

A Deep Dive into Baxter BioPharma Solutions' Recent Investment in their Halle/Westfalen Facility

With any facility expansion project, come important technical and budgetary considerations as well as tight project management requirements in order to turn the vision into reality. Kayleigh Hearse, Senior Manager of Technical Projects, Capacity Expansion (PPF) shares details of Baxter BioPharma Solutions' approximately \$100 million expansion of its sterile fill/finish manufacturing facility in Halle/Westfalen, Germany. She explains key attributes of the new building, important learnings, and major considerations that came into play throughout the planning phase.

PHARMACEUTICAL TECHNOLOGY: Can you tell us a little bit about Baxter BioPharma Solutions?

KAYLEIGH HEARSE: BioPharma Solutions (BPS) is a business unit of Baxter, which has over 90 years of experience in sterile injectable manufacturing. BPS partners with pharmaceutical and biotech companies to support their injectable drug product commercialization objectives, and we do that by providing scientific experience through contract manufacturing solutions as well as customized support services. BPS offers services needed to address the unique challenges that parenteral products face.

PT: What is your experience and role on the BPS team?

HEARSE: I started with the team approximately 12 years ago in the Project Management/Business Development Department as a project manager, where I was responsible for the transfer of our client products to the Halle/Westfalen, Germany manufacturing site which allowed for me to leverage my PMP certification and experience, which is something all of our project managers have. After that, I changed roles and went over to the manufacturing operations side where I had the opportunity to lead one of our manufacturing departments as a line manager. In that position, I was responsible for ensuring that all the products were released on time and met all of the quality requirements agreed to with our clients and appropriate regulatory agencies. In my current role, I'm a senior manager for technical projects, and in charge of our newest capacity expansion at our manufacturing site at Halle, Germany

PT: Can you tell us a little bit more about the expansion at the BPS Halle/Westfalen facility?

HEARSE: [The latest expansion to the Halle, Germany facility was announced by Baxter in late 2021 and is worth approximately \\$100M.](#) At the end of 2022, we started the construction of the new building, and we are expecting to be up and running for GMP manufacturing in late 2024. This investment will expand our BPS manufacturing footprint in Halle, and we will be adding state-of-the-art equipment for the filling of vials and pre-filled syringes in order to meet our clients' growing needs. Pre-filled syringes being offered out of BPS' Halle, Germany is exciting as it will be the first time we are able to offer this platform at this manufacturing site. This new platform capability will allow Baxter BioPharma Solutions to offer clients pre-filled syringe manufacturing capacity out of Europe as we currently only offer PFS in the US out of our Bloomington facility.

Both manufacturing lines will be set up to offer a wide range of flexibility. For the vial line, there will be several vial sizes that we will be able to fill, from 2R-50R. On the syringe filling line, we will be able to handle a variety of syringe sizes, 0.5 mL-20 mL. From a compounding perspective, we can offer multi-purpose equipment, dedicated customer equipment, or even single-use equipment. Both state-of-the-art filling lines are designed to help address specific customer needs. For example, we have taken



Kayleigh Hearse

Senior Manager of Technical Projects,
Capacity Expansion (PPF building)
Baxter BioPharma Solutions (BPS)

Sponsored by

Baxter

special precautions to enable us to handle various temperature product requirements or light-sensitive products. In addition, the vial filling line is also set up with the ability to increase the Halle facilities lyophilization capacity in the future, if needed, with room for additional lyophilizers.

PT: Isn't this the second major investment recently made in Baxter's Halle/Westfalen, Germany facility?

HEARSE: Yes, that is true. The Halle facility continues to grow as our customers' needs continue to evolve. In 2015, we completed an approximate 1800 square meter capacity expansion which included one clinical-scale vial filling line and one commercial-scale vial filling line. Recently, this building has undergone another investment, by which BPS has increased lyo capacity by adding two additional lyophilizers over the last two years.

PT: It sounds like there are exciting things ahead for Baxter's Halle/Westfalen, Germany facility. Can you tell us why the decision was made to invest?

HEARSE: Thanks to open communication, the BPS team continues to stay close to our customers and their growing needs. With the expansion, we will be able to meet the customers' demands from both a capability and capacity standpoint. In addition, this expansion also provides BPS with ample flexibility options for future capacity growth.

PT: What major considerations took place throughout the planning phase?

HEARSE: First, we came to an understanding of the internal and external business needs. This means taking into account best processes or lessons learned from our team on site, and more importantly, understanding the needs of our customers. A new manufacturing building does not add any value if you do not ultimately meet the needs of your customers.

It was really important to retain the flexibility to be able to incorporate the latest guideline changes. When this project started, Annex I was still under revision and therefore, we relied heavily on mock-ups and being able to test out various set-ups hands on and then make adjustments based upon the team's feedback. Based on our experience from BPS' manufacturing expertise, it comes down to where can we minimize product loss and how can we increase flexibility.

PT: What are some key learnings you experienced being part of the team responsible for this project?

HEARSE: I learned how important it is to have a cross-functional team in place from the very beginning. Once you have the concept for the process, you move into building the facility and handling the process needs. Our cross-functional team was instrumental as we have staff from manufacturing, qualification, quality, engineering, supply chain, finance,

and project management—having all of those functions involved helped to provide a broad perspective on what is needed for a successful outcome. This team also relied heavily on BPS' Business Development Executives who are the voice of the customer, so from early on, we had our customers' needs in mind as we started to plan out this expansion.

Additionally, one key benefit was having the in-house expertise onsite at our Halle facility, but also more broadly within BioPharma Solutions. Through our sister site in Bloomington, Indiana, USA, we were able to easily share and learn from past lessons, existing projects, from all levels within the organization. This includes shopfloor employees, up to line managers and engineers.

Now, having overcome COVID-19 challenges and obstacles, we find face-to-face meetings are once again key for critical milestones or points of discussion. A lot can be done via Zoom, Teams, or video conference options, but there are certain aspects of projects that are better discussed in person. For example, setting up a mockup line model, seeing suppliers, and conducting on-site testing. We can perform simulations upfront and throughout the process which only helps to further optimize the lines.

PT: Are there any other obstacles or challenges the team has experienced throughout the planning phase and initial build out process?

HEARSE: Like many other companies, we are faced with macro environment challenges, especially with delivery schedules or lead times. It is about staying ahead and understanding where supply chain challenges may come into play and what impact they may have on the project. Early involvement from our supply chain team and BPS leadership team can help to proactively address potential issues that may come up. Knowing which critical parts are needed for the expansion also helps us avoid last minute orders. This, along with close monitoring and having good communication and trust within our team as well as the suppliers, are essential to everything running smoothly and according to plan.

The Halle team is in close contact with our suppliers on a frequent basis about any foreseen obstacles so we can proactively respond. Our future routine team is also involved and kept up to speed on what is happening and how to address obstacles down the line. Knowing what you're doing, knowing what may come up, and making sure you have the key personnel in place now and down the road, are all necessary for routine manufacturing.

PT: If customers have any questions or would like additional information on the latest expansion or BPS' services, capabilities, news, and events, where can they go for more information?

HEARSE: For information or to contact our team, visit the Baxter BioPharma Solutions [website](#).