



## Excellence in Commercial Packaging



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.



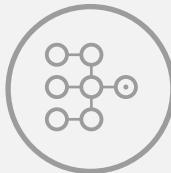
**pci** | MANUFACTURING  
SERVICES

**pci** | CLINICAL  
SERVICES

**pci** | COMMERCIAL  
PACKAGING

# PCI's Molecule to Market Service

PCI's integrated and comprehensive service offering takes you through every step of the product lifecycle and is committed to providing the leading customer experience from molecule to market.



## PRE-CLINICAL

- Formulation Development
- Analytical development/characterization

## PHASE I

- Formulation development
- Analytical development
- Drug in capsule/vial technology (Xcelodose®)
- Phase I product manufacture
- Tablets/capsules
- Blinding via over-encapsulation
- Phase I packaging and labeling
- Package design and development
- Storage and distribution

## PHASE II

- Formulation optimization
- Dosage form process validation
- Analytical testing and stability services
- Phase II product manufacture
- Tablets/capsules
- Blinding via over-encapsulation
- Phase II packaging and labeling
- Package design and development
- Storage and distribution

## PHASE III

- Comparator sourcing
- Scale-up studies
- Phase III product manufacture
- Tablets/capsules
- Blinding via over-encapsulation
- Phase III packaging and labeling
- Analytical testing and stability services
- Package design and development
- Storage and distribution

## COMMERCIAL, LAUNCH AND SUPPLY

- Scale-up for commercial supply
- Commercial product manufacture
- Commercial packaging and labeling
- Validation services
- Analytical testing and stability services
- Product release-to-market and launch expertise
- Package design and development
- Serialization
- Storage and distribution



## Commercial Packaging Expertise

With over fifty years of packaging expertise and in excess of 50 successful product launches per year, PCI is a trusted leader and industry expert in the commercialization of new medicines.



Our global capabilities include packaging for large-scale projects requiring sophisticated integrated technologies and automation and the support of more targeted therapies for select patient populations.

Our insights and expertise enable us to provide packaging solutions that truly differentiate us from the competition. We deliver product to patients creatively and effectively meeting the varying needs of each customer and market that we serve. We adapt to the unique requirements of each global market, from brand and generic ethical pharmaceuticals and biotech medicines, over-the-counter pharmaceuticals, consumer healthcare products, as well as specialized requirements for medical devices, specialty products and animal health. Our exemplary regulatory compliance record combined with our expertise in international legislative requirements ensures that we offer a best-in-class service of each and every customer.

We support global commercial supply with ongoing investment in state-of-the-art facilities and advanced packaging technologies, along with a dedicated workforce focused on delivering a consistently reliable and outstanding performance.





Packaging types supported include:

**Primary Packaging:**

- Blisters
- Bottles
- Pouches/sachets
- Tubes.

**Secondary Packaging:**

- Labeling for parenterals and injectables
- Tyvek blistering for parenterals
- Device assembly including autoinjectors and pens
- Cartoning
- Kitting
- Child-resistant and compliance-promoting packaging
- Overwrapping and pouching
- Walleting.

## Supported Delivery Forms

The true value in a global partner is the ability to successfully guide a product through the various phases of clinical development as well as successfully meet the divergent demands of ongoing commercial supply.

Our experience in commercial product launch is unparalleled. PCI affords its customers agility in a dynamic commercial market, with the flexibility to adapt quickly to changing market demands and capitalize on market opportunities.

We support the needs of a diverse portfolio of products and delivery forms, incorporating both traditional and emerging technologies including:

- Solid oral dose
- Combination therapies
- Liquids
- Gels
- Powders
- Parenterals including transdermal patches, autoinjectors, pens and other injectables, eye care applications
- Cold chain products
- Controlled substances
- Specialized products including biologics, hormonal products, cytotoxins and potent products
- Medical devices and combination products.



## Customers and Product Types



With our breadth of experience and scale of our global packaging operations, we are able to support diverse portfolio requirements including:

- Branded/ethical pharmaceuticals
- Generic pharmaceuticals
- Biotech and specialist medicines
- Over-the-counter products
- Consumer healthcare
- Specialty products
- Medical devices
- Pre-launch/marketing samples
- Animal health therapies.



# Serialization and Anti-counterfeiting Solutions

PCI is leading the global market in serialization. Our dedicated team work with each and every client to understand the requirements, research solutions and provide a bespoke solution based on need.



## **Safety**

Providing patients with safe and effective medicines requires assurance that the pharmaceutical supply chain has robust security, maintaining the highest standards for safety and regulatory compliance.

## **Regulatory Requirements**

Domestic and international governmental regulations have been implemented to address the global integrity of the pharmaceutical supply chain. Through the use of integrated and multi-layered technologies, a systematic methodology has been undertaken to combat counterfeit drug products, thereby allowing for validation of the integrity of each drug package delivered to patients.

## **Technology**

PCI has implemented a sophisticated network of technologies to provide serialized drug product for its global clients. Partnering with clients as they develop and implement their global secure supply chain strategies, PCI provides a flexible and adaptable solution to address each client need. Engaging with leading industry groups such as GS1, expert staff stay ahead of current and future complex serialization requirements as they continue to evolve for both developed and emerging markets.



## Experience

PCI has been actively providing Serialized commercial product for both domestic and global markets for many years, enabling a robust understanding of the detailed industry requirements. This industry expertise is further supported through partnership with leading serialization technology provider Antares, the platform for our global serialization services.

## Expertise and Flexibility

PCI offers clients serialization expertise and services that adapt to the needs of their drug product, package configuration, and ultimate market destination. We offer tailored and scalable solutions depending on project scope, supporting a wide range of drug products, from very targeted therapies with small patient populations up to the largest high volume global medicines.

This flexible approach extends to our adaptable technologies, giving us the ability to support differing regulatory requirements in various countries around the world. PCI supports clients with both integrated serialization technologies for highly automated packaging, as well as configurable off-line serialization technologies capable of providing serialization for almost any package format.

## Packaging Delivery Forms

PCI offers solutions for a variety of package delivery forms, including primary, secondary, and tertiary packaging, as well as providing a finishing solution for prepackaged medicines simply needing the addition of serialized codes.

## Aggregation Solution

To meet individual market requirements and client preferences, PCI also offers in-line product aggregation, providing the confidence of structured parent/child relationships amongst the various levels of packaging integration, from primary, secondary, and tertiary packaging to its pallet and captured in the completed batch. This aggregation solution allows clients to receive a secure and detailed account of their drug product, critical to a safe supply chain.

## Data Exchange

Mirroring the flexibility of PCI's approach to serialization packaging line technologies, PCI's inbound and outbound secure data exchange in support of serialization allows clients to utilize and leverage existing EPCIS and ERP networks as part of their individual global strategy. PCI interfaces with client preferred IT architecture, offering a seamless and secure networked data exchange for inbound codes as well as completed and commissioned codes upon batch release.

PCI leverages a true partnership model in meeting the advancing requirements of global Track and Trace. Let our expert and experienced staff help you craft a global strategy for meeting the needs of a safe and secure supply chain.





## Packaging Services

- Flexible and adaptable solutions for various package types
- Best-in-class technologies
- Multi-level product aggregation
- Integrated and stand-alone serialization services
- Global supply: expertise in meeting individual country requirements
- GS1 compliant
- Customized services.

## Support Services

- Serialization strategy development
- Project management
- B2B system integration
- Secure data integration and data exchange
- Package design and development
- Life cycle management
- Overt and covert anti-counterfeiting technologies.

## Packaging Development and Design Services

PCI works with customers to provide truly innovative package design and speed to market. From concept to reality, we enable products to stand out among the competition.

Our in-house design services feature an experienced and creative team of professionals who bring insightful package design and a practical knowledge of manufacturing to deliver innovative, differentiated and cost competitive packaging.



PCI provides unique services in the area of package development by offering extensive resources from design to commercialization.

Three dimensional modeling and in-house prototyping capabilities facilitate rapid design and development of commercial quality prototypes. This allows for expedited response and efficient concept generation to enable speed-to-market for new products as well as commercial package redesigns.

In addition, PCI offers extensive experience in managing the Consumer Product Safety Commission's Child Resistant and Senior Friendly test protocols required for bringing new products to market. PCI's award winning in-house design team has a proven history of successful market introductions and has received numerous industry awards for design and commercialization.



# Product Launch Services



## Flexibility, Expertise and Adaptability

PCI is the preferred launch partner of many leading companies because of our expertise and experience in bringing new products to market. We support more than 50 product launches per year. We provide a reliable and adaptable solution in managing the uncertainties often associated with commercial launches, with on-demand capacity and flexible packaging technologies coupled with experienced and responsive leadership.

As every launch is unique, our experience and responsiveness in launching new products is unrivaled. At PCI we utilize shared learnings to ensure every detail of your launch is accounted for. With a committed team of experienced

professionals lead by attentive and effective project management, we will guide your product to a successful launch with dedicated customer service for the duration of the project life.

We provide flexibility for our customers and meet the changing demands of every launch. With best-in-class technologies, extensive capacity, and substantial ongoing investment in our business, we provide value as a true partner in managing uncertainty. We assist in the management of risk through measured tactical and strategic planning combined with agile business systems and technologies.

Our expertise and extensive experience ensures speed-to-market for every product every time.



## QP Services

Qualified Persons (QPs) play a vital role in bringing 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.

The diversity of experience within our ever-expanding team of Qualified Persons ensures 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 including the auditing of manufacturing facilities world-wide to ensure batch manufacture in accordance with GMP. The team ensure certification of 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, clinical stages and commercial launch of products.



Our QP services include:

- Site audits
- Supply chain management
- Quality oversight
- Release-to-market.

# Analytical Laboratory Services

PCI provides fully audited, in-house laboratories in both our European and North America locations 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 analytical 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.

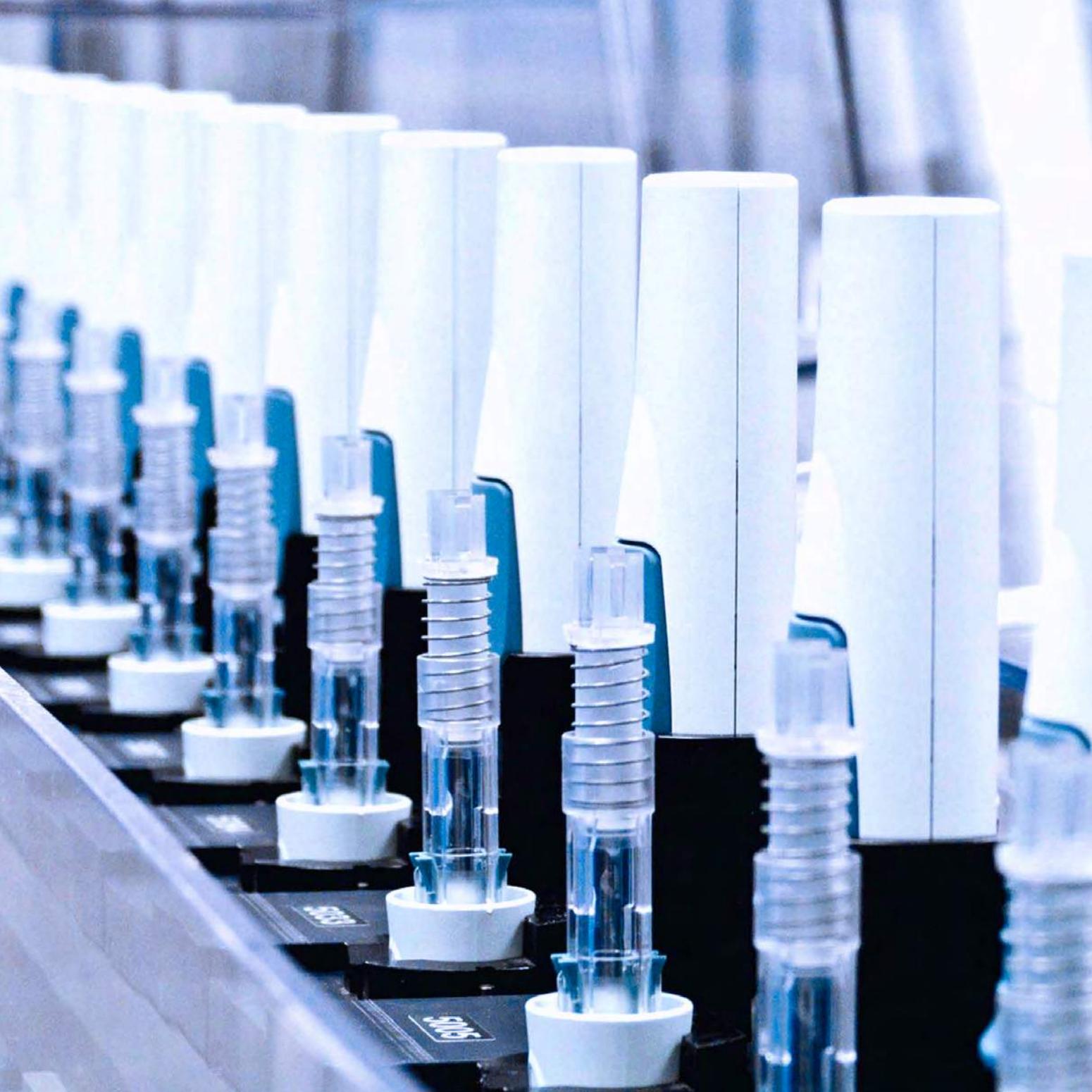
Analytical services are offered on a stand-alone basis or in conjunction with our clinical, commercial and QP services to facilitate a seamless transmission through the drug development cycle.

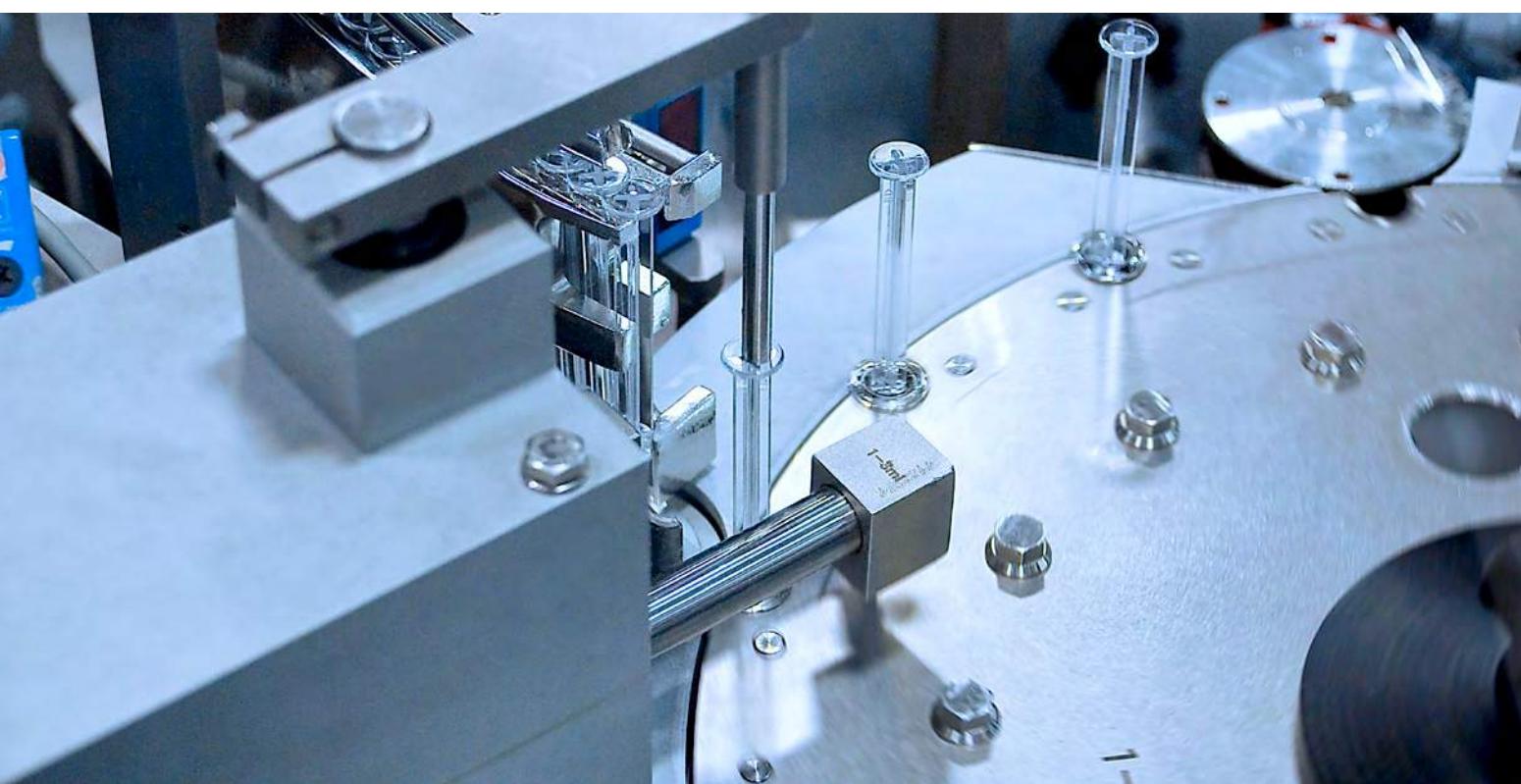
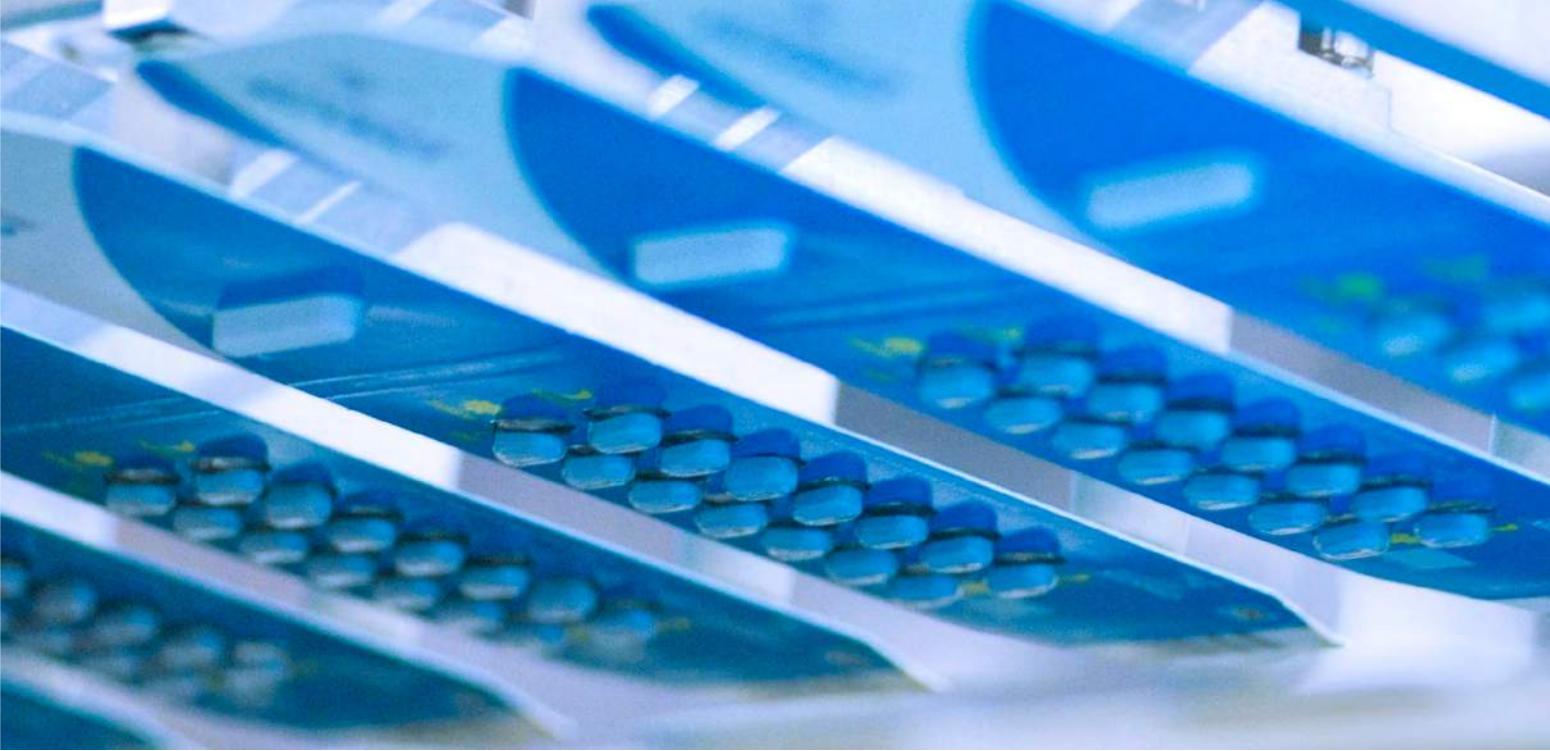




Our analytical services include:

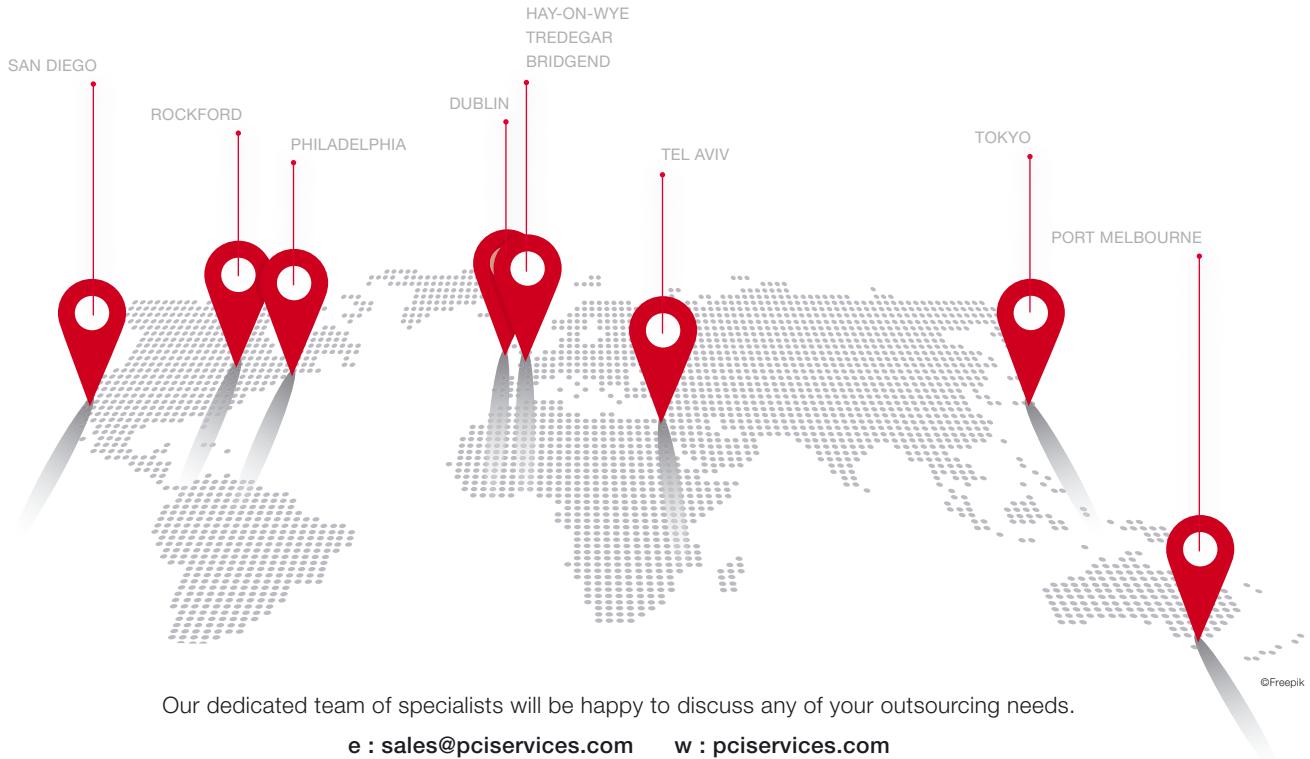
- Stability testing
- ID testing
- Import testing
- Import release testing.





# pci

PHARMA SERVICES



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

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