

Ispe Baseline Pharmaceutical Engineering Guides

ISPE Baseline Pharmaceutical Engineering Guide for New and Renovated Facilities
ISPE Baseline® Guide: Volume 5 - Commissioning and Qualification
Baseline Pharmaceutical Engineering Guide: Commissioning and qualifications
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Process Architecture in Biomanufacturing Facility Design
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an expert single volume overview of the core processes and disciplines of biopharmaceutical production in the newly revised third edition of manufacturing of pharmaceutical proteins from technology to economy renowned chemical engineer dr stefan behme delivers a comprehensive text covering all aspects of biopharmaceutical manufacturing including legal and regulatory considerations production facility design quality assurance supply chain management emerging market regulations and cost control suitable as both a reference book and a training resource this book extensively explores the impact of digital transformation on pharmaceutical protein manufacturers and includes a brand new chapter dedicated to digitalization the distinguished author provides readers with practical understanding of the terminology and principles driving the various fields involved with biotechnological production including operations legal finance and it he also offers a thorough introduction to biopharmaceutical production including value creation product types and biological basics comprehensive explorations of the technology of the manufacturing process and analytics practical discussions of pharmacology and drug safety quality assurance and pharmaceutical law in depth examinations of pharmaceutical protein production facilities including facility design and the planning construction and commissioning of a manufacturing plant perfect for biotechnologists working in the pharmaceutical industry manufacturing of pharmaceutical proteins from technology to economy will also earn a place in the libraries of pharmaceutical engineers seeking a one stop reference for all aspects of biopharmaceutical production

this book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task oriented procedure based cultures to truly integrated quality business systems that are self detecting and correcting chapter flow has been changed to adopt a quality systems organization approach and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends key features presents insight into the world of pharmaceutical quality systems analyzes regulatory trends and expectations includes approaches and practices used in the industry to comply with regulatory requirements discusses recent worldwide supply chain issues delivers valuable information to a worldwide audience regarding the current gmp practices in the industry

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

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