

Single-Dose Drug Delivery Fill-Finish Facility that is Scalable, Flexible, and able to Deliver up to 45M Units Per Month Delivered 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 and 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 ApiJect Prefilled Injectors for scalable, single-dose delivery.

To achieve this, ApiJect agreed to upgrade three existing BFS lines in a U.S. contract manufacturer (previously making single-use eye drops or other non-injectable products). The Government required that each BFS line be upgraded to fill-finish under BSL2 conditions. If necessary, HHS could expand this process to additional existing domestic BFS lines.

Execution Strategy:

ApiJect aligned themselves with The Ritedose Company (TRC), a contract filling operation located in Columbia, South Carolina. An assessment of the facility was performed to upgrade three manufacturing lines to be able to support BSL2 products. The existing facility had already been upgraded a few years ago to handle potent compounds on these formulation and filling lines.

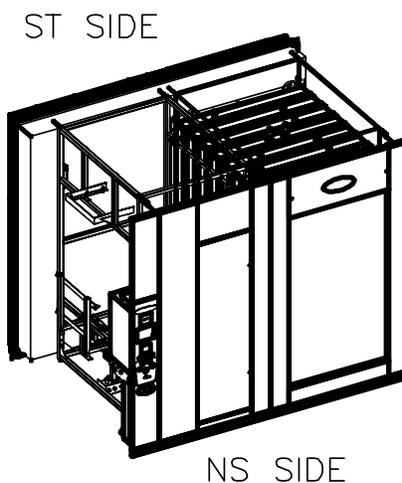


Figure 1 - Image of Decontamination Unit

The improvements to the facility would focus on managing the flows of personnel, materials, and waste to contain the BSL2 organism. The assessment identified several areas of improvement to make the facility capable of filling a BSL2 product:

- Modification of the air handling systems to provide a negative pressure cascade
- Add additional airlocks at the BSL2 boundary
- Add an autoclave for waste decontamination
- Addition of a Biokill system

All these improvements would require a thoughtful execution of design and construction methods to meet the expectations of the Jumpstart program. IPS was brought on as a partner for the execution, design, and construction of this project based on their life sciences experience and long-term relationship TRC. IPS had been involved in designing and implementing the improvements to the TRC facility when it was upgraded to handle potent compounds. IPS has a working relationship with TRC as well as the contractors that have been working at TRC's site for many years.

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. This was made easier because of the long-standing relationships IPS has made with the contractors that support TRC. The design documents were developed with the contractor's input, and the implementation of the design was accomplished with the designers' input. The architects, engineers, and constructors worked hand in hand to deliver the upgrades to the facility in a timely and coordinated fashion.



Figure 2 – TRC Pressurization Plan, Showing Containment

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.

The ability to implement this project in the agreed-upon time frame was only possible as a result of the ongoing relationships between TRC, IPS, and the multiple contractors that work on that site. It is an excellent example of what can be accomplished under trying circumstances when all parties agree to work towards a common objective.

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. 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. ■