

# Final Fill Sani-Tech® Ultra #2

## Challenge

A process engineer at a contract manufacturing organization (CMO) was faced with inconsistent dose fill volumes during final fill operations for monoclonal antibody production and explored viable solutions by incorporating single-use technologies. Material compatibility and elimination of loose visible particulates were critical to the success of their bulk drug substance final fill campaign.

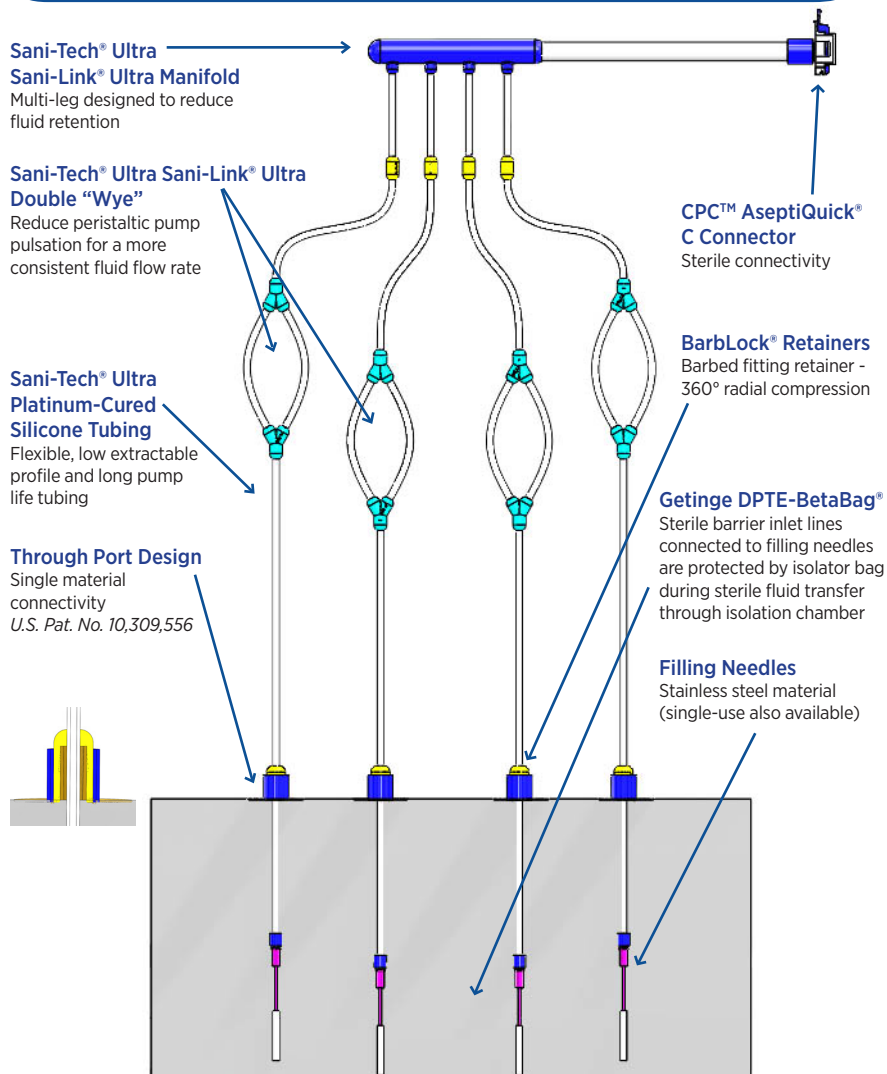
## Solution

Saint-Gobain Collaborative Design Services went to the process engineer's site to learn of their final fill bioprocess challenges. This led to the development of three new Sani-Link® overmold tools that were designed to provide fluid process integrity and greater dose fill volume accuracy of a multi-leg fill requirement. Saint-Gobain's flexible tubing selection was based on their ability to endure the stress of the peristaltic pump fluid transfer process and also to reduce the occurrence of tube swelling to improve filling consistency. In parallel, double wye segments were incorporated into the design to reduce peristaltic pump pulsation. The advantage of working with Saint-Gobain is in our ability to creatively design and build the required validated tools (reducing tee, custom double wye, bag molded coupler) in house as well as leverage the most relevant partnership for the components not produced by Saint-Gobain.

## Customer Experience

Customer was able to maximize process efficiencies following this single-use system integration that significantly improved dosing accuracy, eliminated visible loose particulates with compliance to USP <788> and improved their overall process robustness.

## Concept



CPC AseptiQuik® is a registered trademark of Colder Products Company CPC. CPC is a Dover Company. BarbLock® / Sani-Tech® / Sani-Link® are registered trademarks of Saint-Gobain Life Sciences. DPTE-BetaBag® is a registered trademark of Geringe La Calhene

## DPTE-BetaBag®

Geringe's single-use DPTE-BetaBag® range is designed for fast contamination-free transfer. The flexible bag docks onto a DPTE® Alpha port for safe leaktight connection to a sterile zone.



Geringe's DPTE-BetaBag® - useful diameter 190 mm, 10 L, polyethylene