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CHALLENGES IN IMPLEMENTING SINGLE-USE PROCESSING FOR THE PURIFICATION OF POLYSACCHARIDES

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Increasingly, bioprocesses are being developed to utilize single-use technologies in an effort to maximize the efficiency of manufacturing facilities. Reduced requirements for key actions such as equipment cleaning and validation help to decrease development and manufacturing costs while factory efficiency improvements are realized through the ability to design flexible, multi-process manufacturing facilities. Examples of the challenges faced when implementing single-use technologies in the manufacturing process of polysaccharides are discussed in this presentation.

Two downstream unit operations presented challenges specifically related to single-use componentry. The first is a tangential flow filtration (TFF) operation utilizing the Pall Allegro single-use TFF system in which the product stream is concentrated and then buffer exchanged. Challenges in meeting process performance expectations were faced due to the design of single-use connectors and mixers chosen to interface with the skid. Specifically, suboptimal design of the assemblies connecting to the inlet of the skid's recirculation pump were found to have a major impact on overall performance of the system including the maximum obtainable cross-flow flux (**Figure 1**) and the ability to maintain transmembrane pressure control during processing. The second unit operation detailed is a pressure-driven filtration that utilizes a single-use filter as well as single-use assemblies upstream and downstream of the filter. The relationship between pressure loss in the system due to length, connection, and diameter of single-use assemblies was demonstrated to have significant impact on filter capacity and the ability to successfully process the desired volume of material. In both instances, lessons were learned regarding how to smartly integrate and select single-use componentry to accommodate your process and avoid unexpected scale-up challenges upon implementation at full-scale.

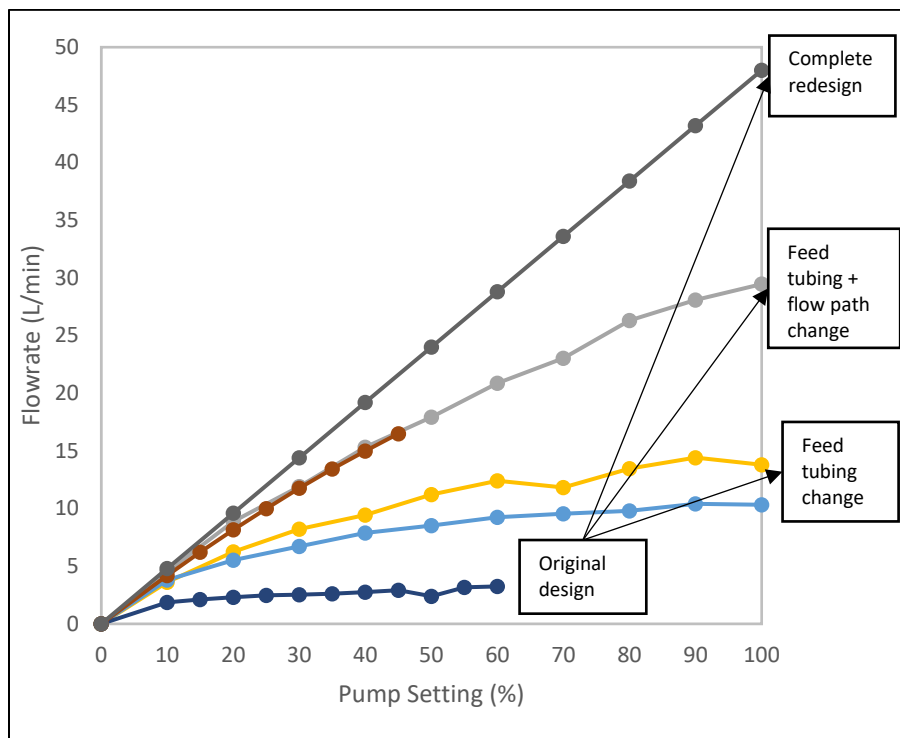


Figure 1: Flow-rate vs. pump output of the Pall Allegro SU-TFF skid when operating with varying single-use assemblies