Your pharmaceutical development destination.
Our world.

Pharmaceutical Development Services

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.

PCI provides full development and manufacturing services for investigational products, including highly potent and sterile drug products requiring specialist handling.

Potent and Non-Potent Pharmaceutical Development Services Overview

With over 35 years of experience in development and manufacturing of potent and non-potent drug products, PCI provides a true partnership and consultative approach for all aspects of pharmaceutical development. This includes formulation development, formulation optimization and process development supported by full in-house analytical development services throughout the product life-cycle.

We are able to provide development and clinical scale manufacturing for potent and non-potent drug products across multiple dosage forms including:

- Tablets, capsules and powder for reconstitution
- Semi-solid gels, creams and ointments
- Non-sterile oral liquids, suspensions and emulsions
- Suppositories and pessaries
- Granules for reconstitution
- Drug in capsule/vial

Analytical Capabilities to Support Potent and Non-Potent Manufacturing Services Include:

- Analysis of multiple dosage forms
- Chromatography by HPLC/UPLC
- GC including a range of columns and electrochemical detection
- Dissolution testing using USP I and II apparatus
- Spectroscopic analysis including UV/Vis, Fluorescence and FTIR
- Physical testing including particle size determination
- Microbiological testing
- Stability testing

We also provide extensive packaging, storage and distribution capabilities throughout the clinical life-cycle including cold chain and ultra-cold chain, complementing our development and manufacturing capabilities providing a true end-to-end service.

Sterile Pharmaceutical Development Services

PCI provides full development and manufacturing services for investigational products, including lyophilization and sterile fill-finish.

With over 20 years of experience, PCI's strength lies in our ability to manage products with unique challenges ranging from small molecules presenting with solubility issues to a large molecule that is only stable as a liquid presentation for a short time.

Whether you are developing a liquid or lyophilized dosage form, we understand that speed and flexibility are critical to the success of your development program. We can screen multiple experimental formulations in parallel to expedite the formulation development phase of your program to enter the sterile fill-finish step. We focus on developing reproducible, scalable, and commercially robust processes, delivering time and cost efficiencies.

Sterile Solubility and Stability

We start by performing a pre-formulation study or by leveraging existing data you may have to understand the key physical characteristics of your product. From this understanding of the chemical properties of the molecule, we are able to develop the strategy for the development program.

Key Studies of Your Development Program May Include:

- In-use (Bulk) stability
- Mixing
- Order of addition
- pH ranging
- Material compatibility
- Filter adsorption
- Freeze/thaw
- Tonicity (SQ/IM)

We are able to provide development and clinical scale manufacturing for sterile drug products including those classified as being potent across multiple dosage forms including:

- Vials
- Cartridges for autoinjectors
- Pre-filled syringes