

## Cell Culture Media Charge

### The Challenge

A Bioprocess Engineer at a contract manufacturing (CMO) facility faced various product contamination challenges using their current stainless steel cell culture media transfer lines as identified by elevated levels of bioburden prior to inoculation.

### The Saint-Gobain Collaborative Design Services' Solution

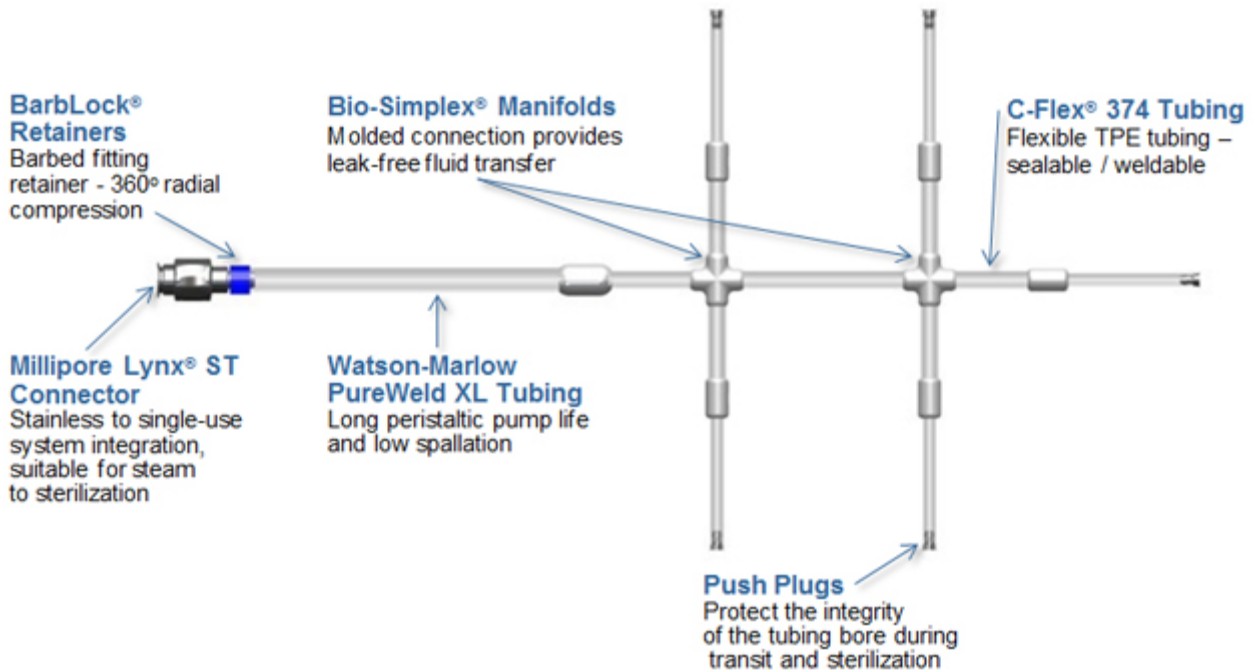
Process layouts from their existing stainless steel system were presented to our Design Services Team for the development of a single-use system that could be readily integrated into the cell culture media charge process.

Key design considerations included ensuring the fluid transfer line could withstand 121°C steam in place, peristaltic pump stress and allow for sterile disconnection at the end of the media charge process to multiple primary bioreactors. Achieving leak-proof assurance during this process was of critical importance. Single-Use System was gamma sterilized to ensure contamination free (10<sup>-6</sup> SAL) process.

Overmolded tooling needed to meet product requirements was not available during project initiation. However, Saint-Gobain built seven new tools to meet new customer requirements and met their desired timing for the completion of this project.

### Customer Experience

The new single-use system allowed the customer product integrity of fluid path and fast turn-around as the single-use assembly was ready for use. This change had a positive impact for the CMO's manufacturing process and gave them additional confidence in our product design and manufacturing capabilities. After this project was completed, eight additional single-use assemblies were created for this CMO and Saint-Gobain awarded preferred supplier status.



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