


Production cost analysis

Business




Production Cost Analysis: Economic Analysis as a tool for Process

Development: Harvest of a High Cell-Density Fermentation For the biotech industry to be profitable, it must consider economics along with process recovery, purity, and product quality. The number of biotechnology-based human therapeutic products in the late-stage pipeline, and the average cost to commercialize a biotech product, have steadily increased. 1, 2 This has required biotech companies to use economic analysis as a tool during process development and for making decisions about process design.

Process development efforts now aim to create processes that are economical, as well as optimal and robust. 3-6  | Novais et al.



recently performed an economic comparison of conventional versus disposables-based technology for the production of an antibody fragment from an E. coli fermentation. 7The authors concluded that the capital investment required for a disposables-based option is substantially reduced—less than 60% of that for a conventional option.

The disposables-based running costs were 70% higher than those of the conventional equivalent. However, the net present value of the disposables-based plant was found to be positive and within 25% of that for the conventional plant. More recently, the economic feasibility of using disposables has been examined for facility design, highlighting the need to perform a thorough analysis for the application at hand.

8, 9  | | Quick Recap |

Harvesting biotechnology products from cell culture or fermentation process streams is often performed by a combination of several-unit operations.

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Centrifugation, depth filtration, and microfiltration are commonly used. In a recent publication, different harvest approaches were investigated for a case study involving recovery of a therapeutic protein from *Pichia pastoris* fermentation broth. 10  | | Figure 1. Schematics for options 1 and 2 | that are examined in this economic analysis | This article, the seventh in the “ Elements of Biopharmaceutical Production” series, describes how economic analysis can be used to compare different processes and assist in designing an “ economical” option. BACKGROUND  | | Table 1.

Comparison of process performance | | for option 1 and option 2. Adapted from | | reference 10. | Figure 1 illustrates the two options that will be examined in this economic analysis.

Option 1 involves a three-unit operation harvest process: centrifugation, followed by depth filtration, and completed with a concentration and buffer exchange via tangential flow ultrafiltration-diafiltration (UF-DF). Option 2 involves a two-unit operation process: microfiltration followed by a concentration and buffer exchange via tangential flow filtration (UF-DF).

Table 1 presents a comparison of process performance under the two options. Under optimal conditions, both options can deliver the desired product recovery (> 80%), harvest time (