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The engineers and biotechnologists who are involved in the full-scale process design of such facilities must be familiar with the variety of unit operations and equipment and the applicable regulatory requirements.

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usually require exceptional purity, making downstream processing a critical component of the overall process. From the regulatory viewpoint, the production process itself defines the biopharmaceutical product rendering proper definition of effective and efficient downstream processing steps crucial early in process development.

1 Downstream Processing of Biotechnology Products

The last two decades have seen a phenomenal growth of the field of genetic or biochemical engineering and have witnessed the development and ultimately marketing of a variety of products-typically through the manipulation and growth of different types of microorganisms, followed by the recovery and purification of the associated products.

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