Pii 25th ANNIVERSARY

PHARMACEUTICS KNOW-HOW™

FORMULATION DEVELOPMENT • ANALYTICAL SERVICES • CTM & COMMERCIAL MANUFACTURING • PACKAGING

DEA Schedules (I-V) • Potent Compounds • Hormones • First-in-Man Phase I • Bioavailability Enhancement

ABOUT Pii

Pharmaceutics Know-How™

Pharmaceutics International, Inc. (Pii) is a premier Contract Development and Manufacturing Organization (CDMO), offering unparalleled scientific insight and depth of product knowledge, while supplying high quality dosage forms that enhance the lives of patients worldwide.

Overview

Pii provides customized and flexible solutions, across several dosage forms and has experience with a broad range of compounds. For twenty-five years Pii has been supporting its pharmaceutical partners (from virtual to multinational) with extensive technical capabilities, know-how, and the highest level of customer service. With more than 400 development programs completed, Pii's scientific team has extensive experience working with drug substances representing a range of physicochemical characteristics (and challenges). Our specialized capabilities, multi-product facilities and knowledge-base, allow us to work with potent compounds , hormones and cytotoxics, develop complex dosage forms, and support varied manufacturing processes.

Facilities & Equipment

Pii operates over 360,000 square feet of state-of-the-art pharmaceutical development and manufacturing space, all located on one campus in Hunt Valley, MD. This includes over 70 flexible, manufacturing suites, several with the required containment controls for handling potent compounds and hormones, as well as a dedicated suite for the production of soft gel capsules.

Licensed to manufacture DEA Schedule I-V products, with capabilities for both oral delivery and parenteral dosage forms, Pii has the depth to support development, clinical and commercial requirements. Facilities are cGMP qualified and include dedicated formulation development centers for solid oral, liquid and sterile products.

Services

- Preformulation Studies
- Dosage Form Development & Manufacturing
- Analytical Development & Testing
- CTM Manufacturing
- Commercial Manufacturing
- Serialization
- Clinical Packaging and Distribution
- Regulatory Support
- Quality Management
- Commercial Packaging

Dosage Form Development & Manufacturing

- Sterile (vials, syringes, lyophilized) (*cartridges coming soon)*
- Injectables (aqueous and non-aqueous)
- Oral solids (soft gels, tablets, capsules)
- Oral liquids (suspensions, syrups, solutions)
- Topicals
- Potent compounds, hormones, cytotoxics
- Solid dispersions

- Controlled release formulations
- Fluid-bed processing (solvent and aqueous)
- Micro & Nanotechnologies
- Coating (aqueous and solvent)

Analytical

Pii's analytical laboratories work under strict compliance with cGMP/GLP requirements, with operations based on comprehensive SOPs and rigorous quality assurance practices. Our analytical group has extensive experience in method development and validation, with a profound understanding of all aspects of the drug development process. We design and execute detailed protocols for full method validation, verification and transfer, covering procedures for APIs and a wide array of drug formulations. Pii's analytical laboratories are designed to perform the following studies in support of all stages of formulation and development:

- Early development stability
- Excipient compatibility
- Component compatibility
- Solubility screening
- Thermal cycling and freeze-thaw
- Photo stability
- Microbiology

Regulatory Affairs

Our team of in-house compliance and validation subject matter experts offer Regulatory strategies for drug development preparation, review and submission of Abbreviated New Drug Applications (ANDA) and New Drug Applications (NDA) for a variety of dosage forms and CMC sections.

- Electronic common technical documents (e-CTD) preparation and amendments
- Life cycle management for approved applications
- Regulatory assessment of post-approval changes, strategy and supplements
- Labeling services (ANDA)

Quality

At Pii, Quality is at the core of everything we do, knowing that the "c" in GMP is a constantly moving target. As regulatory standards continue to evolve, Pii focuses on exceeding "current" GMP guidelines.

Our Quality Systems are designed to achieve consistent product quality through thoughtful quality planning, control and measurement. Pii's Quality Systems consists of four key elements:

- Process performance and product quality monitoring
- Corrective action and preventive action (CAPA)
- Change management
- Internal, customer and regulatory inspections.

Data are compiled, analyzed and regularly reviewed as part of Pii's Key Performance Indicator (KPI) program. This continuous improvement philosophy ensures that we meet and exceed current GMP requirements, and our partners' expectations.

PHARMACEUTICS KNOW-HOW™

Sharing scientific insight,
a depth of product knowledge, and
delivering high quality dosage forms that
enhance the lives of patients worldwide.

CMO LEADERSHIP AWARDS2019

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To learn more about Pii, contact us at bd@pharm-int.com or (410) 584-0001
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