PCI PHARMA SERVICES

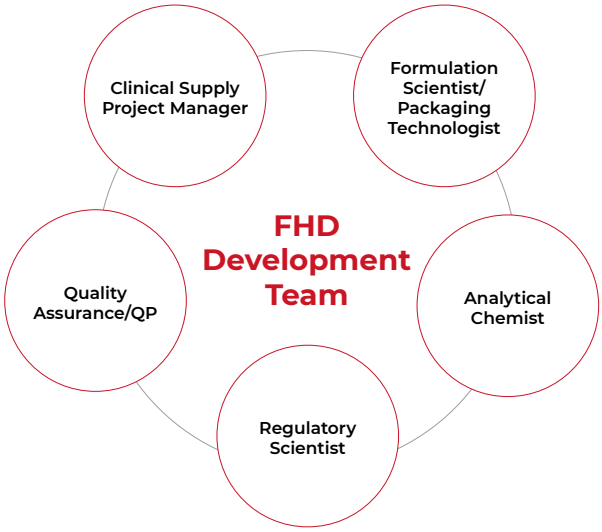
Your world leading CDMO.

SMART First Human Dose (FHD)

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.

SMART First Human Dose (FHD)

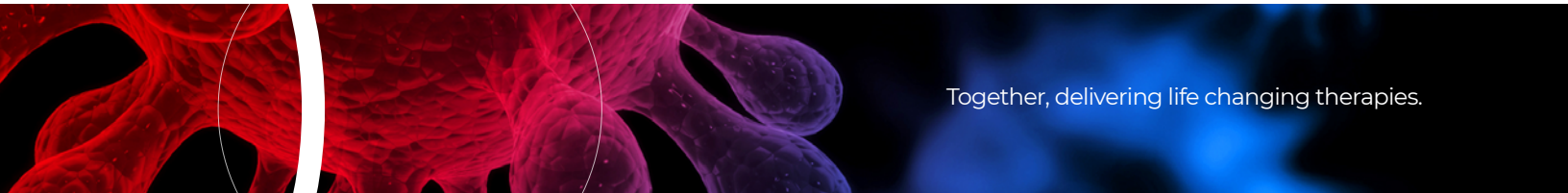
PCI offers customers industry leading expertise in Supply Project Management rapidly transitioning a solid oral dose drug from candidate selection to first human dose clinical trials. The SMART FHD team consists of experienced Clinical Supply Managers, Regulatory Scientists, Formulation Scientists, Packaging Technologists, Analytical Chemists and Quality Assurance/QPs who collectively have hundreds of years of industry experience. This experienced group will oversee all drug development preparation activities plus regulatory and clinical trial supply management.



SMART FHD Services

The SMART FHD team at PCI can provide a development path that will be months faster to first human dose clinical trials and years faster to market than traditional formulation development timelines by managing the following:

- Develop and manufacture min & max drug-in-capsule dosages
- Qualify test methods and conduct a bracketed stability protocol including packaging, storage, and testing and provide reports
- Manufacture Drug-in-Capsule dosages, bottle, and label for clinic use
- Compile all CMC information for regulatory submission
- QP release the clinical drug
- Manage inventory and distribute the drug for clinical use
- Supply project management to organize and oversee all aspect of the development project



Together, delivering life changing therapies.

Overview

PCI's SMART FHD Offering

It can take up to two years to prepare for your first clinical trial in the US. With PCI's SMART FHD that time can be reduced to be just a few months.

DAY	0	30	50	60	75	110	115	120	130	165
	PCI receives DS	Formulation & analytical development	Clinical capsule strengths set	Stability protocol started	Clinical manufacture started	Clinical packaging released	Drug shipped to Canada	1 month stability data	IND filed	US trial begins

Benefits of SMART FHD

- Rapid Access to Clinical Data
- Drug Development Removed from Critical Path
- Receive "White Glove" Service
- Significant Financial Savings
- Time & expense of multiple development activities eliminated
- Flexibility of Supply through Phase 2a (& possible beyond)