

Optimised Solution Handling

Optimised Solution Handling Using single-use disposable bags and open bags in a bioprocess impacts on the operations by improving process productivity, and the flexibility of the facility whilst simultaneously reducing the risk of contamination.

Contamination

A major GMP deficiency reported from biopharmaceutical audits is linked with cross contamination, representing 15% of the total deficiencies. Single-use disposables are closed systems that are used once in the process thereby minimising the risk of cross contamination.

Clean Flexel[®] Tankliners can be utilised to prepare solutions prior to sterile filtering. Closed systems can then be used for the handling of sterile process solutions, product batches, samples and intermediates.

Pre-assembled sterile tubing can be aseptically disconnected and re-connected without introducing additional valves or sections of hard piping simplifying operations and reducing cleaning requirements.

Productivity

Typical CIP and SIP cycles take up to 1 hour and 4 hours respectively, resulting in equipment turnaround times in excess of 5 hours. During this time the equipment is unavailable for use. The application of Sartorius Stedim Biotech Systems allows reduced turnarounds by removing many of the CIP and SIP requirements. The removal of cleaning can also significantly reduce maintenance, utility consumption, and labour, thereby improving the productivity of the plant.

Flexibility

Single-use disposable bags provide flexibility when changing the process. Changes in the process and the scale of operation can be accommodated by the use of bags of different volumes. Standard Flexel[®] 3D bags and Palletanks[®] come in a range of volumes, from 100-1000L, however volumes as large as 2500L can be custom made to meet user requirements. In this way Sartorius Stedim Biotech Systems can be used to cover a 30 fold range of volumes without the costly need to remove fixed equipment. At the same time, the utilisation of Palletanks[®] can also allow a reduction in floor space requirements as a result of stacking.

Flexible tubing also allows alteration to the process layout to be quickly and efficiently accomplished. Pre-assembled sterile tubing manifolds and tube fusers/sealers allow rapid connection, disconnection, and re-configuration of tubing networks in response to process changes.