

Pure-Flo Hygienic Valves: Filtration Skid Application

Skid Design Improves Sterile Manufacturing Environment

The GSK (GlaxoSmithKline) pharmaceutical manufacturing facility in Ulverston, United Kingdom had a manual sterile filtration system inside a clean room. Typically, filter integrity testing involves a number of manual operations and relies on a path to atmosphere to test integrity. Their system consisted of two filters and interchangeable hose connections.

As part of a sterile facility upgrade, GSK implemented a project to design a sterile filtration skid that would:

- minimize the amount of equipment inside the clean room
- automate integrity testing, operation, Clean-in-Place (CIP), and Steam-in-Place (SIP) to eliminate risks of manual operations
- remove the risk of contamination through open ends
- allow for dual filtration and multiple inlets and outlets

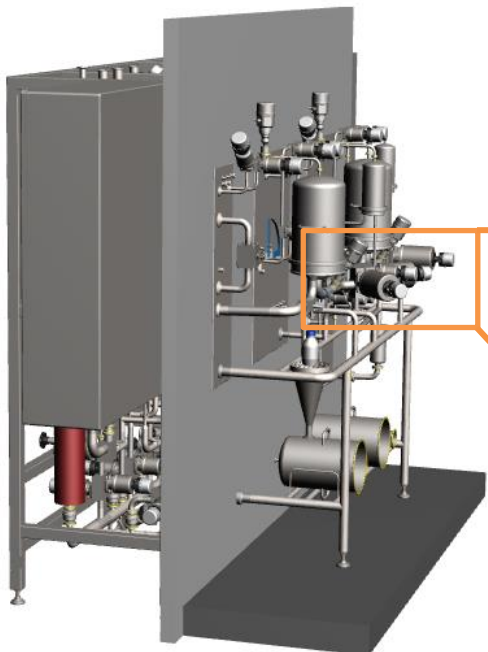
The ITT Impact

The filtration skid was designed with Pure-Flo hygienic diaphragm valves, reducing the risk of contamination and optimizing process efficiency.

Situation

GSK implemented a project to design an automated sterile filtration skid with hard-piped, integrated integrity testing, and no potential routes for contamination during post-sterilisation, integrity testing, and pre-use. Only the change of the filter element would be a manual operation. GSK partnered with Suncombe, as the mechanical designer, and ITT Engineered Valves as the valve manufacturer for the filtration skid.

ITT Engineered Valves worked with Suncombe to design the filtration skid. During the design sessions, the team discussed system requirements and constraints. Using a piping and instrumentation diagram (P&ID), they examined slopes, dead-legs (where fluid can become stagnant) and overall height so that all aseptic design criteria was met.



Filtration skid – front



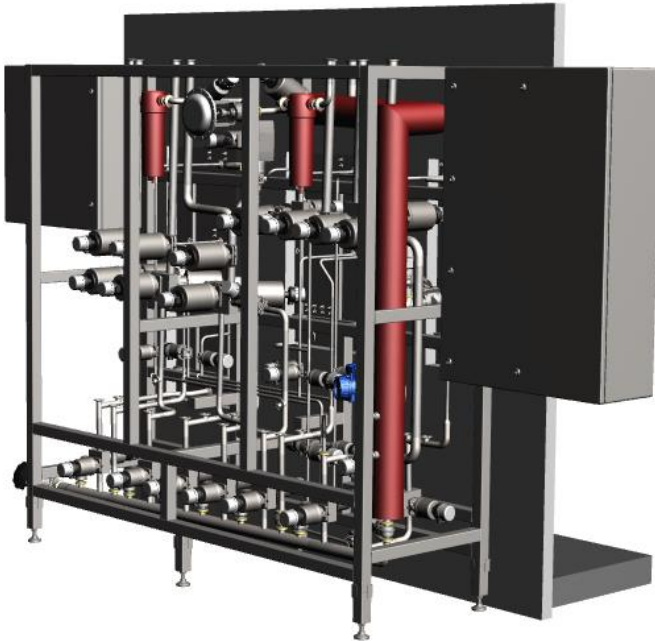
Pure-Flo block and bleed valve used on front of the filtration skid

ITT Solution

The filtration skid was designed with 70 manual and actuated Pure-Flo hygienic diaphragm valves, including many block body valves. The system included repeatable inlet and outlet valve arrangements, optimizing the efficiency of the process and reducing the resources required to produce a batch.

The filtration skid was designed to integrate with a clean room, but keep a majority of the valves in a technical area outside the clean room. It is fully automated, allowing the plant control system to utilize 55 different operating sequences.

Since the filter system will be used in a sterile manufacturing environment, this design will allow GSK to continue supplying quality product to their patients and reducing the risks of manufacturing in a sterile pharmaceutical environment.



Filtration skid – back



Row of Pure-Flo block body valves on the bottom of the filtration skid

IChemE Global Pharma Award 2018

ITT Engineered Valves was proud to win the IChemE Pharma Award 2018 for "Fully Integrated Sterile Filtration Unit" along with GSK, PM Group, and Suncombe Ltd. The team designed a fully integrated sterile filtration skid with in-situ integrity testing and no open ends.



IChemE 2018 Award Winning Team: Alun Cochrane, IChemE Award Host; James Finn, PM Group; Peter Nelson, ITT Engineered Valves; Mark Hodgson, GSK; Peter Farrelly, PM Group; Not Present: Mark Keen, Suncombe