

Process cost-modeling tools for process design and technology selection

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The ability of biopharmaceutical companies to develop manufacturing processes that deliver low costs of goods (CoGs) is becoming more important as the market becomes increasingly competitive. Process cost-modeling tools can be used to understand better the impact of process design and technology choices on overall process throughput and cost of goods. Biopharmaceutical companies can use these tools to determine whether they have a commercially viable process that will achieve the target cost of goods by predicting the impact of switching to alternative process configurations and scaling-up.

Our process-modeling experts typically use the BioSolve Process software from Biopharm Services. They have received the highest levels of training and have gained significant experience through successfully delivering many diverse cost-modeling projects all over the world.

Process modeling can support biopharmaceutical companies during their early stage process development activities. Process development scientists use these tools to identify the most optimized processes delivering the lowest costs. For analysis the software provides helps to identify specific process steps with the potential to have the greatest impact on overall process economics. With this information, managers can direct scientists to invest their time and effort into optimizing these unit operations and deliver the best overall outcome. For example, by using this tool we were able to identify that the steps in a MAb process with the highest costs were the production bioreactor in upstream processing and Protein A and cation-

exchange chromatography step in downstream processing (Figure 1). We can also ascertain how the cost dynamics change with increasing titer. As the titer increases from 5 g/L to 10 g/L the importance of downstream processing costs increase significantly.

Companies can gain valuable insights from process and cost modeling software when considering the design of new biomanufacturing facilities. Increasingly firms have to decide whether to implement stainless steel equipment, single-use technologies or a combination of the two using a hybrid approach. Process modeling with BioSolve Process allows the Sartorius Integrated Solutions team in partnership with clients, to assess different production paradigms during the conceptual phase of facility design. Figure 1 shows a comparison of the costs associated with a stainless steel facility, hybrid facility and a single-use facility.

Equipment sizing and operating approaches can be optimized by making design assumptions based on prior experience and our knowledge of process platforms. These assumptions may include upstream titer, bioreactor volumes, numbers, and the downstream process sequence. Once modeling experts have performed a basic analysis it is possible to compare the cost per batch/year/dose or cost per gram of various different scenarios and for companies to start asking themselves “what if?” questions. Companies are using our expertise in cost modeling, for example, to assess the impact on making major process changes such as moving from batch to continuous processing.