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Research review paper

Mammalian cell culture for production of recombinant proteins: A review of the critical steps in their biomanufacturing

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Abstract

The manufacturing of recombinant protein is traditionally undertaken in mammalian cell culture. Today, speed, cost and safety are the primary considerations for process improvements in both upstream and downstream manufacturing. Leaders in the biopharmaceutical industry are striving for continuous improvements to increase throughput, lower costs and produce safer more efficacious drugs. This can be achieved through advances in cell line engineering, process development of cell culture, development of chemically defined media and increased emphasis on product characterization. In the first part, this review provides a historical perspective on approved biotherapeutics by regulatory bodies which pave the way for next-generation products (including gene therapy). In the second part, it focuses on the application of *in vitro* and *in vivo* cell line engineering approaches, modern process development improvements including continuous manufacturing, recent developments in media formulation, and improvements in critical quality attribute determinations for products produced predominantly in mammalian cells.

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