pci PHARMA SERVICES

Your world leading CDMO.

Quality and Regulatory Services (QRS)

As a world class CDMO, we relentlessly strive to deliver better health outcomes for the patients we serve by combining our experience and expertise in science, manufacturing, and technology with our pristine customer service.

PCI Quality and Regulatory Services (QRS) offers our customers bespoke services to assist with quality and regulatory solutions throughout the drug product lifecycle.

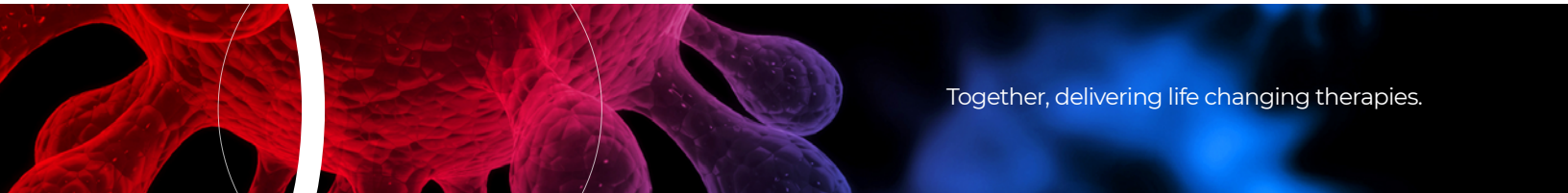
The PCI-QRS team draws on a pool of expertise within the PCI organization and a trusted network of external consultants to provide solutions to ensure your drug product is delivered to patients with the highest levels of quality, safety, and regulatory compliance.

Our industry-leading experts are able to provide quality and regulatory expertise, supporting you through your clinical program through to commercial marketing authorizations.

PCI-QRS Covers a Whole Range of Activities

The services provided can be tailored to your individual needs and include the following:

- **Quality audit services** – PCI-QRS will provide a centralized audit service, giving you an enhanced customer experience. The assigned team member will collaborate with you in the preparation, execution, and remediation to ensure key touch points are covered during the audit process
- **CMC consultancy and writing** – a bespoke service that can be utilized at the level of support you require- from full dossier writing to individual sub-sections or independent review of CMC documents compiled by third parties
- **Regulatory support** – supporting you from a CMC perspective at scientific advice meetings and end of phase meetings
- **PSF fast track readiness** – let us help to align your documentation so that you are ready to launch your EU clinical trial as quickly as possible
- **Commercial readiness** – a support service delivering local market expertise and assistance with commercial registration to complement your in-house capabilities
- **Standalone quality services:**
  - Person in plant – assessment of quality/compliance issues
  - Deviation investigation support
  - Quality Technical Agreement support
  - QMS development
  - Regulatory inspection readiness



Overview

The services offered by **PCI-QRS** can be customized to meet your needs. At the outset and as a potential virtual company, you may choose to utilize **PCI-QRS** to support your core staff and as the relationship grows we can adapt to meet your needs and ensure that we share the knowledge we have attained with your growing team.

PCI-QRS will assess your needs and assign one of our pool of experts most closely aligned with the skills and experience you need. Working with the **PCI-QRS** team we will create a detailed RACI matrix to agree roles and responsibilities and agreed levels of collaboration which are required to support your needs.

Our highly experienced **PCI-QRS** team is also able to guide the establishment of processes and SOPs when they do not exist or are not robust.

The team is able to create process flows and author SOPs to fit within your quality system on any quality or regulatory aspect such as:

- Vendor management
- Deviation management
- Change control
- Lot release
- Validation
- Customer complaints
- Recall and recovery

The **PCI-QRS** team will integrate with your internal team, bridging the gap and aligning objectives.

Key Benefits of Utilizing PCI-QRS Process

- A truly turnkey solution that can be utilized to meet your needs
- Your **PCI-QRS** support will become true subject matter experts in terms of your product, program, objectives, and key regulatory milestones
- Deliver local market intelligence and a gap analysis to identify potential challenges ahead of the regulators
- Access to a pool of expertise that is matched to your specific needs