



# Selecting a CMO Partner for Sterile Injectable Manufacturing

## Jubilant HollisterStier's Value Proposition for Customers

**HARMIK SOHI**  
Director – Injectables and Specialty Formulations  
Jubilant HollisterStier


Performing the transfer of a product or technology from a small-scale development process (or R&D process) to full-scale commercial manufacturing can prove challenging for many drug developers and manufacturing sites. Finding the right contract manufacturing organization (CMO) partner to help navigate this scale-up can greatly simplify the process, but vetting CMOs for their capacity, expertise, and capabilities can pose its own unique challenges.

When it comes to the tech transfer of sterile injectables, vetting manufacturing partners comes down to more than the availability of the facilities or the equipment itself. Companies should also look for CMO partners that offer end-to-end support necessary to maximize production while guaranteeing safety, quality, and efficiency. Jubilant HollisterStier (JHS) possesses a wide range of manufacturing capabilities and experience for both aseptically filled and terminally sterilized products, including small molecules, biologics protein containing products, liquid and lyophilized products, liposomes, oligonucleotides, cold kits for radiopharmaceuticals, and vaccines. Its facilities, capabilities, and equipment, coupled with the expertise and support services that enable rapid scale-up and transfer, make Jubilant HollisterStier an ideal partner for sterile injectable manufacturing.

In-house manufacturing capabilities represent just one piece of JHS's value proposition for clients. The CMO's extensive knowledge and understanding of regulatory and compliance requirements, cross-functional support, and strong project management and process mapping activities allow it to tightly control timelines and costs, while ensuring optimized manufacturing for a wide range of applications. These paradigms are further complemented by JHS's commitment to transparency, collaboration, and open communication throughout the



**Jubilant HollisterStier is a customer-focused, high-quality, full-service CMO uniquely focused on sterile fill finish of liquids and lyophilized injectables, ophthalmic manufacturing, and packaging solutions.**



tech transfer process; together, this holistic approach has resulted in a regulatory and commercial track record that places it among the foremost CMOs for sterile injectable manufacturing.

### **New investments for continued growth**

To meet the ever-growing demands of the industry, Jubilant HollisterStier has also made several strategic business investments, including a \$92 million business expansion for a new filling line that will be operational in 2024. This new high-speed line, which represents the highest degree of quality and compliance to meet current regulatory requirements, features isolator barrier technology, single-use capabilities, a 2mL – 100mL fill capacity, and two lyophilizers. The line with isolators will be equipped with automated H2O2 bio-decontamination to provide a localized ISO-5 environment for aseptic filling of vials. This planned line will include vial depack, an integrated vial washer and depyrogenation tunnel, a vial filler, vial capping under Grade A environment (RABS), and vial transfer and tray loading. The high-speed filler will be capable of filling 300 vials per minute and will be designed to allow processing of 2mL – 100mL tubular and molded vials. The system will utilize integrated peristaltic pumps with a filling range of 0.50mL – 100.0mL and will be equipped with a fully automatic weight check system with integrated in-process control (IPC).

The new filling system will be capable of processing suspension products, which requires recirculation from the product bag/reservoir in order to maintain product homogeneity; it will also be equipped with gas overlay and purge options for oxygen-sensitive products. The line will utilize primarily single-use assemblies; the filler itself will be designed to fill from a 5L single-use bag on a load cell. JHS will offer a variety of pre-developed single-use assemblies for new clients, including single-use redundant filtration assemblies, single-use bag assemblies, filling needles, and compounding tank assemblies. These pre-developed assemblies will provide existing, well-defined options for clients in order to streamline the product/process transfer.

The lyophilizers will support ambient (18 to 25°C), cold (2 to 8°C), and frozen-shelf (-20 to -50°C) loading. These lyophilizers will also be capable of gas backfill with sterile filtered N2, air, or other gases as necessary, as well as automatic stoppering, automated filter integrity testing, automated chamber defrost, automated clean in place (CIP), automated steam in place (SIP), and automated leak testing.

All new equipment control systems are designed, tested, and qualified in accordance with GAMP 5 and will be compliant with 21 CFR Part 11 requirements.



### **Capabilities, facilities, and equipment**

Jubilant HollisterStier's existing facilities represent the core of its value proposition for its clients, healthcare providers, and patients. At its Spokane, Washington facility, two high-speed commercial vial-filling lines, each capable of filling 2mL-100mL vials utilizing diaphragm pump technology, are fully integrated from vial washing through capping. Its filling suites feature reduction systems for O2-sensitive products for both liquid and lyophilized formulations. In addition, the lyophilizers have capability to support ambient (18 to 25°C), cold (2 to 8°C), and frozen-shelf (-20 to -50°C) loading.

The Spokane site also features a clinical trial manufacturing line, capable of sterile liquid filling and lyophilization at a speed of up to 80 vials per minute. This line utilizes an IMA Life Sterifill 100 filler, which is fully servo-driven, and includes a 30-foot squared lyophilizer with automated CIP/SIP cycles, an external condenser, and frozen-shelf loading capability at -45°C.

In addition to its injectables manufacturing and fill finish capabilities, JHS also offers a wide range of packaging possibilities, including primary container labeling, cartoning, trays, inserts, and others, all customizable to conform to client specifications and requirements. JHS's packaging and inspection areas feature automated and semi-automated visual inspection capabilities to complement its analog inspection protocols. Additionally, JHS can provide automated label applications up to 400 vials/minute. The company also has automated unit carton capabilities, as well as experience with serialization and aggregation of unit or multi-pack cartons. This site also offers custom inspection capabilities, including a Lighthouse VISTA/THC headspace analyzer, which performs nondestructive oxygen and vacuum monitoring in vial headspace utilizing diode laser technology. The equipment is capable of inspection speeds up to 300 vials/minute.



The Spokane facility is routinely inspected and accredited by the U.S. Food and Drug Administration (FDA), the UK's Medicines and Healthcare products Regulatory Agency (MHRA) on behalf of the European Medicines Agency

(EMA), the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), Health Canada, the Brazilian National Health Surveillance Agency (Anvisa), and many others.

### **Support services that foster innovation**

Method transfer and validation, analytical quality control (AQC), microbiological quality control (MQC), quality assurance oversight, stability support, regulatory affairs – JHS's support services are designed to address every aspect of process transfer and validation to meet current regulatory and compliance expectations. The AQC group performs testing of APIs, compendial raw materials (USP, EP, JP), analytical testing for stability samples, and in-process and drug product release testing. The method transfer and validation group performs qualification of analytical methods, method development and optimization, technical transfer of analytical methods, and method validation. Stability support offers ICH-compliant storage for all temperature/humidity conditions, back-up power supplies, and continuous monitoring, while the MQC group performs environmental monitoring, bacterial endotoxin testing, bioburden testing, and sterility testing.

At the core of its manufacturing operations is the Technical Services team, which provides turnkey solutions to manufacturing issues as they arise, utilizing its knowledge of the product/process understanding as well as facilities to provide creative resolutions to unique challenges. This approach has been tested repeatedly over the years – particularly through the challenges surrounding the COVID-19 pandemic regarding the material supply chain. In response to the scarcity of process components caused by the COVID-19 response, JHS worked with single-use vendors to develop assemblies, which contain multiple like-for-like options for disposable parts, increasing flexibility and reducing risks associated with the supply chain for these assemblies.

Jubilant HollisterStier's capabilities and equipment, when paired with its codified scale-up processes, make it an ideal CMO partner. The CMO's adaptability in the face of

complexity also sets it apart: in the midst of the COVID-19 pandemic, JHS was able to manage multiple projects related to both vaccine production and treatments related to COVID-19, which include Novavax's NVX-CoV2373, Gilead's Remdesivir, and Eli Lilly's Bamlanivimab, under tight time and resource constraints. JHS rose to the challenge of meeting extremely expedited schedules for many COVID-19 projects, and was able to implement and validate manufacturing processes for these products in very short timeframes to meet public demand without sacrificing product quality or patient safety with no disruptions to planned manufacturing operations.

## Conclusion

With 100 years of manufacturing excellence, Jubilant HollisterStier remains one of the most competitive CMOs in the sterile injectables space, which is attributed to its integrated approach to tech transfer and scale-up and highly cultivated process capabilities. JHS is not merely a facility provider for sterile injectable manufacturing, but collaborates with clients and vendors to develop a robust and reliable process to deliver quality product time

and again. JHS is driven by strong values of quality and inspiring confidence in their partners by delivering as per the commitments. It excels in personalized and customized support, catering to clients' products and processes, including technical and industry knowledge and experience, backed by robust documentation packages.

Its established relationships with many top industry vendors, vast knowledge of sterile manufacturing and aseptic processing, and adaptability in the face of both complexity and materials scarcity make it a leading partner for projects of nearly any scale or developmental phase. By combining extensive supply chain support, regulatory acceptance, and technical expertise, Jubilant HollisterStier offers clients the product road mapping and collaborative communication to take their drug product to market quickly, without sacrificing product quality or efficacy and patient safety.

**SCHEDULE A CONSULTATION**

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



**JUBILANT**  
HOLLISTERSTIER

**STERILE INJECTABLE | LYOPHILIZATION | OPHTHALMIC | STERILE TOPICAL AND LIQUID**

Jubilant HollisterStier LLC is an integrated contract manufacturer of sterile injectables, ophthalmics, otics and sterile topicals and liquids. Our facilities in North America provide specialized manufacturing for the pharmaceutical and biopharmaceutical industries. We provide a full-range of support and services to streamline the manufacturing process such as on-site assistance from process qualifications through product release.