Chapter 26

The Biomanufacturing of Biotechnology Products

John Conner, MS*, Don Wuchterl**, Maria Lopez***, Bill Minshall, MS*, Rabi Prusti, PhD†, Dave Sockair††, Jay Peterson‡ and Chris Allen, MS‡‡

*Vice President Manufacturing Science and Technology, Cytovance Biologics, Inc., Oklahoma City, Oklahoma, **Senior Vice President Operations, Cytovance Biologics Inc., Oklahoma City, Oklahoma, ***Vice President Quality Systems, Cytovance Biologics Inc., Oklahoma City, Oklahoma, †Senior Vice President Regulatory Affairs, Cytovance Biologics Inc., Oklahoma City, Oklahoma, ††Executive Director Quality Control, Cytovance Biologics Inc., Oklahoma City, Oklahoma, ‡‡Manager Manufacturing Downstream Operations, Cytovance Biologics Inc., Oklahoma City, Oklahoma, ‡Manager Manufacturing Upstream Operations, Cytovance Biologics Inc., Oklahoma City, Oklahoma, ‡‡Senior Manager Facilities and Engineering, Cytovance Biologics Inc., Oklahoma City, Oklahoma

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 *multicellular* systems encompassing transgenic plants, animals and *unicellular* microbials (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 1 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

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Jian-Jiang Zhong

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Biotechnology Entrepreneurship Craig Shimasaki,2014-04-08 As an authoritative guide to biotechnology enterprise and entrepreneurship Biotechnology Entrepreneurship and Management supports the international community in training the biotechnology leaders of tomorrow Outlining fundamental concepts vital to graduate students and practitioners entering the biotech industry in management or in any entrepreneurial capacity Biotechnology Entrepreneurship and Management provides tested strategies and hard won lessons from a leading board of educators and practitioners It provides a how to for individuals training at any level for the biotech industry from macro to micro Coverage ranges from the initial challenge of translating a technology idea into a working business case through securing angel investment and in managing all aspects of the result business valuation business development partnering biological manufacturing FDA approvals and regulatory requirements An engaging and user friendly style is complemented by diverse diagrams graphics and business flow charts with decision trees to support effective management and decision making Provides tested strategies and lessons in an engaging and user friendly style supplemented by tailored pedagogy training tips and overview sidebars Case studies are interspersed throughout each chapter to support key concepts and best practices Enhanced by use of numerous detailed graphics tables and flow charts Development of Biopharmaceutical Drug-Device Products Feroz Jameel,John W. Skoug,Robert R. Nesbitt,2020-03-13 The biotechnology biopharmaceutical sector has tremendously grown which led to the invention of engineered antibodies such as Antibody Drug Conjugates ADCs Bispecific T cell engager BITES Dual Variable Domain DVD antibodies and fusion proteins that are currently being used as therapeutic agents for immunology oncology and other disease conditions Regulatory agencies have raised the bar for the development and manufacture of antibody based products expecting to see the use of Quality by Design QbD elements demonstrating an in depth understanding of product and process based on sound science Drug delivery systems have become an increasingly important part of the therapy and most biopharmaceuticals for self administration are being marketed as combination products A survey of the market indicates that there is a strong need for a new book that will provide one stop shopping for the latest information and knowledge of the scientific and engineering advances made over the last few years in the area of biopharmaceutical product development The new book entitled Development of Biopharmaceutical Drug Device Products is a reference text for scientists and engineers in the biopharmaceutical industry academia or regulatory agencies With insightful chapters from experts in the field this new book reviews first principles covers recent technological advancements and provides case studies and regulatory strategies relating to the development and manufacture of antibody based products It covers topics such as the importance of early preformulation studies during drug discovery to influence molecular selection for development formulation strategies for new modalities and the analytical techniques used to characterize them It also addresses important considerations for later stage development such as the development of robust formulations and

processes including process engineering and modeling of manufacturing unit operations the design of analytical comparability studies and characterization of primary containers pre filled syringes and vials Finally the latter half of the book reviews key considerations to ensure the development and approval of a patient centered delivery system design This involves the evolving regulatory framework with perspectives from both the US and EU industry experts the role of international standards design control risk management human factors and its importance in the product development and regulatory approval process as well as review of the risk based approach to bridging between devices used in clinical trials and the to be marketed device Finally case studies are provided throughout The typical readership would have biology and or engineering degrees and would include researchers scientific leaders industry specialists and technology developers working in the biopharmaceutical field Endotoxin Detection and Control in Pharma, Limulus, and Mammalian Systems Kevin L. Williams,2019-07-24 Endotoxin detection and control is a dynamic area of applied science that touches a vast number of complex subjects The intersection of test activities includes the use of an ancient blood system from an odd living fossil Limulus It is used to detect remnants of the most primitive and destructive forms of life prokaryotes as contaminants of complex modern systems mammalian and Pharma Recent challenges in the field include those associated with the application of traditional methods to new types of molecules and manufacturing processes The advent of at will production of biologics in lieu of harvesting animal proteins has revolutionized the treatment of disease While the fruits of the biotechnology revolution are widely acknowledged the realization of the differences in the means of production and changes in the manner of control of potential impurities and contaminants in regard to the new versus the old are less widely appreciated Endotoxin as an ancient dynamic interface between lifeforms provides a singular perspective from which to view the parallel development of ancient and modern organisms as well as the progress of man in deciphering the complexity of their interactions in his efforts to overcome disease *Genetic Engineering News* ,2006 F & S Index United States Annual ,1995 **Predicasts F&S Index of Corporate Change** ,1991 Predicasts F & S Index United States ,1996 A comprehensive index to company and industry information in business journals **Moody's OTC Unlisted Manual** ,1994 **Downstream Industrial Biotechnology** Michael C. Flickinger,2013-03-12 DOWNSTREAM INDUSTRIAL BIOTECHNOLOGY An affordable easily accessible desk reference on biomanufacturing focused on downstream recovery and purification Advances in the fundamental knowledge surrounding biotechnology novel materials and advanced engineering approaches continue to be translated into bioprocesses that bring new products to market at a significantly faster pace than most other industries Industrial scale biotechnology and new manufacturing methods are revolutionizing medicine environmental monitoring and remediation consumer products food production agriculture and forestry and continue to be a major area of research The downstream stage in industrial biotechnology refers to recovery isolation and purification of the microbial products from cell debris processing medium and contaminating biomolecules from the upstream process into a finished product such as

biopharmaceuticals and vaccines Downstream process design has the greatest impact on overall biomanufacturing cost because not only does the biochemistry of different products e g peptides proteins hormones antibiotics and complex antigens dictate different methods for the isolation and purification of these products but contaminating byproducts can also reduce overall process yield and may have serious consequences on clinical safety and efficacy Therefore downstream separation scientists and engineers are continually seeking to eliminate or combine unit operations to minimize the number of process steps in order to maximize product recovery at a specified concentration and purity Based on Wiley s Encyclopedia of Industrial Biotechnology Bioprocess Bioseparation and Cell Technology this volume features fifty articles that provide information on down stream recovery of cells and protein capture process development and facility design equipment PAT in downstream processes downstream cGMP operations and regulatory compliance It covers Cell wall disruption and lysis Cell recovery by centrifugation and filtration Large scale protein chromatography Scale down of biopharmaceutical purification operations Lipopolysaccharide removal Porous media in biotechnology Equipment used in industrial protein purification Affinity chromatography Antibody purification monoclonal and polyclonal Protein aggregation precipitation and crystallization Freeze drying of biopharmaceuticals Biopharmaceutical facility design and validation Pharmaceutical bioburden testing Regulatory requirements Ideal for graduate and advanced undergraduate courses on biomanufacturing biochemical engineering biopharmaceutical facility design biochemistry industrial microbiology gene expression technology and cell culture technology Downstream Industrial Biotechnology is also a highly recommended resource for industry professionals and libraries **Biomanufacturing for Sustainable Production of Biomolecules** Vijai Singh,Pau Loke Show,2023-01-26 This book elucidates the sustainable production of commercially important biomolecules in medicines food and beverage processing through biological systems including microorganisms animal cells plant cells tissues enzymes and in vitro It discusses promising technologies for the manipulation of cells including genetic engineering synthetic biology genome editing and metabolic engineering The initial chapters of the book introduce topics on biomanufacturing circular economy strain design and improvement upstream and downstream processing The subsequent chapters cover artificial intelligence assisted production designer cell factories biosensors for monitoring biomolecules different cells factories biosynthetic pathways and genome editing approaches for scale up biomanufacturing Lastly the book discusses the opportunities and challenges of implementing biological systems for the production of biomolecules This book is a valuable source for students researchers scientists clinicians stakeholders policymakers and practitioners to understand biomanufacturing for the sustainable production of biomolecules **Biomanufacturing** Jian-Jiang Zhong,2004-05-03 With contributions by numerous experts **Continuous Biomanufacturing in Microbial Systems** Christoph Slouka,Christoph Herwig,Peter Neubauer,Frank Delvigne,2021-07-29 Christoph Herwig is founder of Exputec GmbH **Biomanufacturing** Jian-Jiang Zhong,2014-01-15 The Business of Bioscience Craig D. Shimasaki,2009-10-02 My journey into this fascinating

field of biotechnology started about 26 years ago at a small biotechnology company in South San Francisco called Genentech I was very fortunate to work for the company that begat the biotech industry during its formative years This experience established a solid foundation from which I could grow in both the science and business of biotechnology After my fourth year of working on Oyster Point Boulevard a close friend and colleague left Genentech to join a start up biotechnology company Later he approached me to leave and join him in of all places Oklahoma He persisted for at least a year before I seriously considered his proposal After listening to their plans the opportunity suddenly became more and more intriguing Finally I took the plunge and joined this ent preneurial team in cofounding and growing a start up biotechnology company Making that fateful decision to leave the security of a larger company was extremely difficult but it turned out to be the beginning of an entrepreneurial career that forever changed how I viewed the biotechnology industry Since that time I have been fortunate to have cofounded two other biotechnology com nies and even participated in taking one of them public During my career in these start ups I held a variety of positions from directing the science operations regulatory and marketing components to subsequently becoming CEO

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