Process Validation In Manufacturing Of Biopharmaceuticals Third Edition Biotechnology And Bioprocessing 2012 05 09

A study of biopharmaceutical process validation. It aims to enable developers and producers to ensure safe products, reduce the risk of adverse reactions in patients, and avoid recalls by outlining sophisticated validation approaches to characterize processes, process intermediates, and final product fully. The text emphasizes cost effectiveness while determining what level of validation is required for different phases of development, license application, and process improvements.
The first complete one-volume reference on the topic, this book describes all aspects of process validation in the licensure of recombinant biologics, for both protein and non-protein products. It covers product synthesis, purification, and filling/finishing.
Often considered a necessary evil by the pharmaceutical industry, validation is still understood by many as unrestrained bureaucracy, paperwork, and procedures whose roots and logic are obscure and only serve to slow down progress. Thoroughly defining the philosophy, application, and processes, Facility Validation: Theory, Practice, and Tools explores the validation issues relevant to the start-up of a new or upgraded manufacturing facility. The author describes policies, guidelines, and regulations relating to GMPs in the pharmaceutical industry and explores the relationship between these GMPs and the validation process. He outlines the theory and clarifies the philosophy and key principles of validation such as life-cycle approach and qualification practices. The book includes coverage of common pitfalls and how to avoid them, the difficulties and constraints a validation team has to manage, and the dangers of not adopting and following the recommended best practices. Facility validation has, in fact, become good business. It can be a tool for enhancing reliability, cost, and quality. This book makes the case that design, engineering, commissioning, and validation activities can be integrated and streamlined to accelerate a pharmaceutical manufacturing plant start-up effort, and demonstrates how to use best practices to achieve the results you desire in your organization.
Process Validation in Manufacturing of Biopharmaceuticals
Process Validation and Supplier Controls
Process Validation of Oral Solution- a Case Study
Process Validation, Area and Equipment Qualification
Process Validation in Biopharmaceutical Manufacturing
A COMPREHENSIVE HANDBOOK FOR INTERPRETING AND IMPLEMENTING DESIGN CONTROL REGULATION

For the past decade, process validation issues ranked within the top six of Food and Drug Administration (FDA) form 483 observation findings issued each year. This poses a substantial problem for the medical device industry and is the reason why the authors wanted to write this book. The authors will share their collective knowledge: to help organizations improve patient safety and increase profitability while maintaining a state of compliance with regulations and standards. The intent of this book is to provide manufacturing quality professionals working in virtually any industry a quick, convenient, and comprehensive guide to properly conduct process validations that meet regulatory and certification requirements. It will aid quality technicians, engineers, managers, and others that need to plan, conduct, and monitor validation activities.

The third edition of this text contains additional chapters which cover troubleshooting procedures, validation in contract manufacturing and current harmonization trends.

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in

The Basics, Volume 1

Validation by Design

Modeling Supplier Coordination in Manufacturing Process Validation

A Cost-benefit, Timing, and Risk Reduction Analysis for Medical Device Manufacturing Companies

Solid Oral Dose Process Validation, Volume Two

Process Validation of Semi-Solid Formulation

Manufacturing area with new equipment having high capacity compared to previous one (Production Line) i.e. FBD, RMG, Co Mill and Container Mixer. Manufacturing of Metformin ER 500mg tablets is planned to do in new area with new equipment. As the size and capacity of the equipments are bigger than previous equipments, batch size of Metformin ER tablets is increasing from 0.4 mio to 0.6 mio. As the production in new area and new equipment, qualification of area, equipment, water and air was carried out as per qualification protocol. Now, further the process of optimization was performed for Metformin ER tablets by identifying the critical Process parameters i.e. standardization batch (BATCH I). Before going to start process validation, one standardization batch was taken, where the process optimization of critical parameter like mixing speed, mixing time, lubrication time was carried out; fast, 15 min, 15 min respectively the results for that. Three process validation batches (PV-1, PV-2 and PV-3) of commercial batch size were taken in which Manufacturing Process, critical parameters, Validation status of equipments & Validation criteria's were considered.

This book contains both the theory and practice of risk management (RM) and provides the background, tools, and application of risk in pharmaceutical and biologics manufacturing and operations. It includes case studies and specific examples of use of RM for biological and pharmaceutical product manufacture. The book also includes useful references and a bibliography for the reader who wishes to gain additional knowledge in the subject. It aids in assisting both industry and regulatory agencies to implement compliant and effective risk management approaches, and includes case studies to help with understanding.

Validation of computer systems is the process that assures the formal assessment and report of quality and performance measures for all the life-cycle stages of software and system development, its implementation, qualification and acceptance, operation, modification, requalification, maintenance and retirement (PICS CSV PI 011-3). It is a process that demonstrates the compliance of computer systems functional and non-functional requirements, data integrity, regulated company procedures and safety requirements, industry standards, and applicable regulatory authority’s requirements. Compliance is a state of being in adherence to application-related standards or conventions or regulations in laws and similar prescriptions. This book, which is relevant to the pharmaceutical and medical devices regulated operations, provides practical information to assist in the computer validation to production systems, while highlighting and efficiently integrating worldwide regulation into the subject. A practical approach is presented to increase efficiency and to ensure that the validation of computer systems is correctly achieved.

A Guide to Best Practice

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition

Guidelines, Current Practices, and Industrial Case Studies

Pharmaceutical Process Validation

Validation of Pharmaceutical Processes

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in final form on January 24, 2011. The book also provides guidelines and current practices, as well as industrial case studies illustrating the different approaches that can be taken for successful validation of biopharmaceutical processes. Case studies include Process validation for membrane chromatography Leveraging multivariate analysis tools to qualify scale-down models A matrix approach for process validation of a multivalent bacterial vaccine Purification validation for a therapeutic monoclonal antibody expressed and secreted by Chinese Hamster Ovary (CHO) cells Viral clearance validation studies for a product produced in a human cell line A much-needed resource, this book presents process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing, including chromatography, chemical modification reactions, ultrafiltration, and microfiltration. It also provides practical methods to test raw materials and in-process samples. Stressing the importance of taking a risk-based approach towards computerized system compliance, this book will help you and your team ascertain process validation is carried out and exceeds expectations.
Process Validation and Supplier Controls are hot-button issues for all stages of the design and manufacturing process, from the design and supply of polymers to product design and production. These procedures are especially critical in highly regulated sectors such as Medical Devices. Vinny Sastri uses his extensive experience in the plastics and Medical Device industries to provide an accessible and practical guide to implementing Process Validation and Supplier Control regimes on both sides of the supply chain: materials design and supply, and product design and manufacture. Best practice guidance is supported by a detailed explanation of the FDA and ISO regulatory frameworks for Process Validation and the Medical Device and Pharmaceuticals industries. Strp-by-step guidance is also provided regarding the validation process and related documentation. The importance of design and development, risk management and the process validation life cycle are highlighted, and the good automated manufacturing process (GAMP) model is discussed. In addition, statistical methods and modeling are covered. Sastri makes his content come to life by providing step-by-step instructions, flow charts and case studies from industry, along with templates and checklists that can be put to work straight away. Written for all stages in the process: raw material specification and compliance issues, process validation and design. Provides best practice guidance on the use of risk management in process validation Illustrates the importance of establishing critical process parameters and raw material specifications
Process validation is a requirement of the Current Good Manufacturing Practices Regulations for Finished Pharmaceuticals, 21 CFR Parts 210 and 211, and of the Good Manufacturing Practice Regulations for Medical Devices, 21 CFR Part 820, and therefore, is applicable to the manufacture of pharmaceuticals and medical devices. Lyophilization is an essential component of synthesis and formulation processes in chemical and pharmaceutical industry. Therefore, it is needed to be validation and per regulatory requirements. Successful process validation programs begin with a thoughtful and comprehensive corporate policy concerning the process validation program. This policy should recognize that process validation begins at the initial stages of development, and does not end until the lifetime of the product is over. It is important that all employees be fully trained and understand their role in the program. Good science, well-documented development programs, proactive procedures and definitions, and well-written protocols will increase the chances of successful process validation.
Lifecycle approach application. Volume two
A Guide to Process Validation
Guideline on General Principles of Process Validation
ISPE Good Practice Guide
Manufacturing Process Validation of New Bottle Filling, Capping, Sealing and Labeling Line for Hematology Reagents
Berlin Hilton Hotel, Berlin, Germany, 6-7 September, 2001

The aim of the book is:To add value to the process by eliminating variance, batch rejects and ultimately product recall. To reduce production costs of sorting and rework due to the manufacture of non-conforming products (products that do not meet their specifications).To meet regulatory requirements. Regulatory bodies, such as the FDA, may require process validation. To provide documented evidence for the operation sequencing and scheduling of manufacturing processes and to determine the critical parameters of the manufacturing process of oral liquid preparations.To provide assurance that manufacturing process is suitable for intended purpose and consistently meets its predetermined specifications and quality attributes, as per (Master Formula Record) MFR.The aim of this book is to systematically conduct the validation studies pertaining to the manufacturing activities of oral liquid and to conclude on a high degree of assurance that manufacturing process, consistently meets the predetermined specifications and quality attributes. Hence the quality product output can be increased, leading to increase in quality, productivity and decrease the need of reprocessing.
Process Validation in Manufacturing of Biopharmaceuticals, Third EditionCRC Press
Revised to reflect significant advances in pharmaceutical 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
Method Validation in Pharmaceutical Analysis
The Statistical Handbook for Pharmaceutical Process Validation
Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing
An International
Facility Validation
PDA Technical Report No. 42

Principles of Parenteral Solution Validation: A Practical Lifecycle Approach covers all aspects involved in the development and process validation of a parenteral product. By using a lifecycle approach, this book discusses the latest technology, compliance developments, and regulatory considerations and trends, from process design, to divesting. As part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin, this book incorporates numerous case studies and real-world examples that address timely problems and offer solutions to the daily challenges facing practitioners in this area. Discusses international and domestic regulatory considerations in every section Features callout boxes that contain points-of-interest for each segment of the audience so readers can quickly find their interests and needs Contains important topics, including risk management, the preparation and execution of properly designed studies, scale-up and technology transfer activities, problem-solving, and more

Updated to reflect current good manufacturing practice (CGMP) regulations, this text discusses current concepts in validation. New topics covered include: validation of cleaning systems and computer systems; equipment and water systems validation; and lyophilized and aerosol product validation.

Attempting to fill the gap Regulatory documents and inspections have put increasing emphasis on process validation for all types of products, including biological and biotechnological ones. Until now, no description of a process validation for complex biological processes exists, let alone any concrete suggestion how to attain it: this book, however, attempts to fill the gap. Taking the current state of scientific practice in process validation as a starting point, this volume portrays the expectations of the regulatory community and provides detailed examples of how various types of biological and biotechnological processes could be validated. Considering the sizeable difficulties in designing a single method of process validation suitable for all types of processes and products, the authors discuss the implications and present many possible routes to a successful validation process.

A Practical Lifecycle Approach

Process Validation Concepts for the Medical Device Manufacturing Industry

Practical Process Validation

Theory, Practice, and Tools

Implementing Modular Process Validation

Pharmaceutical Process Validation, Second Edition

The textbook addresses the lifecycle concepts (Stage 1, 2, 3) of Process Validation. Regulatory bodies such as US FDA, EMEA, WHO, PIC/S have adopted the ICH lifecycle approach. Organizations have an opportunity to harmonize and align PV activities for all regulated markets. The concepts discussed provides a direction on how to approach solid dose manufacturing process validation for regulatory compliance. Solid Oral Dose Process Validation, Lifecycle Approach: Application, Volume Two and the companion Volume One, Solid Dose Process Validation, The Basics, also available as a set, provide directions and solutions for the pharmaceutical industry. The topics and chapters give a systematic understanding for the application of lifecycle concepts in solid dose pharmaceutical manufacturing. Since solid dose formulations encompass majority of the pharmaceutical preparations, it is essential information for pharmaceutical professionals who use the process validation lifecycle approach. This set is published as a comprehensive solution for solid dose process validation.

Currently there are no process validation (PV) textbooks addressing the lifecycle concepts (Stage 1, 2, 3). Recent regulatory guidance's such as US FDA, EMEA, WHO, PIC/S have adopted the ICH lifecycle approach. The concepts are now harmonized across regulatory guidance's and organizations have an opportunity to align PV activities for all regulated markets. Therefore a need exists for consensus and direction on how to approach solid dose manufacturing process validation for regulatory compliance. Solid Dose Process Validation: The Basics, Volume One and companion Solid Dose Process Validation: Lifecycle Approach Application, Volume Two, also available as a set, provide directions and solutions for these unmet needs for the pharmaceutical industry. The topics and chapters give a systematic understanding for the application of lifecycle concepts in solid dose pharmaceutical manufacturing. All approaches meet the regulatory requirements enlisted in the guidance’s, which is the precursor to applying the concepts. This set is published as a comprehensive solution for solid dose process validation. Since solid dose formulations encompass majority of the pharmaceutical preparations, it is essential information for pharmaceutical professionals who use the process validation lifecycle approach.

Adopting a practical approach, the authors provide a detailed interpretation of the existing regulations (GMP, ICH), while also discussing the appropriate calculations, parameters and tests. The book thus allows readers to validate the analysis of pharmaceutical compounds while complying with both the regulations as well as the industry demands for robustness and cost effectiveness. Following an introduction to the basic parameters and tests in pharmaceutical validation, including specificity, linearity, range, precision, accuracy, detection and quantitation limits, the text focuses on a life-cycle approach to validation and the integration of validation into the whole analytical quality assurance system. The whole is rounded off with a look at future trends. With its first-hand knowledge of the industry as well as regulating bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmaceutists, QA officers, and public authorities.

Process Validation of Protein Manufacturing

Solid Oral Dose Process Validation

Lifecycle Approach Application

A Biopharmaceutical Case Study

for the Medical Device and Pharmaceutical Industries

Good Manufacturing Practice Process Validation and Relationship to Statistical Process Control

Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations, this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and

competitive. The many chapters added to the prior compilation examine va

At over 200 pages, this pocket book will bring you up to speed quickly on the requirements of process validation. It is divided into logical chapters that sets out the journey of validation in a clear fashion. Many components of Validation for medical devices are transferable. Understanding the fundamental principles of validation allows the reader to apply them to different products and different manufacturing processes. This book is ideal for professionals new to Process Validation. Although it has a practical approach, it is also suited to the academic. Chapter 1: Validation Planning, Chapter 2: Facilities And Utilities Qualification Chapter 3: Equipment And Software Validation Chapter 4: Process Validation Chapter 5: Packaging Validation Chapter 6: Test Method Validation Chapter 7: Measurement Chapter 8: ISO 13485 Chapter 9: Lean

Process validation is a main part of quality assurance, Validation assure that aspecific process for good quality of product in the manufacturing unit that meets itspredetermined specification. Manufacturers can and should seek out/select technology-specificguidance on applying process validation to their particular situation. Validation is reasonablystraightforward, the decision of the manufacturer to evaluate every process for potentialvalidation may lead to uncertainty. Some regulatory requirements state that every process thatcannot be verified by subsequent monitoring or measurement be validated. Process Validationreduce the production costs of sorting and rework due to the manufacture of non-conformingproducts (products that do not meet their specification).Validation part decreases the risk of regulatory non-compliances and should beconducted in according with predefined protocols. Process validation is the means of ensuringand providing documentary evidence that processes (within their specified design parameters)are capable of repeatedly and reliably producing a finished product of the required qualityconsistently and should cover all the critical elements of the manufacturing process. Ointmentsection constitute an important category of dosage forms for active molecules because of theirstability in the aqueous environment.The objective of the process validation was to verify the effectiveness ofmanufacturing procedures and also to ensure that product should comply with the prescribedquality standards. In the present work Process validation of diclofenac diethylamine and methylsalicylate was carried out. As the manufacturing process of anti-inflammatory gel is mainlydependent on mixing time.

Process Validation for Manufacturing of Biologics and Biotechnology Products

Lyophilization Process

Process Validation for Medical Devices

Practical Implementation of the Lifecycle Approach to Process Validation

Handbook of Validation in Pharmaceutical Processes, Fourth Edition

How to Validate a Pharmaceutical Process

This handbook provides the most up to date resource currently available for interpreting and understanding design controls. This handbook is the most exhaustive resource ever written about FDA & ISO 13485 design controls for medical devices with a collection of all applicable regulations and real-world examples. Four-hundred & forty, 8.5" X 11" pages provides an extensive evaluation of FDA 21 CFR 820 and is cross-referenced with ISO 13485 to provide readers with a broad and in-depth review of practical design control implementation techniques. This handbook also covers basic, intermediate and advanced design control topics and is an ideal resource for implementing new design control processes or upgrading an existing process into medical device quality systems. This critical resource also specifically outlines key topics which will allow quality managers and medical device developers to improve compliance quickly to pass internal and external audits and FDA inspections. The author breaks down the regulation line by line and provides a detailed interpretation by using supportive evidence from the FDA design control guidance and the quality systems preamble. Numerous examples, case studies, best practices, 70+ figures and 45+ tables provide practical implementation techniques which are based on the author's extensive experience launching numerous medical device products and by integrating industry consultant expertise. In addition, bonus chapters include: explanation of medical device classification, compliance to design controls, risk management, and the design control quality system preamble. 20-40 pages are dedicated to each of the major design control topics: Design and Development Planning, Design Input, Design Output, Design Transfer, Design Verification, Design Validation, Design Change and Design History File.

How to Validate a Pharmaceutical Process provides a “how to approach to developing and implementing a sustainable pharmaceutical process validation program. The latest volume in the Expertise in Pharmaceutical Process Technology Series, this book illustrates the methods and reasoning behind processes and protocols. It also addresses practical problems and offers solutions to qualify and validate a pharmaceutical process. Understanding the “why is critical to a successful and defensible process validation, making this book an essential research companion for all practitioners engaged in pharmaceutical process validation. Thoroughly referenced and based on the latest research and literature Illustrates the most common issues related to developing and implementing a sustainable process validation program and provides examples on how to be successful Covers important topics such as the lifecycle approach, quality by design, risk assessment, critical process parameters, US and international regulatory guidelines, and more

DESIGN CONTROLS, RISK MANAGEMENT & PROCESS VALIDATION FOR MEDICAL DEVICE PROFESSIONALS

Process Validation of Metformin HCL ER Tablets in New Equipment Set Up with Equipment Qualification, Area Qualification

Principles of Parenteral Solution Validation

Validation of Biopharmaceutical Manufacturing Processes

Pharmaceutical and Medical Devices Manufacturing Computer Systems Validation