

Final Fill (Sani-Tech Ultra®) #1

The Challenge

The manufacturer of a final fill machine recommended replacing existing stainless steel lines in their customer's vaccine manufacturing process with Saint-Gobain single-use systems. It was critical that this customized single-use system be easily integrated into their existing final fill operations consisting of a recirculation process to keep the partial vaccine in suspension and to obtain repeatable small volume fill delivery. The development timeline was crucial at this stage of bioprocess and needed to align with upstream cell culture operations.

The Saint-Gobain Collaborative Design Services' Solution

Saint-Gobain Design Services collaborated closely with the customer to create a single-use system that would mate to their specified recirculation loop and yield optimum dosing accuracy. The customer's product requirements included specific working pressure and flow rate for the fill process. Frequent communication between Saint-Gobain, the customer and the filling needle supplier took place during product development. Filling needle considerations during the selection process included anti-foaming, chemical reactivity, drip/flow rate and ease of integration into the single-use assembly design for their existing operation. New Sani-Tech® Sani-Link® molded manifolds were internally developed at Saint-Gobain to produce the single-use system's T-section and reducer-section (3/8" to 1/32"). Upon design finalization, the single-use system was validated in compliance with international pharmacopoeia.

Customer Experience

Upon implementation of the single-use system into the final fill operation, Saint-Gobain's customer immediately experienced quick turnaround time and significant cost savings.

