

Support Applications

Bioprocesses require large support infrastructures to provide sterile salt/complex solutions needed to produce, recover, and purify the product. Currently support applications constitute a major use of Sartorius Stedim Biotech bag systems. Additionally, open bags such as Flexel® Tankliners have applications where sterile operations are not an issue. Specific process support applications are:

1 [Solution Preparation](#)

The preparation of solutions used by process unit operations.

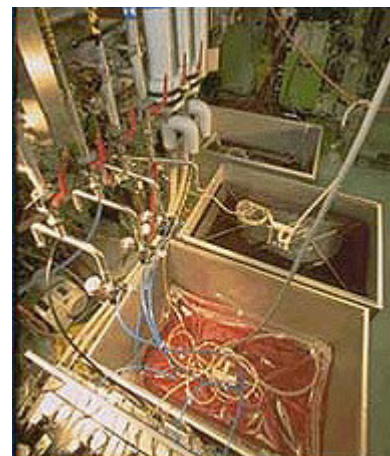
2 [Solution Storage](#)

The temporary storage of previously prepared solutions prior to use.

3 [Waste Collection](#)

In-process waste collection.

Cell culture media hold utilising Flexel® 3D bags



Solution Preparation

The majority of bioprocess unit operations require the addition of one or more solutions as part of their operating sequence. These solutions are broadly divided into media required for fermentation, and buffers used by all other unit operations. In both cases solutions are typically prepared using either a solution concentrate, or powder that is added to and mixed with water of a type defined by the process requirements.

Solution preparation activities therefore require high levels of mixing to be achieved within the vessel volume to ensure homogeneity of the resultant solution. Flexible bags are by nature a closed system and can therefore not be mixed using conventional impellers. Small solution volumes may be prepared using the Flexboy® mixing system by recirculation.

In-Line Sterile Filtration of Buffer Solution



Flexel® Tankliners provide a solution for mixing. The Flexel® Tankliners bags may be placed in a drum, and a solution prepared using an impeller introduced from above. The open nature of the Flexel® Tankliners means that sterility of the mixer cannot be guaranteed. However this may be circumvented through the use of in-line sterile filters feeding into a closed Flexel® 3D Bag. Customised Flexel® Tankliners are also available with bottom ports that simplify the transfer of material from the preparation to the storage vessel.

For larger volumes mixing can be carried out through re-circulation of material within a Flexel® 3D Bag.

Aseptic mixing by recirculation using a peristaltic pump is simple to set-up and requires one connection.

Solution Storage

Following the mixing of a process solution it will often be temporarily held prior to use. Sartorius Stedim Biotech Systems are well suited to solution storage. Their closed nature allows the storage of sterile solutions when used in conjunction with sterile filters. Sterile filtration can be performed using separate filters between the preparation and storage vessels, or single-use filters built into the bags themselves, so simplifying the connection requirements. The flexible nature of bags can also help

prevent the entrainment of air into the tubing system since they can expand and collapse as the volume of solution within varies.



Buffer solution storage and distribution for chromatography in 200L and 500L customised Palletanks®. Connections made using portable LAF cabinet.

The use of Sartorius Stedim Biotech Bags may help reduce the risk of cross contamination between different production suites, and between different production campaigns in multiple product facilities.

The flexible nature of single-use disposables also allows a solution storage system to cope with a wide range of storage requirements through the use of partial filling, and multiple bags. These changes may come about through process improvements driving up throughput, or the introduction of new processes, especially in facilities used for the manufacture of multiple products.



Waste Collection

Waste fluids are generated by most unit operations within a bioprocess. This waste must be collected and handled prior to subsequent processing where required. Single-use disposables are well suited to collection of low volume process waste, without introducing additional cleaning, or piping requirements.

Waste collection using a Flexel® Tankliner (lower right). Product collection using a Flexboy® bag.



Where sterility and material hazards are not a concern, such as waste cell mass following centrifugation/homogenisation, [Flexel® Tankliners](#) are an obvious choice. Closed systems, such as [Flexboy®](#) or [Flexel® 3D](#) Bags, are required to capture waste containing viable hazardous organisms, cytotoxins, or other hazardous materials.

The application of Sartorius Stedim Biotech Bag Systems may be especially attractive in downstream purification, where a re-configurable sequence of process workstations is often used to allow a facility to meet processing requirements for a range of products, and hazardous organisms have been removed from the process. Typical purification waste collection activities may include the collection of non-product containing chromatography solutions.