

# The Biomanufacturing of Biotechnology Products

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What is biologics manufacturing? How is it different from small molecule pharmaceutical manufacturing? Biologics manufacturing, or biomanufacturing for short, is a complex process that produces a product largely derived from discoveries using recombinant DNA technology to develop processes and analytics to manufacture biotherapeutic products. These recombinant products were developed from several platforms such as whole *animal/falder* systems encompassing transgenic plants, animals and *unice/falder* microbial (bacteria and yeast), and insect and mammalian cell cultures. The discovery and “proof-of-concept” from the research bench is transferred to a process and analytical group that will use science and engineering as well as regulatory experience to scale-up the product efficiently with sufficient product yield to support the clinical program and a quality product expressing the quality attributes of the product as well as profile any product-associated impurities. The process for different biologic platforms are complex and unlike traditional chemical synthesis the biologic product resulting from a living system is not as an exact science as chemistry.

The long-existing paradigm for biologics was “the process is the product” and any variation in the process could impart a change in the product’s safety and efficacy. Although today’s raw materials, process and analytics are better defined and allow a lot more flexibility in the design and development of the process. Changes in the process or materials could severely alter the product’s safety and characteristics, thus one may end up with a product with a different profile. Changes in the manufacturing process can alter the “impurity profile” of a biologic, thus imparting changes in the product’s purity which can have an adverse

effect on safety. It has been demonstrated that endogenous adventitious viruses may result from processing changes or the extension of the production process. Therefore, end of production processes and genotypic studies on the cell line have been required to understand the implications of changes in the production process that can affect the product’s quality attributes, impurity profiles that could impact the safety of the therapeutic. Today’s biologic manufacturing facilities incorporate analytical and process development capabilities to develop and test the scale-up of the process to deliver sufficient productivity of a quality product. The development will support a Phase I clinical study focusing on safety and efficacy of the product. If the product can demonstrate safety and efficacy, the product with regulatory agency and business-positive feedback will continue the manufacturing of the biologics until reaching final approval and licensing.

## THE HISTORY OF BIOTECHNOLOGY AND BIOMANUFACTURING

Biotechnology is technology based on biology. It utilizes the biology of living systems and their genetic manipulations of these systems and processes to develop technologies and products that help improve the lives and health of individuals worldwide. These biological processes of microorganisms have been used for thousands of years to make food products from fermentation, such as bread, beer, wine, pickles and cheese—these processes are still used today. Modern biotechnology provides discoveries of recombinant DNA technology to discover and develop

# Chapter 26 The Biomanufacturing Of Biotechnology Products

**L Cohen**



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## Unveiling the Power of Verbal Beauty: An Psychological Sojourn through **Chapter 26 The Biomanufacturing Of Biotechnology Products**

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