GMP compliant warehouse.

Overview

Commercial Manufacturing

PCI offers flexible and globally compliant commercial scale manufacturing and packaging of multiple dosage forms including tablets, capsules, creams, gels, ointments and oral liquids for both highly potent and non-potent drug products.

Investments include separate suites for large volume tablet and liquid manufacture as well as specialist roller compaction technology for heat and moisture sensitive formulations.

A dedicated department of validation specialists ensure a seamless transition from clinical phase to commercial launch as well as supporting ongoing commercial supply through Continuous Process Verification (CPV).

Commercial manufacturing and packaging is supported by an experienced team of Qualified Persons (QPs), a full analytical release testing laboratory and a GMP compliant temperature controlled warehouse with storage down to -20°C.

Specialized Manufacturing of Highly Potent Products

Building on 35 years in potent processing, we offer two purpose-built facilities utilizing the very latest in containment technology, enabling the safe development, clinical and commercial scale manufacture of products with an Occupational Exposure Limit (OEL) as low as 0.01µg/m^3.

The facilities include multiple levels of containment built into the design. Dispensing of API is undertaken within isolators and subsequent processes within appropriately contained equipment, ensuring operator safety and preventing cross-contamination.

Our fully integrated facility utilizes common equipment trains from development to commercial scale with geometric scale-up, delivering reproducibility and ultimately speed-to-market.

Contained Operations Overview

- Two purpose-built contained manufacturing facilities
- Multiple compound processing
- From small-scale clinical to large-scale commercial manufacturing
- Geometric scale-up ensures reproducibility and a seamless transition from development to launch
- Processing of OEL down to 0.01µg/m^3
- Segregated people and material flow
- Secure access with client viewing gallery
- Automated cleaning procedures
- Contained engineering eliminating the need for Personal Protective Equipment (PPE)
- HVAC system with single pass air
- Purpose-built, high performance, bespoke effluent treatment facility
- Design-for-manufacture delivering true speed-to-market
- Meeting regulatory standards for major markets including Japan, TMoH, the MHRA, FDA and ANVISA

High Potent Packaging Facility (HPPF)

Our new state-of-the-art purpose-built potent packaging facility delivers primary and secondary packaging of highly potent actives. Capabilities include bottle and blister formats and full serialization to provide a seamless end-to-end solution.