

Economic Analysis

When comparing single-use bag applications to stainless steel vessels the amount and proportion of costs within a process changes:

- Reduced capital costs and project timelines.
- Reduced labour associated with validation, maintenance & operation.
- Increased materials costs

A quantitative study has been completed for a single product 1000L monoclonal antibody perfusion process. The numbers used refer to the outcomes of this study. On balance the application of single-use disposable bags reduces both the initial capital outlay and the cost of goods (COG) over the lifetime of the plant. Costs were divided into the following categories (see fig 1):

The breakdown of costs associated with the manufacture of the sample product in a new facility are shown in the chart below.

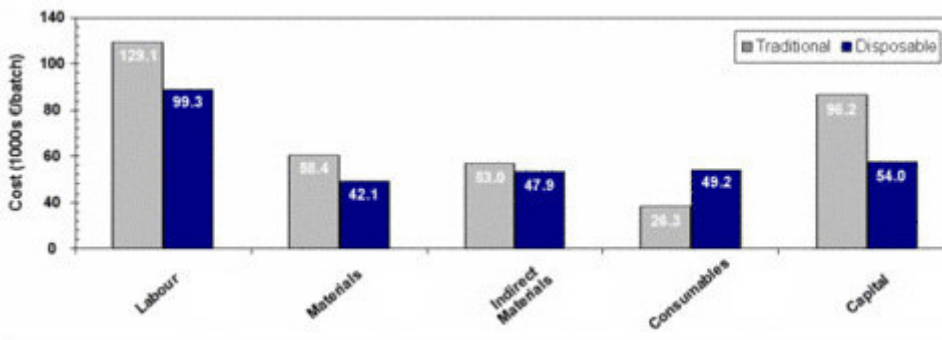


Figure1: Cost Breakdown - Traditional vs. Sartorius Stedim Biotech Systems

- Labour - the cost of labour associated with the facility, including support activities such as engineering
- Materials - the cost of materials utilised by and associated with the process, including bags
- Indirect Materials - the cost of indirect materials and engineering spares
- Consumables - the cost of materials that are used in the production of every batch
- Capital Charge - purchase, installation, and construction costs for the facility

For an in depth look into the concept facility, including a [3D walkthrough](#) (see in "Literature")

Overall the savings associated with the adoption of Sartorius Stedim Biotech Bag Systems were found to more than compensate for the increase in materials costs, leading to an estimated overall reduction of 19.4% in the COG for the sample process. Furthermore the use of single-use disposables can reduce the time taken to build a new facility.

Simulation Based Study

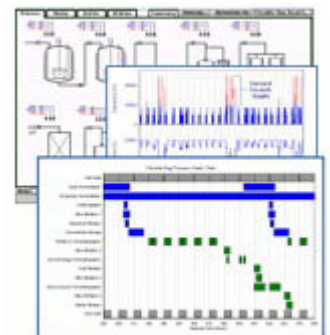


Figure 2: Impact on Total Cost when comparing Traditional vs. Stedim Biosystems Systems

Cost Category	Net Effect
Labour	-8.2%
Materials	-4.5%
Indirect Materials	-1.4%
Consumables	6.3%
Capital	-12.6%
Total Savings	-19.4%

The capital charge is reduced by 41% on the basis of existing applications (N.B. Single-use disposable filters are not included in this study, nor are the aseptic connectors with the potential for higher savings).

