APPLICATION OF SINGLE PASS TFF TO ENABLE INTENSIFIED AND CONTINUOUS BIOLOGICAL MANUFACTURING

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Single pass TFF is a new technology for the bioprocessing industry that has used only batch TFF processes. It is a low footprint, easy-to-use and inexpensive technology to reduce volumes and concentrate proteins. It first found application in volume reduction to debottleneck downstream operations to handle higher bioreactor titers. Savings in plant expansions can be over $100 million. It can also be deployed in combination with other steps, significantly enhancing their performance. One example is its application prior to a flow through Q polishing step. It can improve HCP clearance, improve capacity by a factor of 4, and improve productivity by a factor of 5. Additional examples of SPTFF operation will be provided showing its benefits at several points in downstream purification such as bind elute chromatography and virus filtration where higher concentration enables higher capacities and productivities. These improvements lead to more economical smaller columns and filters, enable the use of single-use technologies and facilitate low capital flexible facilities. Development of these intensified steps and implementation of the intensified processes will be described.