

STERILE PRODUCT FACILITY DESIGN AND PROJECT MANAGEMENT

Second Edition



Jeffery N. Odum



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Sterile Product Facility Design And Project Management

Jeffery Odum, Michael C. Flickinger



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Process Architecture in Biomanufacturing Facility Design Jeffery Odum, Michael C. Flickinger, 2018-01-26 Essential information for architects designers engineers equipment suppliers and other professionals who are working in or entering the biopharmaceutical manufacturing field Biomanufacturing facilities 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 s 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 state of the art equipment are energy efficient and sustainable and meet 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 facility and process based laboratory and sustainability considerations as well as an outlook on the facility of the future Provides 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 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

Manufacturing of Pharmaceutical Proteins Stefan Behme, 2015-02-13 Structured like a textbook the second edition of this reference covers all aspects of biopharmaceutical manufacturing including legal and regulatory issues production facility design and quality assurance with a focus on supply chain management and regulations in emerging markets and cost control The author has longstanding industrial expertise in biopharmaceutical production and years of experience teaching at universities As such this practical book is ideal for use in academia as well as for internal training within companies

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

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good design practices Project Management Kimmons,2017-11-22 Highlighting the practical side of real life project execution this massive reference stresses project management as an independent profession detailing the varied applications where project management is used and examining the numerous and diverse project management responsibilities and tools

Process Validation in Manufacturing of Biopharmaceuticals Anurag Singh Rathore, Hal Baseman, Scott Rudge, 2023-12-18 The fourth edition of *Process Validation in Manufacturing of Biopharmaceuticals* is a practical and comprehensive resource illustrating the different approaches for successful validation of biopharmaceutical processes A pivotal text in its field this new edition provides guidelines and current practices contains industrial case studies and is expanded to include in depth analysis of the new Process Validation PV guidance from the US FDA Key Features Offers readers a thorough understanding of the key concepts that form the basis of a good process validation program for biopharmaceuticals Includes case studies from the various industry leaders that demonstrate application of these concepts Discusses the use of modern tools such as multivariate analysis for facilitating a process validation exercise Covers process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing including chromatography chemical modification reactions ultrafiltration and microfiltration and practical methods to test raw materials and in process samples Providing a thorough understanding of the key concepts that form the basis of a good process validation program this book will help readers ensure that PV is carried out and exceeds expectations Fully illustrated this is a much needed practical guide for biopharmaceutical manufacturers **Approved: The Life Cycle of Drug Development** Narendra Chirmule, Vihang Vivek

Ghalsasi, 2025-04-29 Drug development stands at a transformative threshold in modern medicine Over the past three decades biotherapeutics have redefined medical innovation paving the way for treatments that are not only effective but also accessible This book provides a comprehensive exploration of the intricate world of drug development shedding light on the essential balance between efficiency regulatory compliance and quality to achieve both innovation and affordability Written by leading experts this guide delves into the multi faceted process of drug development covering critical areas such as pharmacology biomarkers toxicology product development manufacturing and clinical trials all framed within the stringent requirements set by the FDA Readers will find in depth discussions on the latest technologies statistical approaches and quality assurance measures essential to navigating today s complex regulatory landscape With practical case studies project reports and curated article reviews this book offers valuable insights into risk assessment and mitigation at every stage of development It serves as an indispensable resource for students educators and industry professionals aiming to foster a deeper understanding of the challenges and opportunities in drug development and to inspire the next generation of scientific innovators **CleanRooms** ,2007-02 A central resource of technology and methods for environments where the

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production and regulatory expectations Handbook of Validation in Pharmaceutical Processes Fourth Edition examines and blueprints every step of the validation process needed to remain compliant and competitive This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions As the industry s leading source for validation of sterile pharmaceutical processes for more than 10 years this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio pharmaceutical production processes Handbook of Validation in Pharmaceutical Processes Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals Key Features Provides an in depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program and suggests the newest and most advanced solutions Explores distinctive and specific process steps and identifies critical process control points to reach acceptable results New chapters include disposable systems combination products nano technology rapid microbial methods contamination control in non sterile products liquid chemical sterilization and medical device manufacture Bulletin Parenteral Drug Association,1976 *Books In Print 2004-2005* Ed Bowker Staff,Staff Bowker, Ed,2004 **Variabilisierung von Fixkosten durch Facility Management** Philipp Kaufmann,2002-04-30 Inhaltsangabe Einleitung Der fixe Kostenblock von Anlagen und Gebäuden wurde in der betriebs und volkswirtschaftlichen Betrachtung bisher nicht zufriedenstellend behandelt Die Methoden der Kostenrechnung versagen bei immobilienrelevanten Fixkosten sie verteilen einen für sie unbekannten Kostenblock durch Zuschlags- oder verrechnen diesen mit komplizierten Verfahren Darüber hinaus verfügt das Management über keine effizienten Instrumente die es ermöglichen den Bereich von Anlagen und Gebäuden tatsächlich managen zu können Unternehmen haben mit dieser methodischen Schwäche zu leben gelernt Verändert hat dies jedoch folgende Situation Organisationen haben nach der Verbesserung ihrer Kernprozesse schließlich feststellen müssen dass größere Optimierungs- und Effizienzsteigerungspotentiale bei diesen teilweise nicht mehr vorhanden sind Diese Einsicht lenkte die Aufmerksamkeit auf die nicht direkt wertschöpfenden bzw auf die unterstützenden Unternehmensprozesse und hier besonders auf die Gebäude und Anlagen für die jedoch keine schlüssigen Konzepte vorliegen Gang der Untersuchung Diese Arbeit beschäftigt sich mit der Fragestellung ob durch die Einführung von Facility Management FM diese Fixkosten variabilisiert und dadurch optimiert werden können Im ersten Teil wird die Immobilie als Betrachtungsgegenstand erörtert und definiert Dabei werden besondere Charakteristika von Immobilien erarbeitet welche besondere Rahmenbedingungen für das FM als Immobilienmanagement vorgeben Als Grundlage werden weiters die möglichen Nutzungsarten der beteiligten Marktpartner sowie die Einflüsse auf das Immobilienmanagement insbesondere die Lebenszyklen von Immobilien dargestellt Danach wird geklärt wie Fixkosten in der betriebswirtschaftlichen Literatur behandelt werden Nach notwendigen Begriffsdefinitionen wie fixe vs variable Kosten werden die wesentlichen Methoden der Kostenrechnung vorgestellt vom Pionier SCMALENBACH mit seiner Deckungsbeitragsrechnung aus dem Jahr 1899 bis RIEBEL mit seinem eigenen System von relativen Einzelkosten und

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biologists chemists and engineers is brought into a common language aiding the understanding of complex biological
chemical engineering issues Problems to be addressed by the future R D activities and by new technologies are described
and summarized in the last chapter Updated references Studying bioprocessing problems looking at opportunities for
improvements and technology developments *Economic Analysis of Fermentation Processes* Harold B.
Reisman,2019-06-05 Published in 1988 It is the purpose of this book to outline and detail the many steps which are involved
in bringing a fermentation product to market **Enhancing compliance to good manufacturing practices and
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