

STERILE PRODUCT FACILITY DESIGN AND PROJECT MANAGEMENT

Second Edition



Jeffery N. Odum

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Babak Arjmand



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that are designed and built today are radically different than in the past. The vital information and knowledge needed to design and construct these increasingly sophisticated biopharmaceutical manufacturing facilities is difficult to find in published literature and it is rarely taught in architecture or design schools. This is the first book for architects and designers that fills this void. *Process Architecture in Biomanufacturing Facility Design* provides information on design principles of biopharmaceutical manufacturing facilities that support emerging innovative processes and technologies. Use of state-of-the-art equipment is energy efficient and sustainable and meets regulatory requirements. Relying on their many years of hands-on design and operations experience, the authors emphasize concepts and practical approaches toward design, construction, and operation of biomanufacturing facilities, including product-process-facility relationships, closed systems, and single-use equipment. Aseptic manufacturing considerations, design of biocontainment facilities, and process-based laboratory and sustainability considerations, as well as an outlook on the facility of the future, are provided. Guidelines for meeting licensing and regulatory requirements for biomanufacturing facilities in the U.S.A. and WHO, especially in emerging global markets in India, China, Latin America, and the Asia-Pacific regions, are included. Focuses on innovative design and equipment to speed construction and time to market, increase energy efficiency, and reduce footprint, construction, and operational costs, as well as the financial risks associated with construction of a new facility prior to the approval of the manufactured products by regulatory agencies. Includes many diagrams that clarify the design approach. *Process Architecture in Biomanufacturing Facility Design* is an ideal text for professionals involved in the design of facilities for manufacturing of biopharmaceuticals and vaccines, biotechnology, and life science industry, including architects and designers of industrial facilities, construction equipment vendors, and mechanical engineers. It is also recommended for university instructors, advanced undergraduates, and graduate students in architecture, industrial engineering, mechanical engineering, industrial design, and industrial interior design.

Downstream Industrial Biotechnology Michael C. Flickinger, 2013-07-17. *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 downstream 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

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Perinatal Tissue-Derived Stem Cells Babak Arjmand, 2016-12-01 This book covers several aspects of perinatal tissue derived stem cells from theoretical concepts to clinical applications Topics include functions and different sources immunomodulatory properties translational point of view GMP facility design and manufacturing for clinical translation therapeutic potentials and finally ethical considerations The text provides a brief review of each type of perinatal stem cells and then focuses on their multi or pluripotent properties regenerative capacity and future therapeutic potential in regenerative medicine Additionally the book discusses GMP compliance in stem cell facilities and the manufacture of stem cells for clinical translation The chapters are authored by world renowned experts in the perinatal stem cell field Perinatal Tissue Derived Stem Cells Alternative Sources of Fetal Stem Cells part of Springer's Stem Cell Biology and Regenerative Medicine series is essential reading for basic and clinical scientists clinicians and pharmaceutical experts working or conducting research in the fields of stem cell biology molecular aspects of stem cell research tissue engineering regenerative medicine and cellular therapy

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



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