



HollisterStier

CONTRACT MANUFACTURING

A Jubilant Organosys Company

HollisterStier Contract Manufacturing

3525 N. Regal St.

Spokane, WA 99207-5788

Tel: (509) 489-5656

Fax: (509) 484-4320

Web: HScontract.com

E-mail: fill@hollister-stier.com



Vital Statistics

Year Founded: 1921

Number of Employees: 520

Who We Are

CONTRACT MANUFACTURING AT HOLLISTERSTIER is located in a 190,000ft² facility situated on 20 acres in Spokane, WA, USA. HollisterStier has become recognized globally for quality and project execution, a strong regulatory track record and the ability to provide "one stop shop" services to customers. Highly skilled, cross-functional teams provide custom solutions to customer-specific project goals from development through commercialization. HollisterStier is designed for multi-product operations and houses four separate manufacturing areas that includes two commercial high speed fill lines and clinical trial and small lot manufacturing. HollisterStier offers lyophilization services, multiple options for compounding as well as a full-service 6,000ft² laboratory that includes quality analytical testing services and microbiological support.

Facilities

Commercial Manufacturing

- Two high speed commercial fill lines
- 2 -100 mL vials, Lyo and Liquid Fill
- Lot sizes up to 375,000 vials/day
- Four lyophilizers; automatic cold shelf loading/unloading
- Terminal Sterilizing Autoclave

Clinical and Small Lot

- ❑ **Clinical Trial Manufacturing (CTM)**
 - Phase I – Phase III
 - Lot sizes up to 5,000 vials/day
 - Aseptic Compounding Area
 - Class 100K Compounding Suites
 - SIP Station for Equipment
 - Class 100 Area Cameras for Monitoring Activities
 - CIP and Manual Cleaning Station
- ❑ **Small Lot Manufacturing (SLM)**
 - Phase I – Commercial
 - Lot sizes up to 10,000 vials/day
 - 30ft² lyophilizer
 - Small Scale Vial Filling

Services Offered

Fill/Finishing

- Process Development
- Compounding and Aseptic Compounding
- Filling
- Lyophilization
- Terminal Sterilization
- Inspection
- Labeling
- Packaging
- Multiple Storage Conditions
- Vendor Qualification

Analytical and Microbiological

- Method Validation
- Qualification of analytical methods
- Technical transfer of methods
- Sterility Testing
- Biological Assays
- Stability Storage and Testing (ICH Standards)
- Finished Product and Raw Materials Testing

Validation

- Process Validation
- Project Master Plans
- Protocol Writing and Summary Reports
- Installation Qualification
- Operational Qualification
- Performance Qualification
- Project Management
- Component Evaluation

Regulatory

- Formulate Regulatory Strategy
- Facilitate Effective Interaction with Regulatory Authorities
- Drug Master File
- Provide Guidance and Expert Review of Regulatory Submissions
- Prepare and Supply a Complete Range of Regulatory Documents
- FDA, EMEA, PMDA, ANVISA, Health Canada
- MHRA Investigational Medicinal Products (IMPs) Certification for SVP lines, CTM and SLM

HScontract.com