pci PHARMA SERVICES

Excellence in Global Clinical Supply Chain Solutions

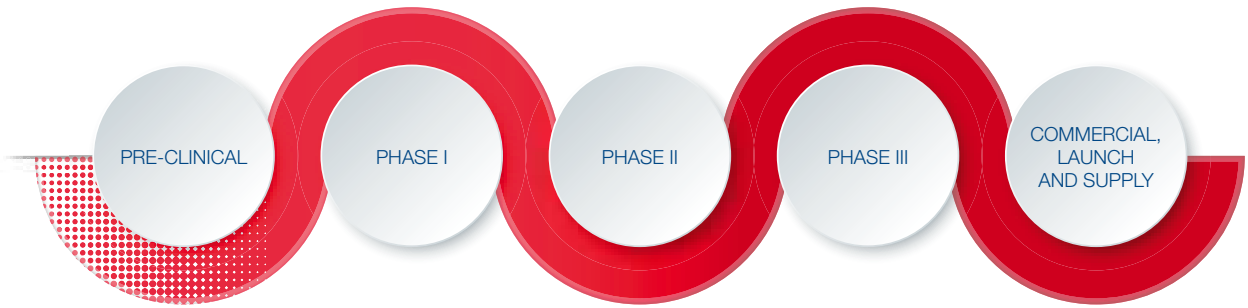
pci CLINICAL SERVICES

EXCELLENCE IN PHARMACEUTICAL OUTSOURCING FROM MOLECULE TO MARKET

pci PHARMA SERVICES

Excellence in Pharmaceutical Outsourcing from Molecule to Market

As a respected industry leader and trusted partner we provide a comprehensive range of outsourced pharmaceutical services that stretches all the way from early stage development to long-term commercial supply. This reputation is based on best-in-class technologies, cutting-edge research, an exceptional team of outstanding people and a consistent record of meeting the highest regulatory and quality standards. Equally important is our commitment to an exceptional customer experience and we share our customers' passion for supplying lifesaving medicines to patients around the world. We're committed to meeting their evolving needs by leveraging our experience and expertise to develop the best possible solutions to their drug development challenges.



pci MANUFACTURING SERVICES

pci CLINICAL SERVICES

pci COMMERCIAL PACKAGING

Clinical Trial Supply

Pharmaceutical companies face continued pressure to develop and commercialize their medicines. PCI Clinical Services is committed to supporting clients at every stage of the clinical cycle, delivering best-in-class services efficiently and effectively.

Using our extensive knowledge of pharmaceutical development, clinical manufacturing, packaging, labeling, storage and distribution, we provide unparalleled expertise and a seamlessly integrated drug development service, delivering speed-to-market and commercial success for our client's products.

From our facilities located in North America, Asia Pacific and Europe, the PCI Clinical Services team offers a truly global service balanced with a localized focus, delivering over 200 clinical protocols a year in over 100 countries across the world.

Our clinical team is committed to continued research and investment in both people and best-in-class technologies enabling us to drive innovative solutions and ensure our associates are a true extension to our client's teams, providing the industry's leading customer experience.

Integrated Solutions – Molecule to Market

PCI is an integrated full service provider expertly delivering a seamless transition from development to commercialization.

Pharmaceutical Development

We provide formulation development and analytical support services across a wide range of pharmaceutical dosage forms.

Clinical Manufacturing

We offer manufacturing services for each stage of development including process optimization as your product moves through the clinical cycle.

Packaging and Labeling

PCI offers flexible and scalable industry leading packaging solutions to meet the specific needs of each product and patient.

Global Storage, Distribution and Returns Services

We offer a worldwide integrated network of dedicated storage, distribution and returns management systems for clinical trials, meeting the needs of multi-country and multi-language studies.

Analytical Services

We deliver comprehensive analytical solutions to support your drug substance at each product development stage.

Qualified Person Services

PCI expertly facilitates development and release of a wide range of dosage forms across the spectrum.

Support Services

PCI's rigorous attention to detail is paramount to successful execution of global clinical trials. Our team, systems and processes are designed to be fast and flexible allowing us to focus on swifter expedition of supplies and enabling quicker initiation of studies for our clients.

Pharmaceutical Development

Our comprehensive service offering includes early stage formulation and analytical development, API capsule and vial filling using Xcelodose® technology, scale-up and stability testing, process validation, technology transfer and associated analytical support services.

Our strength lies in the integrated nature of our services, combining formulation development and analytical services with clinical trial supplies.

PCI provide CMC Consultancy services to generate the optimum development strategy for your compound. By involving our experts early in the strategic development of your new product, we can assist in optimizing the process, ensure that regulatory hurdles are minimized and that the most efficient routes to clinic are delivered for potent and non-potent molecules. We are able to offer formulation development services 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.

Clinical Manufacturing

PCI offers a broad range of services to address the manufacturing needs of our clients at each stage of the product lifecycle. Central to PCI's international service offering is our capability to manufacture a range of dosage forms in compliance with current GMP standards.

For over 35 years, we have been successfully developing pharmaceutical dosage forms. Our strength lies in the integrated nature of our services, combining formulation development and analytical services with clinical trial supplies for potent and non-potent molecules as well as Aseptic compounding. Our comprehensive and flexible services are delivered at each stage of the development process by our experienced project management team.

Our facilities have been designed to allow flexibility in processing technology and are approved for the manufacture of investigational and commercial products. With a comprehensive range of qualified analytical equipment and extensive stability storage resources, we are able to develop and validate analytical methods to support development programs.

By combining formulation and analytical testing with GMP clinical trial manufacturing and packaging, we are able to offer a seamless service throughout your development journey.

Xcelodose® Technology for Early Stage Clinical Development

Traditional product development of a formulated solid oral drug for Phase I clinical trials involves a range of activities. This process can take considerable time to complete and at a significant cost for product development alone.

Filling an Active Pharmaceutical Ingredient (API) directly into a capsule is potentially the quickest and most cost-effective option for entering early phase clinical trials by minimizing the formulation and analytical development requirements.

Using Xcelodose® removes the need for initial formulation development and the associated stability testing enabling PCI to achieve fast times to first-in-man studies on behalf of its clients. The fully programmable system provides exceptional levels of accuracy and precision. Waste of drug substance is minimized and batch records allow traceability of individual capsules that meet GMP requirements.

At PCI we utilize both Xcelodose® 120 and 600S instruments which can be used for formulation development, pre-clinical and clinical trial batch manufacturing.

Both technologies offer full containment solutions enabling the safe early stage development of highly potent molecules.

Features of Xcelodose® Technology

Highly consistent dose accuracy

- Programmable and precise dispensing of dose weights from 100 micrograms to 100 milligrams and beyond
- Weight of each capsule content is recorded, allowing traceability of samples that meet GMP requirements.

Capsules can be filled with drug alone

- Simplifies analytical development and stability requirements, reducing development time
- Reduces waste and eliminates the need for a “powder blend”
- Ability to handle moisture-sensitive compounds
- Xcelodose® 120 system is able to fill capsules and a variety of small dose containers including; vials, tubes, blisters and cassettes
- Precision closing of capsules.

Optimization of the filling process

- Compensates for variability in drug powder properties
- Simplification of method development
- Improved data transfer.

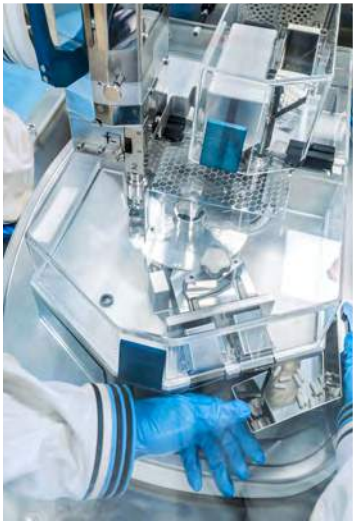
Xcelodose® 120 and 600S instruments

- Can be used for formulation development, pre-clinical and clinical trial batch manufacturing for both potent and non-potent molecules.

Contained Xcelodose® Technology

In addition and to complement the Xcelodose® technology, PCI have invested in containment solutions which ensure we are able to support customer demand for the early stage development of highly potent molecules.

PCI's latest investment in Xcelohood™ and Xceloprotect™ technology provides contained Xcelodose® solutions, ensuring safety by preventing operator exposure. The high levels of containment provide Occupational Exposure Limit (OEL) as low as 0.1µg/m^3 over an eight hour time weighted average meeting.



Contained Manufacturing

Our purpose-built, award-winning facility allows the manufacture of potent drug product in specially designed contained engineering equipment.

These state-of-the-art systems will safely process Active Pharmaceutical Ingredients (APIs) with a minimum Occupational Exposure Limit (OEL) of 0.01µg/m^3 based on an 8-hour time-weighted average. The design concept uses contained processing to minimize the need for Personal Protective Equipment (PPE) for routine operations.

We have adopted a clear design-for-manufacture approach with geometric scale-up to ensure reproducibility from development scale (1kg) to commercial scale (120kg) delivering true speed to market for our customers.

Clinical Trial Packaging & Labeling

With unrivaled experience in packaging and labeling, PCI combines knowledge, experience, and innovative technologies, ensuring our ability to supply high quality products reliably and effectively wherever in the world our clients need them.

Combining extensive label design experience with flexible primary and secondary packaging suites, PCI provides packaging solutions for the most demanding Phase I through Phase IV studies.

Our scalable packaging systems meet the specific needs of each unique study and the investigational product. Our sites also manage comprehensive studies that require product blinding and over-encapsulation.

Our secondary packaging facilities feature cutting edge technologies that provide solutions for precise assembly and release of patient kits for global studies.

Utilizing our in-house expertise in package design and development, we work with clients to ensure pack design meets the needs of all stakeholders enabling optimal patient compliance to the regimen.

At PCI our philosophy is to employ and maintain best-in-class equipment and technologies. This investment ensures robust packaging solutions for each application and project scope, including manual, semi-automated, and fully automated technologies. Our on-line inspection systems guarantee product safety and maintain trial supply integrity, whilst our ultra-modern packaging environments accommodate product needs for light and oxygen sensitivity, temperature controls supporting cold chain management, and low-humidity conditions. The versatility of equipment platforms offers technological solutions for each trial, regardless of scale.

Our comprehensive packaging service includes:

- Package design and development
- Temperature controlled facilities from controlled ambient (15-25°C) to ultra cold chain (-196°C)
- Support services including QP services and product release.

Package types supported include:

Primary Packaging

- Blisters
- Bottles
- Pouches
- Tubes.

Secondary Packaging

- Labeling for parenterals and injectables
- Tyvek blistering for parenterals
- Device assembly
- Cartoning
- Kitting
- Child resistant and compliance prompting packaging
- Overwrapping and pouching
- Walleting
- Expiry date extension and over-labeling
- Just-in-Time labeling
- Potents, controlled substances
- Hormones, penicillins, animal health
- Controlled substances.

Cold Chain Packaging and Labeling Expertise

PCI deals with biologically-derived products which are both costly and sensitive. As such, the implementation of an efficient and effective packaging and labeling process is crucial.

Processes and materials must be robust and validated to prevent unnecessary temperature excursions, as well as exposure to other potential hazards such as light and vibrations that may be experienced throughout the supply chain.

Utilizing state-of-the-art, validated cold plate and dry ice systems, PCI employs industry best practices to identify and provide innovative solutions at a range of temperatures from Controlled Room Temperature (CRT) (15-25°C) down to -196°C. This will ensure product integrity by minimizing potential temperature excursions, whilst delivering the accuracy and flexibility needed to overcome the most challenging obstacles in your cold chain packaging process.


pci
PHARMA SERVICES

Global Storage, Distribution and Returns Services

PCI offers over 30 years experience in the storage and distribution of clinical trial materials, effectively storing and shipping thousands of patient kits to over 100 clinical trial countries across the world, across developed and emerging market geographies.

A core part of our service is the development of detailed global supply chain strategies to keep sites supplied with product, while optimizing the supply chain.

The key to any successful clinical trial is having a robust, responsive and efficient logistics plan to enable consistent global supply. At PCI we work with our clients to develop a tailored and dedicated service which meets the needs of their trial requirements whatever the size or global reach. Our dedicated teams of logistic experts will handle assembly, dispatch and receipt as well as full evaluation and reconciliation of returns to ensure complete accountability and appropriate chain of custody throughout the trial life cycle.

Cold Chain Expertise

PCI is a market leader in the provision of cold chain management services and has extensive capacity and unrivaled expertise to accommodate our client's refrigerated and frozen storage and distribution requirements.

Our extensive cold chain storage areas are all fully validated, continuously monitored and alarmed providing different storage temperatures, from Controlled Room Temperature (CRT) (15-25°C) down to -196°C. The breadth and quality of our service offering, from one-off samples through to clinical supplies, makes us highly flexible and responsive to every client's needs.

Our expertly trained and experienced associates handle thousands of temperature sensitive global shipments each year. Well versed in the challenges of global cold chain distribution, PCI understands the specific requirements for

each drug project and utilizes an integrated and trusted global supply chain. PCI utilizes cutting-edge validated shipping technologies and a proven network of fully audited international couriers and depot network.

We are not only qualified to collect, store and deliver clinical trial and pharmaceutical products, we can also provide the collection, storage, return and reconciliation of patient samples including blood, urine and tissue.

We pride ourselves on our flexibility and where a specific requirement is needed we partner with customers to create a bespoke offering at custom temperatures. PCI offers dual facilities storage providing the additional storage and risk mitigation for our clients' samples.

Secure Storage

Clinical trial supplies are stored in facilities dedicated to investigational medicines, offering extensive environmental controls and monitoring, meeting full requirements for GMP and GDP. Facilities feature round-the-clock security and environmental monitoring.

PCI has the facilities to store and ship both controlled and dangerous goods throughout the world.


MODULA
LIFT
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Facilities feature expansive controlled substance vaults and cages which have been approved by the necessary authorities to handle all classifications of controlled drugs, as well as the cutting-edge security systems supported by robust procedures.

Returns Management

In keeping with client requirements, we can arrange for the return, storage and ultimate destruction of clinical trials materials at the end of a project. Returns can be reconciled to one of three levels before being securely stored until the approval for destruction is received:

Level 1 – Reconciliation of the number of shippers returned only

Level 2 – Reconciliation of the contents of the shippers against a packing list

Level 3 – Full reconciliation down to individual tablets, capsules and vials.

Destruction is carried out by an approved third party including witnessed destruction for controlled drugs. Certificates of Destruction are provided to clients to facilitate full reconciliation of clinical trial supplies.

Analytical Services

PCI provides fully audited, in-house laboratories offering a range of analytical services to support clients in the development and commercialization of new medicines.

Staffed with expertly qualified analytical chemists, trained and accredited in the most comprehensive laboratory standards, we provide a complete range of resources and responsive services at each stage of the product lifecycle across a wide variety of dosage forms.

Our state-of-the-art facilities feature best-in-class and fully GMP and ICH compliant equipment enabling our teams to perform simple ID testing and analytical method transfers, through method development and validation, to EU product release and ICH stability testing, ensuring data reliability and regulatory compliance.

Our facilities also include HEPA filtered air handling systems for the analysis of cytotoxic, teratogenic and uncharacterized products, a darkroom for the analysis of light sensitive products, and the capabilities to work with Schedule II-IV controlled substances.

Analytical services are offered on a stand-alone basis or in conjunction with our clinical, commercial and QP services to facilitate a seamless transmission through the drug development cycle.

QP Services

Qualified Persons (QPs) play a vital role in bringing products, especially new products, to market within Europe. Global clients look to the diverse range of skills and specialisms of our highly experienced team of QPs to ensure their clinical studies not only meet the most rigorous standards but also run smoothly, seamlessly and cost effectively.

PCI QPs have earned the highest credentials in accordance with the European Union standards and requirements. Each is qualified to degree level in pharmacy, chemistry or biology and continuous professional development ensures understanding of and adherence to legislation impacting operations and clients' products.

The diversity of experience within our ever-expanding team of QPs means we deal quickly and expertly with specific issues and technical challenges right across the pharmaceutical dosage spectrum, from small molecules to biopharmaceuticals and Advanced Therapeutic Medicinal Products (ATMPs).

Our QPs take responsibility for all stages of the compliance process which includes auditing manufacturing facilities anywhere in the world to ensure that each batch has been manufactured in accordance with GMP compliance, as well as certifying products for use in clinical trials and, for registered products, release to market.

At PCI our QPs also offer a consultancy service to ensure that operations are in-line with all relevant EU directives and other necessary regulations. This service extends to CMC advice beginning with requirements for Active Pharmaceutical Ingredients (APIs) and extends through the formulation process. The amount of data required varies depending on the phase of the clinical trial and strategic advice can be offered to ensure that regulatory expectations are met with a minimum of expense.

Support Services

Rigorous attention to detail is paramount to the successful execution of global clinical trials. We offer the expertise to assist our clients overcome the most complicated of challenges, with a collaborative approach to problem solving. Engaging our clients at the earliest stages of clinical protocol development enables our team to provide insights into optimizing trial costs and efficiency, critical to expediting clinical trial execution.

Dedicated Project Management

At PCI our mission is to offer the industry's leading customer experience. This dedication is championed by our highly motivated and professional project management teams. Our teams work with clients on all aspects of their projects, leading to successful outcomes and ensuring client satisfaction. Project managers are involved at the earliest stages of project development, providing insights and experiences to guide projects and optimize critical timelines.

Complementing developmental project management teams are dedicated storage and distribution project managers who are versed in best storage and distribution practices and country specific requirements. This experience and dedication ensures that the correct product is delivered to the designated site at the optimal time, each and every time.

Protocol Interpretation

Efficient and effective clinical trials start with a clear understanding of the trial requirements. PCI's project management team brings significant expertise to this vital part of the process, calling on many years of experience when helping clients in designing the most effective packaging solution to to support the trial, global supply chain strategy and global logistics.

webflow™

Webflow™

PCI's Webflow™ solution is a proprietary and bespoke client access portal which utilizes the latest web-based technologies to provide easy to access, secure and real-time information 24/7 from anywhere in the world.

The system allows users to proactively manage inventory levels, track investigational site shipments and access other related clinical trial information in an instant. Clients also have access to real-time stock levels, pending and outbound order information as well as the ability to track inventory and shipments across our global partnered depot network.

Webflow™ allow convenient and secure access to:

- Key projects and documents from any location anytime
- Real-time stock levels by stock item and status
- Dynamic sales order information such as orders being processed and dispatched orders
- Blinded or un-blinded sales and stock information
- Tracking of dispatched orders
- Real-time inventory management
- Efficient and effective supply management
- Proactive control of inventory
- Visibility of stock levels and status
- Greater visibility of shipment information
- Easy access to project related documents
- Complimentary service
- ALL available 24/7 utilizing desktop or mobile applications.

Our pci fasttrack™ offerings

PCIFastTrack™ offering is an expedited approach to the delivery of secondary packaging, labeling, release and distribution of clinical supplies based on patient and site requirements. Designed by applying industry best practices, PCIFastTrack™ will deliver compliant clinical trial supplies for time-critical studies in the shortest possible time without compromising on quality. Depending on the availability of materials these projects can be turned around within 10 business days.

PCIFastTrack™ response within 10 working days

Developed in advance of packaging operations and maintaining rigorous cGMP standards, the PCIFastTrack™ service uses custom operating procedures and workflows created to significantly streamline processes. This is achieved by the deployment of a team of highly-skilled, dedicated and cross-trained personnel.

pci fasttrack™ Project set-up to dispatch in 10 working days

pci fasttrack™ On Demand Re-supply packaging run of material within 3 working days

pci fasttrack™ Just In Time Application of a protocol or expiry label to the outer of a semi-finished kit at the point of dispatch within 3-4 days

Benefits

- Efficient use of clinical drug product
- Reduction in waste
- Reduced risk to supply
- Faster delivery of projects
- Project status visibility
- Dedicated and expert team empowered to deliver your projects.

Interactive Response Technologies (IRT)

PCI is partnering with industry leader Suvoda to deliver a best-in-class seamless IRT system to our customers. Utilizing innovative technologies, system flexibility and creative design the Suvoda solution ensures exceptional customer service.

In partnership with suvoda

Flexibility and Speed

Utilizing proprietary architecture with modularity, the Suvoda IRT system is engineered for rapid deployment, design flexibility and continuous enhancement. The modular system architecture enables the services team to select modules from a central library, configure them for a specific study and create new modules to meet unique study-specific needs with rapid deployment. These new modules are then assessed, validated and included in iterative releases of the central feature library for re-use in future studies. This is done using a proprietary process that marries the software engineering methodology of “continuous deployment” with the requirements for regulatory compliance, resulting in rapid innovation with assured quality and compliance.

Comprehensive Features

Utilizing state-of-the-art technologies the Suvoda IRT system delivers a set of comprehensive features for both drug supply and study managers. This allows users to set their system in a way that suits their study-specific needs.

The Suvoda system also features integration in PCI’s supply network for packaging and labeling services, global storage and distribution, as well as returns management including reconciliation and certified distribution.

Easy Integration

The Suvoda platform has been designed for easy integration with third party systems and has been built to be fully interoperable with other systems through standard Application Programing Interfaces (APIs), ensuring users receive maximum functionality as well as interoperability.

Comparator Sourcing

Through our network of specialist suppliers, PCI is able to source comparator products throughout the world. All comparator supplies are accompanied with the necessary documentation to assist with final release for the trial.

Distribution and Logistics Planning

At PCI, we understand the importance of a well detailed, global logistics strategy. We partner with the client and the IVRS supplier to determine the necessary supply strategy overage needed to support recruitment in the selected countries, offering a comprehensive global distribution plan through our in-house distribution facilities and our strategic supply network. We offer flexibility, including specialized services that support a logistics strategy including Just-in-Time (JIT) labeling or point-of-dispatch customization and Direct-to-Patient.

Language Translation

PCI provides a comprehensive translation service through our network of approved suppliers.
We provide efficient translation and guarantee accuracy. All translations are accompanied with a certificate of compliance with their country specific regulatory requirements.

Multi-language Labeling

At PCI, we offer extensive experience in providing translations and in-labeling supplies for global trials. We offer packaging solutions based on client preference and trial requirements, including packaging for individual countries, combined regions, pooled supplies or generalized global formats. PCI offers a highly professional and experienced label design service for both single panel (multi-language) labels and multi-language booklet labels. This includes label solutions for cold chain refrigerated and frozen supplies.

Randomization

Our label design and printing systems feature solutions for offering highly complex randomizations. Our flexible systems can accommodate importing pre-prepared randomizations, or work with our clients to develop the randomizations as part of their trial planning and development. We can work with any block size and randomization design, including building any required stratifications.

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Our dedicated team of specialists will be happy to discuss any of your outsourcing needs.

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