

CUSTOMER CASE STUDY

Biopharmaceutical Industry

STANDARDIZING A SEMI-MANUAL TFF OPERATION THROUGH AUTOMATION

Customer

An industry leader in the development and production of biopharmaceuticals with a USA-based commercial-scale GMP manufacturing facility.

Objective

To automate a semi-manual tangential flow filtration (TFF) step to eliminate process risk without requiring any modification to the client's Drug Master File while also standardizing the process to add the capability of greater cross-training.

Specification

- GMP solution with 21 CFR Part 11 compliant data collection
- Scale-up of process by up to 8 times.
- Capable of executing the existing semi-manual SOP
- Reduce learning curve to enable cross training
- Fits into small designated space



Standardize



Requirements

The client preferred SOP-driven processes with a single or few skilled operators trained to carry them out to ensure repeatability. However, this left operators constantly supervising GMP processes during campaigns and, when the decision was made to scale-up the process, this was unsustainable.

An automated solution for a previously manual TFF process was required which was capable of executing their existing SOP while simplifying and standardizing the process from the operators' point of view so a greater number could be trained to carry out the process step. In addition, the solution had to have a small enough footprint to fit into the designated space.

Parker domnick hunter Solution

The Parker domnick hunter SciPure TFF GMP-ready automated single-use TFF system was able to deliver an automated solution with SciPres single-use pressure sensors inline for pressure monitoring and interlocks as well as a 21 CFR Part 11 compliant data historian directly into their semi-manual process.

The tipping point was demonstrating that the SciPure TFF would be capable of executing their SOP. The added benefit is that the SciPure TFF added the capability for cross-training and eliminated the learning curve associated with gaining experience in running the process.

Additionally, as the room is incredibly small, the SciPure design was able to eliminate two scales by integrating a WeighStation gravimetric fluid handling platform into the skid to mount the retentate bioprocess container, and adding automation to calculate and display the permeate weight without requiring a physical permeate scale.

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