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Within this chapter we also discussed key partners in the biomanufacturing process such as raw material suppliers, outsource testing vendors, as well as key support teams such as facilities, engineering, process development, quality assurance, quality control, environmental monitoring, manufacturing, and manufacturing science and technology teams required to fully develop and manufacture a biologic that can meet all of the critical safety, quality, and regulatory parameters.

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Chapter 26 The Biomanufacturing Of Biotechnology Products

Biomanufacturing is a new type of production that uses biological systems to construct commercially-relevant biomaterials to add to medicine, industrial applications and the food and beverage industry. Biomanufactured products are found in natural sources like cultures of microbes, blood or plant and animal cells that have been artificially grown in specialized equipment.

What is Biomanufacturing and How Will it Change the World?

Biomanufacturing protection strategies depend first and foremost on attaining primary and secondary containment of hazardous process materials. Primary containment refers to the protection of personnel and the immediate environment from exposure to hazards. Secondary containment refers to the protection of the environment outside the facility.

Chapter 2 Facilities - Biomanufacturing

This chapter provides an overview of microbiological control in the biomanufacturing industry. After completing this chapter the student will be able to: Explain why microbiological control is important in a biomanufacturing facility and provide a number of examples as to how it is achieved and maintained.

Chapter 8 Microbiological Control - Biomanufacturing

The biomanufacturing product development process is time consuming and expensive. It is estimated to take 8–15 years, at a cost of $500 million–$1 billion, to bring a biopharmaceutical to the market, with some estimates being less conservative. The sooner the product is brought

Chapter 12 Process Development - Biomanufacturing

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Biomanufacturing, a specialization within biotechnology, is an advanced-technology manufacturing industry responsible for making biopharmaceuticals (biologics). Biopharmaceuticals are any biotechnology-based therapeutics that structurally mimic components found in a living organism.

Chapter 1 Introduction - biomanufacturing.org

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Introduction to Downstream Processing Downstream processing is the phase of biomanufacturing typically considered to begin with harvest of bioreactor cell culture medium containing expressed active pharmaceutical ingredient (API) and finishing with a highly purified and appropriately concentrated product ready for final formulation and packaging.

Chapter 11 Downstream Processing - Biomanufacturing

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