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Chris Preti
President
Jubilant HollisterStier



The Importance of Expertise in Sterile Fill Finish

Sterile injectable manufacturing requires much more than available capacity and equipment – although those are important. This critical stage of the drug manufacturing process, when outsourced, calls for a contract manufacturing organization (CMO) that can prove its value in the following key areas: product/molecule range, regulatory and compliance, cross-functional support, agile tech transfer, strong project management for maximum safety and quality, efficient production, and overarching commitment to customer success.

Drug Development & Delivery recently interviewed Chris Preti, President of Jubilant HollisterStier, to discuss how the CMO is handling increased demand for sterile fill finish and how expertise makes a difference to customer relationships and finished product quality.

Q: Jubilant HollisterStier proudly asserts its expertise in fill finish manufacturing, a critical stage in biopharmaceutical production. How does JHS distinguish itself as an outsourcing partner?

A: Our mantra is to be a customer-focused, high-quality, full-service CMO. We are uniquely focused on sterile fill finish of liquids and lyophilized injectables and also ophthalmic manufacturing and packaging solutions. This singular focus on fill finish has allowed us to build expertise that today benefits our customer base, from big and small-to-mid-sized pharma to biotech and specialty companies across 40 countries. While narrow in what we do, we're quite broad in our offering – handling both aseptically filled and terminally sterilized products, whether small molecule, biologics protein-containing products, liposomes, oligonucleotides, complex formulations, cold kits for radiopharmaceuticals, or vaccines. Our employees are skilled and knowledgeable in very specific manufacturing processes and bring that expertise to every project. They're able to anticipate challenges and provide solutions based on that expertise, which results in smoother, faster manufacturing processes for our customers. We pride ourselves on white-glove project management. Having joined as president just this year,

my goal is to bring forward this focus on expertise, superb full-service customer service, and quality as key differentiators for Jubilant HollisterStier. When I see that many of our customers have been with us for 5 and 10 years, and expand their product portfolio with us, that tells me our singular focus and attention to quality are meaningful to our customer relationships.

Q: It's said that fill finish is a common bottleneck in vaccine manufacture and deployment. Why is that, and how are you, as a contract manufacturer, removing friction from this stage?

A: Capacity constraints are well known throughout the industry and were, of course, heightened during Covid-19. But governments have also stepped up to partially fund capacity expansion projects, and Jubilant HollisterStier is a beneficiary of that at both our Spokane, WA, facility and our Montreal, Canada, facility. In the next 2 to 5 years, our own investments, in partnership with the US and Canadian governments, will double our capacity in both facilities and that will go a long way toward solving one kind of bottleneck. We're already taking orders for mid-2024 on a new high-speed filling line that features isolator barrier technology, single-use capabilities, up to 2,000-L batch size, 2mL-100mL fill capacity, and two lyophilizers.

Effective project management is also a difference-maker. Managing capacity and understanding what it will take to bring a product to fruition are skills that are earned over time – and our project managers have put in that time at Jubilant HollisterStier. We have a strong bench of experienced professionals leading our projects, from the tech transfer through regulatory approval.

Q: JHS has made significant infrastructure investments – in facilities and equipment – at your Spokane, WA, and Montreal locations. What was behind those investments? When do you expect them to be operational? And what has customer response been to these announcements?

A: We've undertaken a \$285-million investment in our Spokane manufacturing facility. This is part of a cooperating agreement of \$149.6 million with the US Government to expand critical domestic vaccine manufacturing capacity. This project doubles our capacity with two high-speed injectable fill lines with isolator technology and lyophilizers that will start taking production slots in mid-2024. We also recently announced a \$78-million investment in our Montreal manufacturing facility that includes one new high-speed filling line (liquid and lyo) and additional

investments to enhance our full-service ophthalmic offering for liquids, ointments, and creams. This is expected to be complete in 2026.

Customers are very enthusiastic and looking forward to expanding available projects as soon as we're ready.

Q: What did you learn from the Covid-19 pandemic, and what changes has this driven in your organization?

A: Covid taught us we can be even more agile and adaptable than we thought. Of course, there were a lot of contributing factors behind the speed with which vaccines were developed, manufactured, and distributed. But Jubilant HollisterStier responded to the call to manufacture and fill finish Covid-19 therapeutics in record time for six different customers. That wasn't without its challenges. Across the various projects, we had to re-engineer a complex process for FDA compliance; we dealt with cold chain supply issues and brought freezer trucks to our facilities; we worked supply chains hard to meet raw materials needs, and had to bring in or adapt certain equipment to keep pace with demand. Whatever it took, we were able to find a way forward. Our agility and expertise from tech transfer to bringing the products to market is one reason the US and Canadian governments chose to partner with us; we'd proven we could deliver.

Q: As the new president of JHS, what changes can customers expect from your leadership and vision for the company?

A: My goal is really to shine a light on the extraordinary talent and skill of our employees and the way they maximize their experience and our facilities and equipment to deliver what I like to call white-glove customer service from a customer-focused, high-quality, full-service CMO. Manufacturing is critical to achieving commercial success, and I'm delighted to be heading up an industry leader that's committed to providing the highest quality comprehensive services in partnership with our customers. Jubilant HollisterStier is a company with longstanding customer relationships, where we've maintained working partnerships with customers for a decade and longer, and continue to grow our engagements with them. That is the story we want to tell prospects, people who are looking not simply to get a project complete, but to have a great experience, to be confident in the process and the result, and know they are bringing a high-quality finished sterile injectable or ophthalmic product to market in the safest, most efficient, and cost-effective manner possible.