County into a Manual of

# STERILE PRODUCT FACILITY DESIGN AND PROJECT MANAGEMENT

Second Edition



Jeffery N. Odum



Characteristical Municipal



**Stefan Behme** 

Sterile Product Facility Design and Project Management, Second Edition Jeffrey N. Odum, 2004-03-29 Knowing how to deal with the regulatory issues understanding the impacts of cleanliness and recognizing the affect that poor facility layout will have on GMP spaces are only some of the issues an experienced Project Manager must focus on Completely revised and updated Sterile Product Facility Design and Project Management Second Edition provides comprehensive guidance on how to develop and execute biotech and other sterile drug facilities based on current industry best practices Each chapter highlights a specific issue centered on managing biotech facilities projects in a GMP environment The author uses real world examples of common industry practice to lead you through the idiosyncrasies of a biotech project in an effort to answer some of the more common and often perplexing questions that can stand in the way of success You get a mini seminar on each topic covered Breaking the project life cycle into four phases the text takes you through each phase from the Project Manager's viewpoint Unlike other books that cover design technology and validation in general terms this book addresses the industry specific issues that make biotech facilities so costly and difficult to deliver It puts the pieces of the puzzle together in a manner that increases your opportunity for success **Sterile Product Facility Design and Project Management** Jeffrey N. Odum, 2019-10-07 Knowing how to deal with the regulatory issues understanding the impacts of cleanliness and recognizing the affect that poor facility layout will have on GMP spaces are only some of the issues an experienced Project Manager must focus on Completely revised and updated Sterile Product Facility Design and Project Management Second Edition provides comprehensive guidance on how to develop and execute biotech and other sterile drug facilities based on current industry best practices Each chapter highlights a specific issue centered on managing biotech facilities projects in a GMP environment The author uses real world examples of common industry practice to lead you through the idiosyncrasies of a biotech project in an effort to answer some of the more common and often perplexing questions that can stand in the way of success You get a mini seminar on each topic covered Breaking the project life cycle into four phases the text takes you through each phase from the Project Manager's viewpoint Unlike other books that cover design technology and validation in general terms this book addresses the industry specific issues that make biotech facilities so costly and difficult to deliver It puts the pieces of the puzzle together in a manner that increases your opportunity for Sterile Product Facility Design and Project Management Jeffrey N. Odum, 2004-03-29 Knowing how to deal with success the regulatory issues understanding the impacts of cleanliness and recognizing the affect that poor facility layout will have on GMP spaces are only some of the issues an experienced Project Manager must focus on Completely revised and updated Sterile Product Facility Design and Project Management Second Edition provid Sterile Drug Products Michael J. Akers, 2016-04-19 Sterile Drug Products Formulation Packaging Manufacturing and Quality teaches the basic principles of the development and manufacture of high quality sterile dosage forms The author has 38 years of experience in the

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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

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