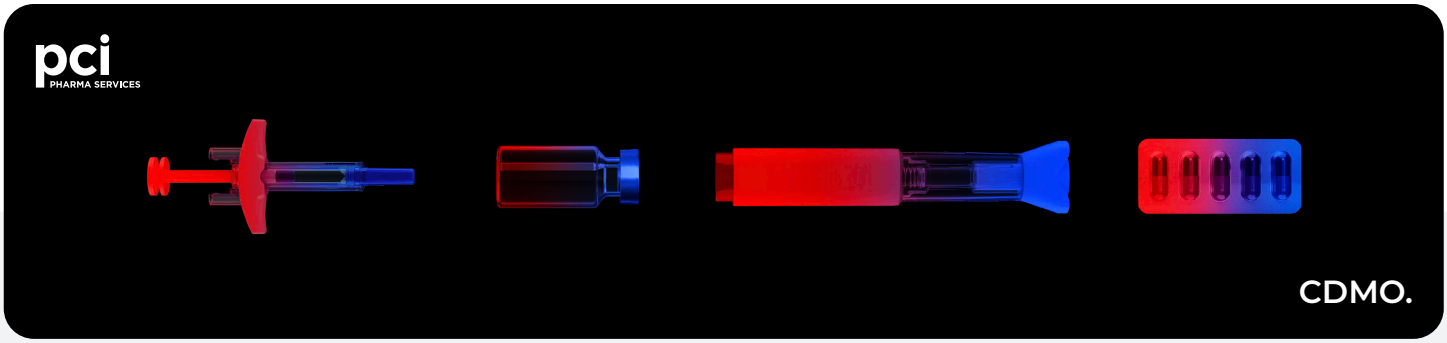
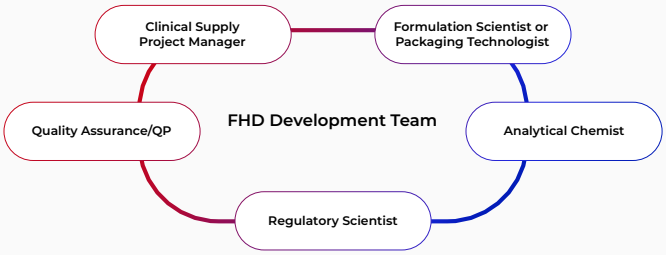


First Human Dose. **Accellerated.**

SMART FHD™ (First Human Dose Acceleration) is our specialized service designed to compress the path to clinic from years to months by rapidly advancing solid oral dose drugs from candidate selection to First Human Dose trials.

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

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
PCI recieves DS

DAY 30
Formulation & analytical development

DAY 50
Clinical capsule strengths set

DAY 60
Stability protocol started

DAY 75
Clinical manufacture started

DAY 110
Clinical packaging released

DAY 115
Drug shipped to Canada

DAY 120
1 month stability data

DAY 130
IND filed

DAY 165
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