



PHARMACEUTICS KNOW-HOW™

GENiSYS® R ASEPTIC FILLING SYSTEM

With the increased demand for production of smaller batches, as well as greater operational flexibility and efficiency, our aseptic manufacturing expertise and innovative GENiSYS® R filling technology provides the customized solution needed by pharmaceutical companies.

Our GENiSYS® R, fully robotic filling line, has a number of automated capabilities that ensure sterile drug products, whether for clinical or commercial supply, are processed in shortened timelines according to strict cGMP requirements. The isolator-barrier system can easily adapt to varied processing requirements, provides for container options with programmable recipes and simple change parts, giving Pii the ability to process all ready-to-fill vials, syringes and cartridge formats. The unit further allows the user to set the statistical in-process control (IPC) system from 0 to 100 percent during the batch run, ensuring fill accuracy throughout the batch. For larger batches, the system can identify the need for an uninterrupted pump calibration correction to ensure fill accuracy, regardless if a batch is 10,000 units or more. The GENiSYS® R filling line provides reliable and flexible processing, minimizes manual operations, and reduces product waste, common at the beginning and end of batch manufacturing.



Pii's GENiSYS® R Aseptic Filling System

- Batch sizes ranging from 500 – 20,000 units
- Average fill rate 20 units/minute
- Highly flexible line
- Maximize Product Yield – Minimize API Loss
- Electronic Batch Records
- Highly accurate product filling
- Stability & Engineering Batches
- Clinical to Commercial Production
- R&D and Process Development
- Aseptic, Toxic, Cytotoxic Drug Products
- Aggressive product delivery timelines
- Multi RTU formats
 - Vials
 - Syringes
 - Cartridges

Pii

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Pii provides customized and flexible solutions, across several dosage forms and has experience with a broad range of compounds. For over twenty-five years Pii has been supporting its pharmaceutical partners 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 and hormones, develop complex dosage forms, and support varied manufacturing processes.

CAPABILITIES

- Sterile (vials, syringes, lyophilized)
- Injectables (including viscous)
- Oral solids (soft gels, tablets, capsules)
- Oral liquids (suspensions, syrups, solutions)
- Potent compounds, hormones, cytotoxics
- Solid dispersions (spray drying)
- Controlled release formulations
- Fluid-bed processing (solvent and aqueous)
- Micro & Nanotechnologies

SERVICES

- Preformulation Testing
- Dosage Form Development
- Analytical Development & Testing
- CTM Manufacturing
- Commercial Manufacturing
- Aseptic Filling
- Clinical Packaging and Distribution
- Regulatory Support



**FORMULATION
KNOW-HOW**



**PROCESS AND
MANUFACTURING
KNOW-HOW**



**COMMERCIAL
KNOW-HOW**



**QUALITY
KNOW-HOW**



**PROJECT
MANAGEMENT
KNOW-HOW**



**REGULATORY
KNOW-HOW**