ThermoFisher SCIENTIFIC

CASE STUDY

The power of partnership

Thermo Fisher Scientific supports rapid global COVID-19 manufacture

A mid-size pharmaceutical company based in the United States (US) and Europe (EU) was developing a COVID-19 vaccine using a prioritized protocol with an extremely aggressive timeline. In the race to develop a successful vaccine, this company's product demonstrated safety and efficacy against the virus. As a result, they entered into contracts with governments in the US and EU to supply millions of doses. To meet contractual demands, the company needed to ensure rapid but smooth technology transfer to multiple production sites at the same time.

Because the company had a small, in-house team, they sought a collaborative partner with the expertise, capabilities, and capacity needed to navigate the main challenges of the COVID environment, including supply chain issues and the need to scale up production to meet enormous, urgent, global demand.

Situation

The company began manufacturing its COVID-19 vaccine in Greenville, North Carolina, in the US but needed to develop a presence in the EU. The decision was made to continue the vaccine production at two additional sites in Monza and Ferentino, Italy, which would require a technology transfer. Given the growing impact of the pandemic on the world stage, this work needed to be completed under an extremely aggressive timeline simultaneously. The request was made in September 2021, and the product initially needed to be on the market by December 2021.

The company also needed support with their equipment supply chain because certain items had long lead times that threatened timely production of the vaccine. They needed assistance with the resourcing of equipment for accelerated analytical method transfer to meet testing requirements for the equipment once it was received. Further complicating the process was a decision made in November 2021 to shift from 10R to 2R vials after qualification batches in the initial sizes had been completed. This change required several rapid adjustments in the technology transfer process to meet the new targeted to-market date of June 2022. This timeline was still considered aggressive as development needed to keep up with variants in the virus.

In short, the company was looking for a partner that had the network, capabilities, and expertise to coordinate all project activities and provide solutions to simplify technology transfer to other sites, overcome challenges with analytical methods and equipment, and meet aggressive timelines. Without this partnership, the company would not be able to provide the large volumes of product needed to fulfill government contracts and to help address the worldwide pandemic. Overcoming the demands promised great benefits to the patient and also the company, however, promised great benefit to the company in the form of recognition and business reputation with potentially millions of lives saved through prevention of COVID-19 infection.

Solution

After initially partnering with another contract manufacturing organization (CMO) that did not have the network or internal resources to overcome supply challenges, the company chose to partner with Thermo Fisher Scientific.

Thermo Fisher offered several solutions to address the company's aggressive timeline challenge.

- **A global governance model** with a single point-of-contact to execute the entire project and a highly efficient, specifically designed information sharing process across sites reduced the number of touchpoints for the company. This approach saved additional project management steps and required the company to confirm the information only once at the beginning of the project. From there, the Company could take a hands-off approach, knowing that their project was in safe hands.

- **True end-to-end capabilities** enabled by leveraging the full-scope of Thermo Fisher's internal capabilities. For example, in collaboration with Thermo Fisher's bioproduction experts, the project team was able to create a single use system prototype which we used to close the supply chain gap. This single-use system approach to production used used an interlocking building block concept (see Figure 1) where standard components that could be sourced internally were stacked to reduce the external supplier lead time and prioritization challenges.
- **Long lead times** for receipt of critical equipment were addressed using Thermo Fisher's extensive global network to find faster and optimized solutions internally.

To minimize the strain on the customers' limited internal resources, Thermo Fisher set up internal global steering committees at each site to mitigate risks, provide solutions, and facilitate collaboration. These committees optimized internal training and addressed analytical and equipment gaps for the customer. 'Lessons learned' reviews provided guidance to continually improve the customer's experience and processes for future projects.

To further support the customer, Thermo Fisher also provided fill-finish services to ensure the production of high-quality, safe sterile drug products. The project team developed cold chain procedures and contingency plans to handle the COVID vaccines according to ICH requirements at different production stages. This process was very precise, and all requirements were successfully created and adopted without a previous template to follow.

The well-managed and efficient procedures established at the beginning of the project enabled the project team to accommodate the customer's unexpected post-launch vial size change. The size adjustment required additional components and a revised regulatory strategy for their integration. By collaborating closely with customer's regulatory teams and leveraging Thermo Fisher's regulatory experience and expertise, the team was able to efficiently navigate the approval process and further accelerate the speed of providing product to the patient.

Results

Through the partnership efforts described here, successful technology transfers were simultaneously completed at three sites within 4-6 months. Further, the project was able to remain in regulatory compliance despite the unexpected shift in vial size requirements, and the required volume of millions of doses of vaccine were manufactured and distributed right the first time to the population.

Summary

In 2021, the urgent need for the development and successful manufacture and distribution of an effective and safe vaccine for COVID-19 was top of mind for billions of people. Leveraging the power of a single network, Thermo Fisher developed solutions to simplify the supply chain and ensure rapid and predictable technology transfer for one of the world's most promising vaccine developers. Working in partnership with a reliable CDMO for a highly prioritized protocol, the Company was able to facilitate an historical step forward in the fight against COVID-19. Millions of doses of vaccine were delivered on time to the waiting world. Importantly, the partnership will continue, as will its efforts to prevent further COVID-19 infections.

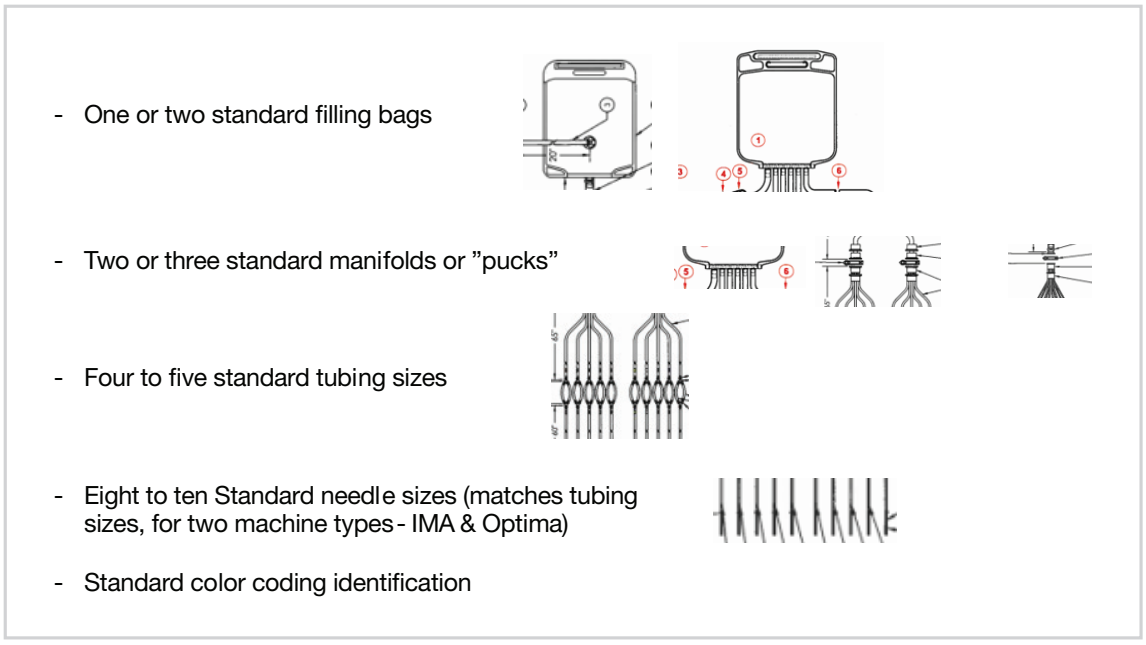

Figure 1. Filling assembly using interlocking building block concept

About Thermo Fisher Scientific

Thermo Fisher boasts almost 50 years of contract pharmaceutical manufacturing experience. They provide industry-leading pharma services solutions for drug development, clinical trial logistics, and commercial manufacturing through the Patheon brand. With over 60 locations across 5 continents, including 35 manufacturing sites, Thermo Fisher has a long track record of excellence and a broad range of highly qualified scientists and technicians.

In 2021, Thermo Fisher managed 232 active tech transfer projects, but they were still able to offer this customer dedicated capacity, the ability to source the materials quickly, and the expertise needed to simplify technology transfer to meet their required timelines. Thermo Fisher's regulatory track record and regulatory support offering also contributed to the Company's decision to build the partnership.

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