clinicalSMART™

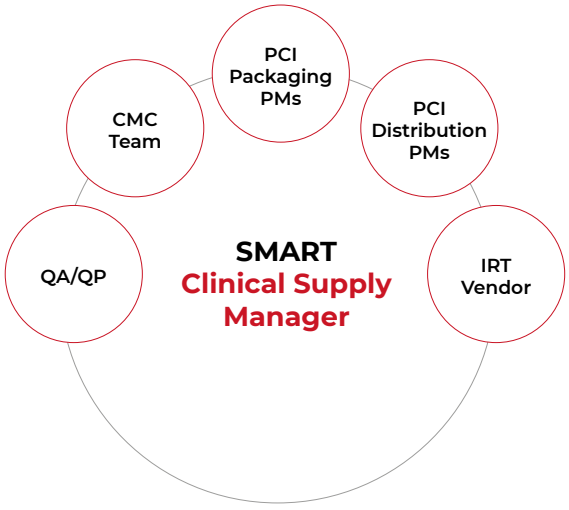
Supply Management And Readiness Team

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.

Clinical Supply Management (Supply Management And Readiness Team – SMART)

PCI offers customers industry leading expertise in Clinical Supply Project Management. The **SMART** team consists of experienced Clinical Supply Managers who collectively have hundreds of years of industry experience.

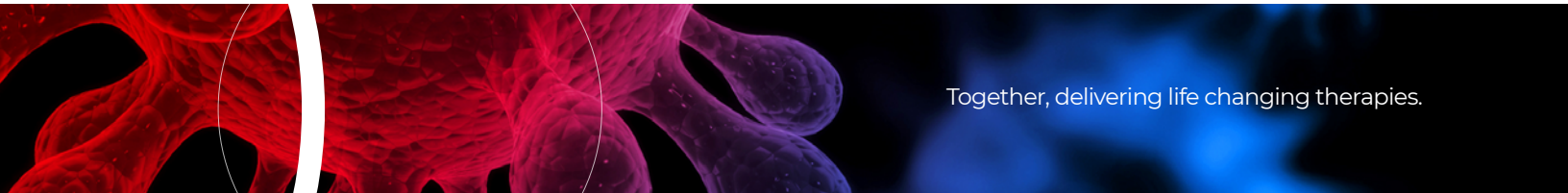
This experienced group are able to provide supply chain expertise, supporting clinical programs across all phases of development.



SMART Services

Clinical Supply Management Services at PCI can supply end-to-end support for clinical trial supplies management. The services provided can be tailored to individual customer needs and may include the following:

- Initiate RFQ document writing for outsourcing requirements
- Lead the clinical supply cross-functional team
- Provide input into protocol development
- Create drug supply demand/forecast plans
- Contribute to and edit pharmacy manuals
- Develop drug supply strategy and timelines
- Direct IRT system development and user acceptance testing
- Create basic English label text for drug supply per protocol and regulatory requirements
- Coordinate packaging schedule with PCI project managers
- Manage the IRT and complete lot release activities
- Track screening/enrollment and adjust supply strategy as per study needs
- Track shipments and manage temperature excursions
- Monitor and manage drug supply inventory at sites and depots
- Manage trial close-out activities



Services

The services offered by PCI's clinical **SMART** team can be customized to meet specific study requirements and can be adapted as the trial or clinical plan progresses. **SMART** Clinical Supply Managers (CSMs) have the expertise to manage single trials or entire clinical programs. Working with your **SMART** CSMs will create a detailed RACI to agree roles and responsibilities and agreed levels of collaboration which are required to support the study.

Our highly experienced CSM team are also able to guide the establishment of processes and SOPs when they either don't exist or are not robust. The team is able to create process flows and author SOPs to fit within your quality system on any clinical supply related aspect such as:

- Label text creation and approval
- Temperature excursions
- Lot release
- Recall and recovery

Overall, clinical **SMART** CSMs integrate into the entire supply chain and are your advocate within PCI.

Key Benefits of Utilizing SMART RFQ Process

- Review key study assumptions and estimates in order to establish an initial study supply plan
- RFQ and relevant documentation prepared for your customer
- Thorough evaluation of study requirements and accuracy of the quotation
- RFQ submitted to **SMART** team for peer review, which ensures that you benefit from hundreds years of **SMART** experience

Key Benefits of SMART CSM Service

- Access to experienced clinical supply project managers
- Tailored customer support on a consultative basis or operational execution of clinical supply management activities, as per agreed requirements
- Dedicated experienced project management resource with end-to-end capabilities from protocol development to study close
- Provides expertise and capabilities that may not be available internally
- Provides resource when required without the need to add internal headcount