

CUSTOMER CASE STUDY

Biopharmaceutical Industry

SCALING UP VIRUS FILTRATION IN SINGLE-USE MANUFACTURING OPERATIONS



Customer

Contract manufacturer with two fully single-use GMP manufacturing operations on-site and employing a built-in contract process development lab that brings in and scales-up products for clinical trials or other stages in the product life-cycle.



Objective

To deliver a customized pumping solution for two existing SciFlex NFF systems used for viral filtration which is comparable between process development and GMP manufacturing to facilitate technology transfer.



Specification

- 2 x SciLog® SciFlex NFF
- 2 x on board peristaltic style pumps
- Maximum operating pressure for the units is <55 psi using single-use SciLog® SciPres sensors and Bioprene 60 tubing elements
- Expanded GMP SciFlex NFF flow rates up to 22.5 L/min in low pressure applications

Scale-Up



Requirements

After purchasing a SciLog® SciFlex NFF unit, the operating flow rate range for their viral filtration process, as determined by the process development group, was much lower than the typical operating range of the pump on the SciFlex NFF unit.

Due to the size of the large pump purchased to achieve the high pressures needed for viral filtration, the flow rate initially chosen would only accomplish one exchange of all the fluid in the pump cavity every 30 minutes.

As a result of this extreme residence time, the pump dissipated a huge amount of heat into the protein product, completely denaturing it. The flow rate values specified by the process development group were not practical for the GMP production.



Parker domnick hunter Solution

Our solution provided two SciFlex NFF units, one for process development and the other for GMP manufacturing, each making use of two peristaltic style pumps instead of one on the typical SciFlex NFF units.

By delivering the same system but with different pumping capabilities the client could accomplish more realistic filter sizing studies and eliminate any variables introduced by differing control logic.

The two previously purchased SciFlex NFF units were each retrofitted with two peristaltic style pumps, sized for their processes, which could accomplish the low flow rate and high pressure requirements of their viral filtration process. This brought the process development system's flow rate capabilities up to overlap with the GMP system.

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