

Executive Summary

Bioprocessing is the branch of biotechnology dealing with the production and purification of biological materials of commercial interest, mainly but not exclusively for the pharma industry. It is a wide-ranging discipline in which bioengineering, equipment design, molecular biology, cell genetics, cell culture technology, analytical chemistry, and polymer science are applied to the goal of rapidly, consistently and economically producing high-molecular weight, complex molecules.

In recent years there has been a huge expansion in the use of disposables at both the upstream and the downstream end of the production chain. Today, many GMP CMOs are available, and the customer has a vast range of options from which to choose. This has forced monumental changes in the industry, making available workable solutions at affordable cost to small companies and permitting the production of material for clinical trials of less promising, second-tier candidates. Many studies have been carried out comparing disposable versus reusable up/down stream technology. In almost every category—cost, speed of adoption and size of carbon footprint—disposable technologies far outperform reusables. The one exception is very large scale (several thousand liters and up), in which the large disposable bags are too cumbersome and hard to handle.

This exploding marketplace has caused major biotech companies to question their strategy of large capital investments in massive plants and reusable equipment. Indeed, some observers of the industry suggest that large biomanufacturing plants, gleaming with stainless steel, are akin to the dinosaurs and will never be replicated.

The upstream versus downstream gap continues to be a problem for the industry, given the fact that progress toward producing more protein per unit volume of culture medium has moved more rapidly than increases in the rates at which these materials can be purified at the downstream end. At the same time, there have been new developments in various biological systems, and a number of biologics manufactured with yeast, bacteria and plant systems are in clinical trials. These trends in both the upstream and downstream areas are encouraging, and should provide help in holding down the costs of these very expensive biological molecule therapeutics.

While most antibody biologics are anti-cancer agents, there are a number of other areas of disease management in which biologics are starting to play a significant role. These include immune dysfunction, infectious disease and mental illness. Because of this expansion, there is a continuing demand for improved bioprocessing technology forcing the industry forward at a rapid pace. This expansion has motivated law-making bodies in Europe to redefine intellectual property guidelines and rules governing biogenerics. Legislation governing biosimilars has been passed in the United States as part of the recent 2010 healthcare legislation.

Much concern has been raised over the threat of Asian competition to the American bioprocessing industry. While the threat is cogent and serious, many analysts ignore a raft of problems that China must deal with as it struggles to move into high technology-based biomedical sciences. These include an oppressive political system, a large measure of discontent among the Chinese population, and a regulatory and intellectual property structure that will require years to mature. If China takes over high-tech bioprocessing as it has taken over the manufacture of Walmart items, it will be because the United States surrendered the industry without a struggle.

Management should also beware of aggressive competition from the European Union. With a combined population and GDP comparable or greater than that of the United States, and a mature regulatory and intellectual property framework, an excellent network of universities and research institutions, the European Union presents a formidable adversary. Throughout the continent, the construction of a robust 21st-century infrastructure is proceeding with a vengeance, promising to expedite the flowering of a high-tech industrial sector.

Medical device technology is advancing at a faster pace than drug development in general, and with increased cost savings and miniaturization, it is now feasible to install computer-controlled devices on disposable modules. With these new improvements in sensor technology coupled to advances in filtration technology, polymer chemistry and cell culture husbandry, the next decade promises to open up exciting changes in therapeutic protein production.