Parenteral & Lyophilized Clinical Trial Materials

VxP Pharma
Purdue Research Park
5225 Exploration Drive
Indianapolis, IN 46241
Tel: 317.759.2299
Fax: 317.713.2950
VxP Pharma provides an extensive range of services and technical support for the development and production of sterile and lyophilized products for clinical trial materials.

- Liquid Parenterals
  - Solutions, Suspensions, Emulsions, Biologics
- Lyophilized Parenterals
- Potent & Cytotoxic Compounds
- Radiolabeled Products
Regulatory

• **US-FDA Inspection:**
  – Manufacturing facility, November 2015 *(Passed with no 483s)*
  – The entire facility and the quality systems used for the manufacture and release of drug products were subject to a detailed compliance inspection.
  – The inspection found the facility to be compliant with the principles and guidelines of current Good Manufacturing Practices (cGMPs).

• **Pre-Approval Inspection (PAI):**
  – *Successful PAI in 2010 and 2013* associated with a customer’s Abbreviated New Drug Application (ANDA) filing with the FDA.
Services Overview


• Current Manufacturing Capabilities include:
  – cGMP Manufacturing of Drugs and Medical Devices
  – Aseptic Processing of Injectables and Ophthalmics
  – Lyophilization
  – Terminally Sterilized Products
  – Non-sterile Liquids: Emulsions, Gels and Suspensions
  – CTM and CMC Support
Facilities & Equipment

- **Clean Rooms:**
  - Class 100 Clean Room with Lyophilizer(s)
  - Class 100 Clean Room General Purpose
  - Class 100 Sterility Testing Suite
  - Class 10,000 Formulation Areas

- **Laboratories/Storage:**
  - Micro Lab (Environmental Monitoring, Bioburden, PET, AME, Sterility, LAL)
  - QC Lab
  - Analytical Chemistry Lab
  - Stability Chambers (5°C and Accelerated Conditions)
Facilities & Equipment

- **Other Equipment:**
  - Autoclave
  - USP Water Manufactured on Site
  - Ampule Filler
  - Tube Filler
  - Syringe Filler
  - Bottle Filler (15-mL to 360-mL)
  - Microfluidizer/Homogenizer
  - -80°C Storage
  - Centrifuges
  - Standard Pharmaceutical Process Equipment
  - Interested in our Fill Rates/Capacities? Contact us today.
Development Services

STERILE DEVELOPMENT & LYOPHILIZED CTM SERVICES
Lyophilization Development and Cycle Optimization

- **Formulation Development:**
  - Sterile liquid products (solutions and suspensions)
  - Sterile lyophilized products (aqueous and non-aqueous)

- **Lyophilization Development:**
  - Focus on robust cycles that are cost efficient
  - 4 to 48 ft² chambers equipped with multiple shelves (316L stainless steel)
  - Fully automatic controls with 24/7 redundant monitoring
  - Sample thief for mid-cycle analysis

- **Process Development:**
  - Focus on scalable compounding and filling processes.

- **Process Transfer:**
  - Ensure smooth transition into our manufacturing facility.

**STERILE DEVELOPMENT & LYOPHILIZED CTM SERVICES**
Analytical & Bioanalytical Testing Services

- **VxP Pharma** provides an extensive range of analytical services and technical support for method development, validation and testing for multiple pharmaceutical and biopharmaceutical applications

  - API Testing
  - Product Development Testing
  - CMC/Compendial Testing
Manufacturing Services

STERILE DEVELOPMENT & LYOPHILIZED CTM SERVICES
Sterile Manufacturing Facility

• Sterile facility is ideal for:
  – Small & Large volume parenterals
  – High valued supplies
  – Terminally sterilized products
  – Lyophilized products

• Self-sufficient facility:
  – WFI generation (cGMP)
  – Clean steam/Autoclaves
  – Sterile filtered Air and Nitrogen
  – Glass and Component Processing

* Blow-Fill-Seal Technology Available
Blow-Fill-Seal (BFS) Technology for Aseptic Processing

• Operating principles:
  – Using the BFS technique, a container is formed, filled, and sealed in a continuous process without human intervention in a sterile enclosed area inside a machine. This technique works exceptionally well to aseptically manufacture sterile pharmaceutical liquid dosage forms.

• BFS Technology provides several important advantages:
  – More Accurate Dosing (Unit-Dose) – BFS allows high-volume, sterile packaging of product in liquid unit-dose form, helping to reduce human error.
  – Preservative Free – Aseptically packaging products eliminates the need for preservatives.
  – Contamination Prevention – Contamination rates in the BFS process are much lower than in many other forms of packaging. The FDA considers BFS to be a superior form of aseptic production.
Our core strength is the ability to handle highly potent drugs including:

- Cytotoxins
- Steroids
- Hormones
- Acutely Toxic
- Radio Labeled
- Small Dose
- DEA Controlled Substances (CS II-V)
Large Molecule Projects

- We have many years of experience with both small molecule and large molecule products:
  - Polymer bound small molecules
  - Polymer encapsulated small molecules
  - Liposomal products
  - Proteins and Peptide Products (adjuvants and actives)
  - Monoclonal Antibodies
  - Antibody-Drug Conjugates

*Interested in Biologics Services? Please ask for a PDF slide deck today.
Phase appropriate approach to method qualification and validation.

Testing needed to support your manufacturing process:

- HPLC/UPLC (RP,SEC,IEX)
- GC
- Bacterial Endotoxins
- Sterility Testing (in-house)
- Container Closure Integrity
- TOC
- UV/Vis
- SDS-Page
- Karl Fisher
- Freezing microscopy
- Differential scanning calorimetry
- NMR
- ELISA
- IEF
- Western Blot
- Vitek 2
- Full ICH Stability Programs
- Particle Size Analysis
THANK YOU

For additional information:

VxP Pharma

[www.vxppharma.com](http://www.vxppharma.com)

Phone: 317.759.2299

Email: [info@vxppharma.com](mailto:info@vxppharma.com)