Oakwood labs

Contract Manufacturing Overview

Non-Confidential

Company Overview

- **Company Profile**
  - Founded in 1997 (25+ years in the pharmaceutical industry)
  - Privately owned
  - Located near Cleveland, OH
- **Facilities and Capabilities**
  - Research and Development (Headquarters)
  - GMP Aseptic Manufacturing Facility
- **Areas of Focus**
  - Development of sustained release injectables
    - Patented Chroniject™ polymer microsphere-based technology
    - Flexible release durations from weeks up to one year
    - Compatible with a variety of different molecules
    - Applications in multiple therapeutic indications
    - Expertise from multiple projects through Phase 3 clinical studies
  - Contract manufacturing of standard injectables
    - 5 FDA approved products manufactured for clients
    - 3 additional registrations pending approval

Manufacturing Capabilities

Parameters	Capabilities
Route of administration	Injectables
Formulations	Aqueous, solvent, suspensions, microspheres
Class of drug	Class III and Class IV controlled substances Safebridge category 3 or less
Container closure system	Vials with plug or lyophilized stopper, capped aluminum seals
Sterilization method	0.22µ sterile filtration, aseptic filling process, terminal sterilization (3rd party)
Market	United States
Vial sizes	2 mL to 30 mL
Fill volumes	0.7 mL to 11 mL (can be expanded)
Maximum Batch size	20,000 to 30,000 vials

GMP Aseptic Manufacturing Facility Overview

- Qualified in 2005
- ISO classified
  - ISO 5/7 filling area & aseptic formulation area
  - ISO 7 equipment/component staging area
  - ISO 8 support areas (equipment/component preparation; non-aseptic formulation)
  - ISO 8 sampling/dispensing area
  - Controlled non-classified area
- Inspection, labeling, and packaging
- WFI & Clean Compressed Air generation and distribution systems
- Nitrogen distribution system
- Building automation system
- QC Chemistry and QC Microbiology labs
- Temperature controlled warehouse

GMP Aseptic Manufacturing Facility Overview

- **Aseptic Process**
  - Media fills are performed at minimum every 6 months
    - 0 turbid units since qualification of the facility
- **Products**
  - 5 FDA approved products manufactured for clients
  - 3 additional registrations pending approval
- **FDA Regulatory Status**
  - Last inspection: 2024 (Full GMP)
    - No major findings


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