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Blog Post

Prioritize Your Finished Goods Experience to Bring Medicine to Patients Safely

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Source: FUJIFILM Diosynth Biotechnologies

Amid the race to deliver a best-in-class therapeutic to patients, the impact of working with an end-to-end manufacturer that offers drug substance, drug product, and finished goods manufacturing cannot be overstated. With the increased development of parenteral drugs for treating rising chronic ailments including cancer, diabetes, cardiovascular disease and respiratory illnesses[1], a variety of biologic drug delivery formats are needed to cover hospital and clinical settings as well as more patient-centric administration. A full-service manufacturer must offer the technology to accommodate a client's need for a variety of finished good container formats. Once the drug product has been aseptically filled into the delivery system of choice, a program enters the finished goods manufacturing phase, where it will be assembled, labeled, and packaged for patient use.

Conventional injection devices and self-injection devices such as traditional syringes, auto injectors, and pen injectors are among the injectable drug delivery systems used to administer medicines to patients, with a growing demand for pre-filled syringes.[2,3] Overall, the global injectable drug delivery market is projected to reach 46.84 billion USD by 2029.[2] As a drug sponsor navigating this space, choosing a contract development and manufacturing organization (CDMO) that will prioritize your objectives and offer expert guidance to usher your product through the finished goods phase will help your program thrive.

Invest in People Who Care

Whether you are partnering from the outset of your program or identifying a dedicated finished goods provider, it is critical to work with a team that will decipher your goals to ensure your program is a success. From the beginning, a manufacturer should aim to understand your ideal project outcomes via transparent communication and then collaborate with you to design a process that delivers a quality product on time to provide for patients in need.

Along the way, a reliable partner will maintain communication to discuss program updates with you. Fostering effective touchpoints will result in beneficial adjustments that will impact the safety, quality, timeline, and cost of your program. A finished goods partner should have the infrastructure needed to guarantee that your program advances seamlessly between assembly, labeling, and packaging steps, including all necessary quality checks. They will also have resources in place to mitigate potential supply chain issues resulting from the use of third parties, avoiding costly delays that could impact patients' access to medicines.

At FUJIFILM Diosynth Biotechnologies (FDB), our systems ensure right-first-time delivery and offer the flexibility to leverage our extensive experience and end-to-end value chain as needed. This includes moving your program successfully from drug substance to drug product to finished goods. As we develop dependable relationships with our clients, we continue to prioritize the people who matter most: patients.

Design a Process with Patients at the Center

True patient centricity keeps patients top of mind throughout each phase of manufacturing. At FDB, we support this initiative with a well-established quality system that strives for continuous improvement. When a new regulation is established, FDB works diligently with the client to solve potential issues. Risk management is an integral part of our process and is bolstered by system efficiency and subject matter expertise.

We recognize how devastating delays are for both patients and families, and our model centers around following the science to deliver quality therapeutics to our clients. To ensure on-time delivery and reduce risk, FDB has designed agile facilities and processes while bringing onboard the best equipment and expertise to fulfill clients' needs. Our end-to-end offerings allow us to further close the gap between manufacturing completion and delivery to patients.

Leverage Flexibility Whenever Possible

An end-to-end manufacturing process must remain extremely flexible and adjustable for new indications. As demand forecasts change, it is critical to be able to seamlessly pivot manufacturing strategies while offering drug product and finished goods capabilities to ensure a cost-effective plan for your needs. With experience comes an ever-expanding knowledge base and the ability to choose a manufacturing process that maintains compliance and satisfies customer expectations.

In terms of drug product delivery systems, there is currently an industry-wide movement towards auto-injectors that allow patients to safely receive treatment at home rather than in clinics; thus, CDMOs need to be adept at assembling them. For certain indications, there continues to be a need for vial and prefilled syringe delivery systems. To accommodate our clients, FDB maintains the flexibility to handle all three types: auto injectors, vials (range: 2-50R; standard: 2-10R), and prefilled syringes (range: 0.5-10 mL; standard: 1 mL).

We continually adapt our capabilities to meet foreseeable market requirements. This is exemplified by our investment to expand DS, DP, and FG offerings at our Hillerød, Denmark site and to establish the largest cell culture manufacturing site in North America in Holly Springs, North Carolina.[4,5] The Holly Springs site will accommodate DS production, automated DP filling, and FG services at commercial scale. FDB is capable of handling labeling and packaging requirements for different countries and offers labeling for all of our drug delivery systems. We also provide a variety of packaging capabilities, including single, multi-unit, blister, top and side loading options, glue/sticker-based tamper evident seals, and serialization solutions.

Deliver a Safe, Quality Product

The apex of any drug life cycle is the successful treatment of a patient via an accessible, high-quality therapeutic delivery system. Forming an end-to-end relationship with a CDMO allows you to collaborate throughout this journey to design efficient, sustainable processes and deliver high-quality biotherapeutics to patients. Find a manufacturer with diverse capabilities and exceptional quality standards that will help you design a mutually beneficial partnership, and together, you'll manufacture a therapy that will impact the lives of patients and their caregivers for years to come.

Read more details about our drug product and finished goods services or contact our team of experts directly.

References

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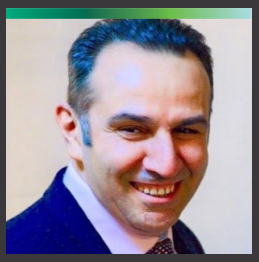
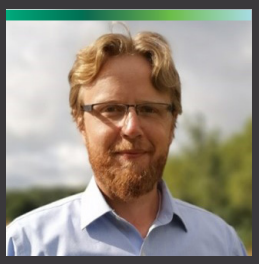
About the Authors

Lenette Brønnum Simonsen is the Senior Director of Drug Product and Finished Goods Manufacturing at FDB in Hillerød, Denmark. She has 19 years of experience in the pharmaceutical and pharmaceutical devices industry with a focus on operations, including process improvement, logistics and quality compliance. Lenette works with leadership within the different aspects of the supply chain, and she also has regulatory affairs experience as a project manager and business partner. Lenette is concurrently leading the Finished Goods council and sponsoring the drug project readiness program at site Hillerød. Her focus is, "Succeeding as a team."



Behrouz Seifi serves partly in the Program Design Team for Finished Goods and partly as a Tech Transfer lead of new products in the Finished Goods Facility for FDB in Hillerød. Behrouz has more than 20 years of experience in the pharmaceutical industry. He has also worked as an applied manufacturing science consultant within the field of process improvement and development through the application of Lean and Six Sigma tools, principles, and concepts. Behrouz also has experience with device development, device assembly, and the labeling and packaging process.



Morten Lahrmann leads the Finished Goods Manufacturing Science & Technology areas responsible for supporting Finished Goods processes at FDB in Hillerød and Holly Springs. With more than 14 years' experience in Manufacturing Science and Technology (MSAT) specializing in Finished Goods, Morten has worked as an SME, project manager, and leader. Morten's focus is on ensuring world-class processes based on close collaboration with vendors and leveraging proven technologies combined with an in-depth knowledge and understanding of cGMP and industry trends.

About FDB

FUJIFILM Diosynth Biotechnologies, a subsidiary of FUJIFILM Corporation, is a world-leading contract development and manufacturing organization partner for the development and manufacture of biologics, vaccines, cell and gene therapies, and oncolytic viruses. The company operates a global network with major locations in the United States of America, the United Kingdom and Denmark and it is building a new manufacturing site in Holly Springs, North Carolina, USA. FUJIFILM Diosynth Biotechnologies has over thirty years of experience in the development and manufacture of recombinant proteins, vaccines, monoclonal antibodies, among other large molecules, viral products and medical countermeasures expressed in a wide array of microbial, mammalian, and host/virus systems. We have drug product filling capabilities to support both clinical and commercial demands. Our Finished Good services, supported by more than 15 years of experience, can accommodate commercial products for more than 65 countries around the world. For more information, go to: www.fujifilmdiosynth.com.