apiject™

Project Profile:
The Ritedose Corporation

In 2020, as part of the U.S. Government's COVID-19 response, ApiJect™ entered into a long-term strategic partnership with The Ritedose Corporation ("TRC"). Together, they were able to make operational 45 million units per month of Blow-Fill-Seal fill-finish capacity for America's COVID-19 response within 7 months out of TRC's facility in Columbia South Carolina.

PHOTO: THE RITEDOSE CORPORATION FACILITY IN COLUMBIA, SC.

Single-Dose Drug Delivery Fill-Finish Facility that is Scalable, Flexible, and able to Deliver up to 45M Units Per Month; Completed within an Accelerated Timeline of Fewer Than 7 Months

In the second quarter of 2020, as part of America's response to COVID-19, the U.S. Government created Project Jumpstart to quickly bring online additional domestic fill-finish capacity for potential COVID-19 vaccines. Under that project, ApiJect commitment to creating emergency temporary fill-finish capacity for up to 45M doses a month of a candidate COVID-19 vaccine on Blow-Fill-Seal (BFS) lines by the end of 2020. All of these BFS-packaged doses could then be used, if necessary, in the manufacture of ApiJect's BFS-based prefilled injectors for scalable, single-dose delivery of injectable vaccines.

To achieve this, ApiJect agreed to upgrade three existing BFS lines in a U.S. contract manufacturer (previously making non-injectable products). The Government required that each BFS line be upgraded to fill-finish injectable vaccines, which resulted in needing bio-safety level 2 (BSL-2) conditions. If necessary, HHS could expand this process to additional existing domestic BFS lines

ABOUT THE RITEDOSE CORPORATION

TRC is a leading sterile pharmaceutical manufacturer that specializes in the use of BFS technology, providing outsourced development and manufacturing of ophthalmic drugs, respiratory drugs, and vaccines. TRC serves a broad range of markets: from small start-ups and large pharmaceutical companies to wholesalers, retail pharmacies, and hospital systems. In January of 2022, TRC announced its acquisition by Novo Holdings A/S, a private limited liability company.

EXECUTION

An assessment of the facility was performed to upgrade three manufacturing lines to be able to support BSL-2 products. The existing facility had already been upgraded a few years ago to handle potent compounds on these formulation and filling lines. In addition, the three lines selected were already located in a separate building, away for their main production suites. This afforded ApiJect and TRC additional assurances in the BSL-2 and biocontainment strategy. Further, the facility already had a number of the machinery and facilities that would be needed for this operation, including three Rommelag® Bottelpack 460-15 BFS machines, several Wilco leak detectors, and formulation suites.

The improvements to the facility would focus on managing the flows of personnel, materials, and waste to contain the BSL-2 organism. The assessment identified several areas of improvement to make the facility capable of filling a BSL-2 product:

- Modification of the air handling systems to provide a negative pressure cascade
- Add additional airlocks at the BSL-2 boundary
- Add an autoclave for waste decontamination
- Addition of a Biokill system

ApiJect met the HHS/DOD timetable for Project Jumpstart. Its first BFS line became operational on October 30, 2020, less than seven months since project launch. The second BFS line became operational a month later and pharmaceutical partners began to take advantage of the fill-finish capacity for their product development activities. ApiJect and the U.S. Government now have domestic surge capacity to fill-finish 45M BFS Containers per month with sterile liquid pharmaceuticals within a BSL-2 environment.

In addition, ApiJect upgraded several of the Rommelag 460-15 machines with new production mold sets and various change parts. When completed, each of these lines was able to potentially output up to 15 million finished units a month in ApiJect BFS container designs, customized to the ApiJect's attachable Needle Hub components.

The implementation of the design required heavy alignment between the design and construction teams. The execution of the project was based on a design-assist model where the contractors were brought into the design process early and worked with the architects and engineers to execute the work as quickly as possible.

Two major pieces of equipment would typically make the execution of this project difficult at best, if not impossible, in a 6-month time frame. The procurement of the decon autoclave was accomplished through the acquisition of an autoclave that had already been manufactured and was sitting in a warehouse. ApiJect was able to acquire this piece of equipment in a timely fashion to support the design and construction of the facility. The procurement of the Biokill system was a slightly easier process due to the simple requirements of the kill system itself. A standard biokill system was purchased and installed within the required timeframe.

RESULTS

ApiJect chose to do this project at TRC due to a combination of their excellent reputation of working with outside parties, strong regulatory track record, the layout of their facility, and their relationships with other necessary vendors. That this project was implemented on a pre-agreed aggressive timeframe is an excellent example of what can be accomplished under trying circumstances when all parties agree to work towards a common objective.