



Advanced Isolator Tech Boosts Manufacturing Efficiency and Quality

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Advanced isolator technology has quickly become the standard for sterile injectable manufacturing. Biopharmaceutical and pharmaceutical companies seeking to reduce risk of contamination caused by operator interventions, pursue production campaigns over longer durations, and enhance the overall level of quality and efficiency in manufacturing are the driving force behind heightened expectations for isolator technology.


The current expectation among both pharmaceutical executives and regulators is that most, if not all, new line installations utilize isolator technology rather than traditional cleanroom. Jubilant HollisterStier's (JHS) advanced isolator technology offers a solution that can scale alongside production to fulfill increasing demand without compromising quality or safety.

Constructed as part of a \$92M, 50,000-square-foot expansion at JHS' Spokane, Wash., production facility,¹ production Line 3 delivers on that expectation. Line 3, a high-speed liquid filling line with 100% weight-checking, is supported by state-of-the-art isolator technology with automated H2O2 bio-decontamination, two new lyophilizers capable of frozen shelf loading, three full-service compounding suites, and disposable single-use technologies. The result is not just additional capacity but also enhanced product quality, yield, and manufacturing speed.

How JHS Implements Advanced Isolator Technology

Per ISO 14644-1:2015,² *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration*, an ISO 8 cleanroom is permitted up to 3.52M maximum particles per cubic meter (m³). An ISO 5-designated cleanroom, meanwhile, is permitted a maximum of 3,520 m³ — 1/1000 the amount. EU-GMP Annex 1 *Manufacture of Sterile Medicinal Products*³ and US-FED-STD-209 E *Airborne Particulate Cleanliness Classes in Cleanrooms and Clean Zones*⁴ impose similar thresholds. In addition to the concentration of airborne particulates, these standards' cleanroom classifications are distinguished by air changes per hour/minute within the isolator/cleanroom environment, filter coverage percent, light fixtures, and numerous aspects of the floor, ceiling, and wall surfaces.

Partially because of these stipulations, isolator technology can be wrongly assumed to require more complex operations, but JHS' system does the opposite. It simplifies processes and promotes efficiency by minimizing human intervention, which is the most significant source of potential contamination. To meet the ISO 5 standard, aseptic filling of liquid and lyophilization of



products on Line 3 takes place within a localized isolated ISO 5 environment, with operators occupying a lower classification of cleanroom (ISO 8) in the background. Operators are not required to wear aseptic garb in JHS' ISO 8 environment, which reduces the cost and time associated with aseptic gowning/de-gowning operations.

This approach separates the operator from the product more effectively versus a traditional line where the operator works inside the aseptic room in full aseptic gowning. Despite this precaution and additional barrier systems being in place, a traditional cleanroom still shares a common room between drug product and operators, leading to greater contamination risk.



Isolators' Impact on Product Quality, Yield, and Production Speed

The most significant difference between isolator technology and a traditional cleanroom, in terms of production efficiency, is the ability to run long campaigns. For example, a multi-day campaign in an isolator is executed with a much lower risk of batch contamination versus a traditional cleanroom and can be justified for longer durations. The production equipment remains similar, but due to open-room processing and greater risk of contamination, single production lot run durations between room turnarounds are typically shorter than those bolstered by isolators.

Isolator technology can run continuously over several days, minimizing operator interaction and other opportunities to introduce contamination. This is ideal for scenarios when demand for product volume is high but the timeline cannot accommodate numerous stoppages and line turnarounds. Conversely, running a small-volume, two-hour batch, isolator technology would be less advantageous in terms of production efficiency — more on par with a traditional line.

Line 3's in-process testing helps to ensure production efficiency and product quality by confirming that every vial produced meets fill volume specifications. This 100% weight testing is accomplished all online; there is no offline testing or destruction of product. Additionally, the filler can dose on weigh scales during startup and end-of-batch to ensure all material within the product bag is fully utilized and to facilitate re-dosing during production should a vial be under-filled. Re-stoppering is an additional product-saving feature, as the filler can pause to re-stopper a vial should the initial stopper not get placed.

By comparison, intermittent weight testing can have disastrous consequences. If a vial is weighed and found to be out of specification (OOS), all product between the last sampling and the sample with a discrepancy is in question and likely must be discarded.

Line 3's lyophilizer systems support ambient shelf, cold shelf (+5°C) and frozen shelf (-50°C) loading. They are capable of gas backfill with sterile filtered N₂, air, or other gases as necessary. Additional automated functions include automatic filter integrity testing, automatic clean-in-place (CIP) and steam-in-place (SIP), and leak rate testing. JHS' lyophilizers on all lines also feature automated cycles, automated vial loading and unloading (up to 400 vials/minute), and are capable of frozen shelf loading at -45°C.

The lyophilizers on Lines 3 and the soon-to-be-operational Line 4 enable JHS to perform enhanced sampling plans. If an operator wants to sample vials in a certain row on the lyophilizer shelf, the equipment can electronically tag and track those vials within the loading and filling systems. Thus, technology exists within the equipment to precisely define which vials are used for sampling. Sampling efficiency and precision are important toward wasting less product, particularly when working with high-value products.

Isolator Tech is Only One Element of Improved Sterile Injectable Manufacturing

The Spokane facility's expansion is spearheading JHS' charge into future preparedness: to meet client capability and capacity demands while continuing to operate at or ahead of changing

industry regulations. Line 3 is operational and Line 4 at the Spokane facility, which will boast similar features, is expected to be operational in 2026. The expansion doubles production capacity, adding 55 million units per year. JHS' intent is to retrofit Lines 1 and 2 in the Spokane facility with similar capability to meet growing demand for outsourcing that enables accelerated project timelines and cost efficiency.

All incoming client projects/products are treated to a top-down analysis, jointly conducted between JHS and the client. JHS' project management and technical transfer teams make sure the necessary equipment has been identified (e.g., for freeze/thaw), logistics are accounted for (e.g., time out of the fridge), and all foreseeable risks have been considered and mitigated before beginning any campaign.

This analysis is the heart of JHS' core capability: evaluating the feasibility of a customer product for manufacture and then developing a road map for optimal process execution. A clinical trial manufacturing line capable of sterile liquid filling and lyophilization — 2mL-30mL vials up to 80 vials/minute — ensures seamless process scale up to commercial production. The clinical line utilizes a fully servo-driven filler, meaning automated filling and stoppering is performed in an ISO-5 environment even at this stage.

Partnering with JHS provides you with immediate access to cutting-edge sterile manufacturing, supported by advanced isolator technology and full cross-functional involvement by JHS project teams throughout development and production. Meet increased demand for sterile injectables while eliminating the capital investment of expanding or upgrading manufacturing facilities, as well as minimizing timelines and regulatory hurdles.

Each project at JHS benefits from our deep aseptic processing expertise and our established relationships with top industry equipment vendors. [Contact JHS today](#) to discuss how our state-of-the-art isolator technology can accelerate your product's journey from development to market.

References

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About Jubilant HollisterStier

Jubilant HollisterStier LLC, a subsidiary of Jubilant Pharmova Limited, is an integrated contract manufacturer of ophthalmics, sterile injectables, lyophilized products, and sterile ointments. We are committed to providing exceptional manufacturing services to the pharmaceutical and biopharmaceutical industries in North America. With facilities located in Spokane, Washington, and Montreal, Quebec, Canada, we ensure that your project is streamlined with a full range of support and services that it deserves by keeping and training the best talent. By investing in people with cross-functional training and development for critical roles, innovative equipment and predictive technologies, we are able to seize your project's potential for next-level performance at every opportunity.

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Jubilant HollisterStier LLC is an integrated contract manufacturer of sterile injectables, ophthalmics, otics and sterile and non-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.