Your highly potent manufacturing destination.
Our world.

Specialist High Potent Manufacturing Capabilities

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.

Specialized Manufacturing of Highly Potent Products

Building on 35 years in potent processing, we offer two purpose-built manufacturing facilities in addition to a state-of-the-art packaging suite all 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.

We are able to offer high potent drug product manufacturing and packaging at all stages of the product life-cycle for a variety of dosage forms including:

- Tablets, capsules and powders
- Gels and creams
- Liquids, solutions, suspensions and emulsions
- Suppositories and pessaries
- Granules for reconstitution
- Drug in capsule/vial

Overview

High Potent Pharmaceutical Development

Our comprehensive pharmaceutical development service offering includes new drug development, early stage formulation and analytical development for highly potent drug products.

We are able to fill API directly into capsules and vials using micro-dosing technology as well as offering the more traditional development pathways. The micro-dosing drug in capsule (DIC) and drug in vial (DIV) approach offers time and cost efficiencies as well as the potential to reduce waste of often expensive APIs.

Following early stage development, we continue with further development, scale-up, and process validation ahead of commercial launch for a variety of dosage forms, all supported by full in-house analytical development and release testing laboratory.

High Potent 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 highly potent drug products.

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

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.

High Potent Commercial Scale Manufacturing

PCI offers flexible and globally compliant commercial scale manufacturing and packaging of multiple dosage forms. Geometric scale-up ensures reproducibility from clinical to commercial scale manufacturing delivering a seamless end-to-end solution.

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.

High Potent Packaging

To complement our highly potent drug product manufacturing services, we operate a global network of packaging centers of excellence with a number of facilities dedicated to the specialist packaging requirements of highly potent drug products. With the ability to package multiple high potent dosage forms including uncoated tablets, coated tablets, sterile liquids, non-sterile oral liquids, creams, gels, and ointments, we provide a truly integrated, full CDMO service for all your highly potent processing needs from development to commercialization.

With one high potent packaging center of excellence being co-located with the Contained Manufacturing Facilities (CMF 1 & 2) for the development, clinical, and commercial manufacturing of highly potent drug products, we are able to provide clinical to commercial scale manufacturing and packaging including serialization under one roof, minimizing supply chain complexity and risk.