Process Validation A Lifecycle Approach

This is likewise one of the factors by obtaining the soft documents of this **Process Validation A Lifecycle Approach** by online. You might not require more era to spend to go to the ebook inauguration as well as search for them. In some cases, you likewise reach not discover the declaration Process Validation A Lifecycle Approach that you are looking for. It will certainly squander the time.

However below, next you visit this web page, it will be therefore extremely easy to acquire as well as download guide Process Validation A Lifecycle Approach

It will not tolerate many era as we explain before. You can reach it though show something else at house and even in your workplace. for that reason easy! So, are you question? Just exercise just what we allow under as well as review **Process Validation A Lifecycle Approach** what you similar to to read!

The Art and Science of Dermal Formulation Development - Marc B. Brown 2019-03-01 The Art and Science of Dermal Formulation Development is a comprehensive guide to the theory and practice of transdermal and topical formulation development, covering preclinical

 Downloaded from ricg.com on by guest

studies, evaluation, and regulatory approval. It enables the reader to understand the opportunities and challenges in developing products and how risks can be mitigated. Over the last 25 years, expertise in this area has declined whilst drug delivery systems for other administration routes have developed significantly. The advantages offered by transdermal and topical drug delivery remain compelling for sectors including the pharmaceutical industry, personal care, and cosmetics. This text addresses the dearth of expertise and discusses how skin can be a route of delivery and the processes in formulation development, but how such an application is very different to that used for oral, IV, and other administration routes. Key Features: Presents a practical guide for both industry and academia Focuses on and draws together the fundamental principles behind transdermal and topical drug delivery Illustrates the practicalities of formulation design using key case studies Gives an understanding of the skin as a route of delivery and how formulation development for such application differs from that for other administration routes

Emerging Non-Clinical Biostatistics in Biopharmaceutical Development and Manufacturing - Harry Yang 2016-11-30

The premise of Quality by Design (QbD) is that the quality of the pharmaceutical product should be based upon a thorough understanding of both the product and the manufacturing process. This state-of-the-art book provides a single source of information on emerging statistical approaches to QbD and risk-based pharmaceutical development. A comprehensive resource, it combines in-depth explanations of advanced statistical methods with real-life case studies that illustrate practical applications of these methods in QbD implementation.

Multivariate Analysis in the Pharmaceutical Industry - Ana Patricia Ferreira 2018-04-24

Multivariate Analysis in the Pharmaceutical

 Downloaded from ricg.com on by guest

Industry provides industry practitioners with guidance on multivariate data methods and their applications over the lifecycle of a pharmaceutical product, from process development, to routine manufacturing, focusing on the challenges specific to each step. It includes an overview of regulatory guidance specific to the use of these methods, along with perspectives on the applications of these methods that allow for testing, monitoring and controlling products and processes. The book seeks to put multivariate analysis into a pharmaceutical context for the benefit of pharmaceutical practitioners, potential practitioners, managers and regulators. Users will find a resources that addresses an unmet need on how pharmaceutical industry professionals can extract value from data that is routinely collected on products and processes, especially as these techniques become more widely used, and ultimately, expected by regulators. Targets pharmaceutical industry practitioners and regulatory staff by addressing industry specific challenges Includes case studies from different pharmaceutical companies and across product lifecycle of to introduce readers to the breadth of applications Contains information on the current regulatory framework which will shape how multivariate analysis (MVA) is used in years to come

Bayesian Methods in Pharmaceutical Research - Emmanuel Lesaffre 2020-04-15

Since the early 2000s, there has been increasing interest within the pharmaceutical industry in the application of Bayesian methods at various stages of the research, development, manufacturing, and health economic evaluation of new health care interventions. In 2010, the first Applied Bayesian Biostatistics conference was held, with the primary objective to stimulate the practical implementation of Bayesian statistics, and to promote the added-value for accelerating the discovery and the delivery of new cures to patients. This book is a synthesis of

 Downloaded from ricg.com on by guest

the conferences and debates, providing an overview of Bayesian methods applied to nearly all stages of research and development, from early discovery to portfolio management. It highlights the value associated with sharing a vision with the regulatory authorities, academia, and pharmaceutical industry, with a view to setting up a common strategy for the appropriate use of Bayesian statistics for the benefit of patients. The book covers: Theory, methods, applications, and computing Bayesian biostatistics for clinical innovative designs Adding value with Real World Evidence Opportunities for rare, orphan diseases, and pediatric development Applied Bayesian biostatistics in manufacturing Decision making and Portfolio management Regulatory perspective and public health policies Statisticians and data scientists involved in the research, development, and approval of new cures will be inspired by the possible applications of Bayesian methods covered in the book. The methods, applications, and computational guidance will enable the reader to apply Bayesian methods in their own pharmaceutical research.

Guideline on General Principles of Process Validation - 1987

Facility Validation - Graham C. Wrigley 2004-03-29

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

 Downloaded from ricg.com on by guest

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.

ICH Quality Guidelines - Andrew Teasdale 2017-09-29

Examining the implications and practical implementation of multi-disciplinary International Conference on Harmonization (ICH) topics, this book gives an integrated view of how the guidelines inform drug development strategic planning and decision-making. • Addresses a consistent need for interpretation, training, and implementation examples of ICH guidelines via case studies • Offers a primary reference point for practitioners addressing the dual challenge of interpretation and practical implementation of ICH guidelines • Uses case studies to help readers understand and apply ICH guidelines • Provides valuable insights into guidelines development, with chapters by authors involved in generating or with experience implementing the guidelines • Includes coverage of stability testing, analytical method validation, impurities, biotechnology drugs and products, and good manufacturing practice (GMP)

Validation of Pharmaceutical Processes - James P. Agalloco 2007-09-25

 Downloaded from ricg.com on by guest

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

Handbook of Analytical Quality by Design - Sarwar Beg 2021-01-09

Handbook of Analytical Quality by Design addresses the steps involved in analytical method development and validation in an effort to avoid quality crises in later stages. The AQbD approach significantly enhances method performance and robustness which are crucial during inter-laboratory studies and also affect the analytical lifecycle of the developed method. Sections cover sample preparation problems and the usefulness of the QbD concept involving Quality Risk Management (QRM), Design of Experiments (DoE) and Multivariate (MVT) Statistical Approaches to solve by optimizing the developed method, along with validation for different techniques like HPLC, UPLC, UFLC, LC-MS and electrophoresis. This will be an ideal resource for graduate students and professionals working in the pharmaceutical industry, analytical chemistry, regulatory agencies, and those in related academic fields. Concise language for easy understanding of the novel and holistic concept Covers key aspects of analytical development and validation Provides a robust, flexible, operable range for an analytical method with greater excellence and regulatory compliance

Process Validation in Manufacturing of Biopharmaceuticals - Anurag S. Rathore 2012-05-09

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

 Downloaded from ricg.com on by guest

on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in

Bayesian Analysis with R for Drug Development - Harry Yang 2019-06-26

Drug development is an iterative process. The recent publications of regulatory guidelines further entail a lifecycle approach. Blending data from disparate sources, the Bayesian approach provides a flexible framework for drug development. Despite its advantages, the uptake of Bayesian methodologies is lagging behind in the field of pharmaceutical development. Written specifically for pharmaceutical practitioners, Bayesian Analysis with R for Drug Development: Concepts, Algorithms, and Case Studies, describes a wide range of Bayesian applications to problems throughout pre-clinical, clinical, and Chemistry, Manufacturing, and Control (CMC) development. Authored by two seasoned statisticians in the pharmaceutical industry, the book provides detailed Bayesian solutions to a broad array of pharmaceutical problems. Features Provides a single source of information on Bayesian statistics for drug development Covers a wide spectrum of pre-clinical, clinical, and CMC topics Demonstrates proper Bayesian applications using real-life examples Includes easy-to-follow R code with Bayesian Markov Chain Monte Carlo performed in both JAGS and Stan Bayesian software platforms Offers sufficient background for each problem and detailed description of solutions suitable for practitioners with limited Bayesian knowledge Harry Yang, Ph.D., is Senior Director and Head of Statistical Sciences at AstraZeneca. He has 24 years of experience across all aspects of drug research and development and extensive global regulatory experiences. He has published 6 statistical books, 15 book chapters, and over 90 peer-reviewed papers on diverse scientific and statistical subjects, including 15 joint statistical works with Dr. Novick. He is a frequent invited speaker at national and international

 Downloaded from ricg.com on by guest

conferences. He also developed statistical courses and conducted training at the FDA and USP as well as Peking University. Steven Novick, Ph.D., is Director of Statistical Sciences at AstraZeneca. He has extensively contributed statistical methods to the biopharmaceutical literature. Novick is a skilled Bayesian computer programmer and is frequently invited to speak at conferences, having developed and taught courses in several areas, including drug-combination analysis and Bayesian methods in clinical areas. Novick served on IPAC-RS and has chaired several national statistical conferences.

Nonclinical Statistics for Pharmaceutical and Biotechnology Industries - Lanju Zhang 2016-01-13

This book serves as a reference text for regulatory, industry and academic statisticians and also a handy manual for entry level Statisticians. Additionally it aims to stimulate academic interest in the field of Nonclinical Statistics and promote this as an important discipline in its own right. This text brings together for the first time in a single volume a comprehensive survey of methods important to the nonclinical science areas within the pharmaceutical and biotechnology industries. Specifically the Discovery and Translational sciences, the Safety/Toxiology sciences, and the Chemistry, Manufacturing and Controls sciences. Drug discovery and development is a long and costly process. Most decisions in the drug development process are made with incomplete information. The data is rife with uncertainties and hence risky by nature. This is therefore the purview of Statistics. As such, this book aims to introduce readers to important statistical thinking and its application in these nonclinical areas. The chapters provide as appropriate, a scientific background to the topic, relevant regulatory guidance, current statistical practice, and further research directions.

Solid Oral Dose Process Validation - Ajay Babu

 Downloaded from ricg.com on by guest

Pazhayattil 2018-11-16
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.

Process Validation in Manufacturing of Biopharmaceuticals - Gail Sofer 2000-03-24
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.

Downloaded from ricg.com on by guest

Pharmaceutical Quality by Design - Walkiria S. Schlindwein 2018-01-11

A practical guide to Quality by Design for pharmaceutical product development Pharmaceutical Quality by Design: A Practical Approach outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and manufacture of drug substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of applications of QbD in actual practice. This important resource: Covers the essential information about Quality by Design (QbD) that is at the heart of modern pharmaceutical development Puts the focus on the industrial aspects of the new QbD approach Includes several illustrative examples of applications of QbD in practice Offers advanced specialist topics that can be systematically applied to industry Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent

 Downloaded from ricg.com on by guest

and high quality products.

WHO Expert Committee on Specifications for Pharmaceutical Preparations - World Health Organization 2019-05-29

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensusbuilding process. The following new guidelines were adopted and recommended for use: Procedure for development of the WHO medicines quality assurance guidelines; Guidelines on Good Manufacturing Practices (GMP) for heating ventilation and air-conditioning systems (HVAC) ? illustrative part; Guidance on GMP for Validation including the general main text analytical procedure validation validation of computerized systems and qualification; in the area of interchangeability of multisource medicines: the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification systembased classification of active pharmaceutical ingredients for biowaiver; Guidelines on Import Procedures for pharmaceutical products; and the Good Practice Guidance document on implementing the collaborative procedures. All of the above are included in this report and recommended for implementation.

Method Validation in Pharmaceutical Analysis - Joachim Ermer 2014-08-27

This second edition of a global bestseller has been completely redesigned and extensively rewritten to take into account the new Quality by Design (QbD) and lifecycle concepts in pharmaceutical manufacturing. As in the first edition, the fundamental requirements for analytical method validation are covered, but the second edition describes how these are applied systematically throughout the entire analytical lifecycle. QbD principles require adoption of a

 Downloaded from ricg.com on by guest

systematic approach to development and validation that begin with predefined objectives. For analytical methods these predefined objectives are established as an Analytical Target Profile (ATP). The book chapters are aligned with recently introduced standards and guidelines for manufacturing processes validation and follow the three stages of the analytical lifecycle: Method Design, Method Performance Qualification, and Continued Method Performance Verification. Case studies and examples from the pharmaceutical industry illustrate the concepts and guidelines presented, and the standards and regulations from the US (FDA), European (EMA) and global (ICH) regulatory authorities are considered throughout. The undisputed gold standard in the field.

Pharmaceutical Quality by Design - Walkiria S. Schlindwein 2018-01-05

A practical guide to Quality by Design for pharmaceutical product development

Pharmaceutical Quality by Design: A Practical Approach outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and

 Downloaded from ricg.com on by guest

manufacture of drug substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of applications of QbD in actual practice. This important resource: Covers the essential information about Quality by Design (QbD) that is at the heart of modern pharmaceutical development Puts the focus on the industrial aspects of the new QbD approach Includes several illustrative examples of applications of QbD in practice Offers advanced specialist topics that can be systematically applied to industry Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent and high quality products.

Sterile Processing of Pharmaceutical Products - Sam A. Hout 2022-01-26

Describes the methodologies and best practices of the sterile manufacture of drug products Thoroughly trained personnel and carefully designed, operated, and maintained facilities and equipment are vital for the sterile manufacture of medicinal products using aseptic processing. Professionals in pharmaceutical and biopharmaceutical manufacturing facilities must have a clear understanding of current good manufacturing practice (cGMP) and preapproval inspection (PAI) requirements. Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments provides up-to-date coverage of aseptic processing techniques and sterilization methods. Written by a recognized expert with more than 20 years of industry experience in aseptic manufacturing, this practical resource illustrates a comprehensive approach to sterile manufacturing engineering that can achieve drug manufacturing objectives and goals. Topics include sanitary piping and equipment, cleaning

 Downloaded from ricg.com on by guest

and manufacturing process validation, computerized automated systems, personal protective equipment (PPE), clean-in-place (CIP) systems, barriers and isolators, and guidelines for statistical procedure. Offering authoritative guidance on the key aspects of sterile manufacturing engineering, this volume: Covers fundamentals of aseptic techniques, quality by design, risk assessment and management, and operational requirements Addresses various regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH Provides techniques for systematic process optimization and good manufacturing practice Emphasizes the importance of attention to detail in process development and validation Features real-world examples highlighting different aspects of drug manufacturing Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments is an indispensable reference and guide for all chemists, chemical engineers, pharmaceutical professionals and engineers, and other professionals working in pharmaceutical sciences and manufacturing.

How to Validate a Pharmaceutical Process - Steven Ostrove 2016-06-07

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

 Downloaded from ricg.com on by guest

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

Bayesian Applications in Pharmaceutical Development - Mani Lakshminarayanan 2019-10-10

The cost for bringing new medicine from discovery to market has nearly doubled in the last decade and has now reached $2.6 billion. There is an urgent need to make drug development less time-consuming and less costly. Innovative trial designs/ analyses such as the Bayesian approach are essential to meet this need. This book will be the first to provide comprehensive coverage of Bayesian applications across the span of drug development, from discovery, to clinical trial, to manufacturing with practical examples. This book will have a wide appeal to statisticians, scientists, and physicians working in drug development who are motivated to accelerate and streamline the drug development process, as well as students who aspire to work in this field. The advantages of this book are: Provides motivating, worked, practical case examples with easy to grasp models, technical details, and computational codes to run the analyses Balances practical examples with best practices on trial simulation and reporting, as well as regulatory perspectives Chapters written by authors who are individual contributors in their respective topics Dr. Mani Lakshminarayanan is a researcher and statistical consultant with more than 30 years of experience in the pharmaceutical industry. He has published over 50 articles, technical reports, and book chapters besides serving as a referee for several journals. He has a PhD in Statistics from Southern Methodist University, Dallas, Texas and is a Fellow of the American Statistical Association. Dr. Fanni Natanegara has over 15 years of

 Downloaded from ricg.com on by guest

pharmaceutical experience and is currently Principal Research Scientist and Group Leader for the Early Phase Neuroscience Statistics team at Eli Lilly and Company. She played a key role in the Advanced Analytics team to provide Bayesian education and statistical consultation at Eli Lilly. Dr. Natanegara is the chair of the cross industry-regulatory-academic DIA BSWG to ensure that Bayesian methods are appropriately utilized for design and analysis throughout the drug-development process.

Principles of Parenteral Solution Validation - Igor Gorsky 2019-11-27

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

The Certified Pharmaceutical GMP Professional Handbook, Second Edition - Mark Allen Durivage 2016-05-26

The purpose of this handbook is to assist individuals for the Certified Pharmaceutical Good Manufacturing Practices Professional (CPGP) examination and provide a reference for the practitioner. The second edition reflects the

 Downloaded from ricg.com on by guest

Body of Knowledge which was updated in 2015. This edition has also incorporated additional information including updated references. The updates reflect the current trends and expectations of the evolving pharmaceutical industry driven by consumer expectations and regulatory oversight. This handbook covers compliance with good manufacturing practices (GMPs), as regulated and guided by national and international agencies for the pharmaceutical industry. It covers finished human and veterinary drugs and biologics, and combination devices, as well as their component raw materials (including active pharmaceutical ingredients (APIs) and excipients), and packaging and labeling operations.

ISPE Good Practice Guide - Ispe 2019-03-25

Encyclopedia of Biopharmaceutical Statistics - Four Volume Set - Shein-Chung Chow 2018-09-03

Since the publication of the first edition in 2000, there has been an explosive growth of literature in biopharmaceutical research and development of new medicines. This encyclopedia (1) provides a comprehensive and unified presentation of designs and analyses used at different stages of the drug development process, (2) gives a well-balanced summary of current regulatory requirements, and (3) describes recently developed statistical methods in the pharmaceutical sciences. Features of the Fourth Edition: 1. 78 new and revised entries have been added for a total of 308 chapters and a fourth volume has been added to encompass the increased number of chapters. 2. Revised and updated entries reflect changes and recent developments in regulatory requirements for the drug review/approval process and statistical designs and methodologies. 3. Additional topics include multiple-stage adaptive trial design in clinical research, translational medicine, design and analysis of biosimilar drug development, big data analytics, and real world evidence for

 Downloaded from ricg.com on by guest

clinical research and development. 4. A table of contents organized by stages of biopharmaceutical development provides easy access to relevant topics. About the Editor: Shein-Chung Chow, Ph.D. is currently an Associate Director, Office of Biostatistics, U.S. Food and Drug Administration (FDA). Dr. Chow is an Adjunct Professor at Duke University School of Medicine, as well as Adjunct Professor at Duke-NUS, Singapore and North Carolina State University. Dr. Chow is the Editor-in-Chief of the Journal of Biopharmaceutical Statistics and the Chapman & Hall/CRC Biostatistics Book Series and the author of 28 books and over 300 methodology papers. He was elected Fellow of the American Statistical Association in 1995.

Parenteral Medications, Fourth Edition - Sandeep Nema 2019-07-19

Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacturing of parenteral dosage forms, effectively balancing theoretical considerations with practical aspects of their development. Previously published as a three-volume set, all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. Key Features: Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations, enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation, processing, manufacturing parenteral

 Downloaded from ricg.com on by guest

technology including advanced delivery and cell therapies. The book is divided into seven sectionss: Section 1 - Parenteral Drug Administration and Delivery Devices; Section 2 - Formulation Design and Development; Section 3 - Specialized Drug Delivery Systems; Section 4 - Primary Packaging and Container Closure Integrity; Section 5 - Facility Design and Environmental Control; Section 6 - Sterilization and Pharmaceutical Processing; Section 7 - Quality Testing and Regulatory Requirements

Solid Oral Dose Process Validation, Volume Two - Ajay Pazhayattil 2019-08-30

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.

Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing - Hamid Mollah 2013-03-18

Sets forth tested and proven risk management practices in drug manufacturing Risk management is essential for safe and efficient

 Downloaded from ricg.com on by guest

pharmaceutical and biopharmaceutical manufacturing, control, and distribution. With this book as their guide, readers involved in all facets of drug manufacturing have a single, expertly written, and organized resource to guide them through all facets of risk management and analysis. It sets forth a solid foundation in risk management concepts and then explains how these concepts are applied to drug manufacturing. Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing features contributions from leading international experts in risk management and drug manufacturing. These contributions reflect the latest research, practices, and industry standards as well as the authors' firsthand experience. Readers can turn to the book for: Basic foundation of risk management principles, practices, and applications Tested and proven tools and methods for managing risk in pharmaceutical and biopharmaceutical product manufacturing processes Recent FDA guidelines, EU regulations, and international standards governing the application of risk management to drug manufacturing Case studies and detailed examples demonstrating the use and results of applying risk management principles to drug product manufacturing Bibliography and extensive references leading to the literature and helpful resources in the field With its unique focus on the application of risk management to biopharmaceutical and pharmaceutical manufacturing, this book is an essential resource for pharmaceutical and process engineers as well as safety and compliance professionals involved in drug manufacturing.

Bayesian Applications in Pharmaceutical Development - Mani Lakshminarayanan 2019-11-07

The cost for bringing new medicine from discovery to market has nearly doubled in the last decade and has now reached $2.6 billion. There is an urgent need to make drug

 Downloaded from ricg.com on by guest

development less time-consuming and less costly. Innovative trial designs/ analyses such as the Bayesian approach are essential to meet this need. This book will be the first to provide comprehensive coverage of Bayesian applications across the span of drug development, from discovery, to clinical trial, to manufacturing with practical examples. This book will have a wide appeal to statisticians, scientists, and physicians working in drug development who are motivated to accelerate and streamline the drug development process, as well as students who aspire to work in this field. The advantages of this book are: Provides motivating, worked, practical case examples with easy to grasp models, technical details, and computational codes to run the analyses Balances practical examples with best practices on trial simulation and reporting, as well as regulatory perspectives Chapters written by authors who are individual contributors in their respective topics Dr. Mani Lakshminarayanan is a researcher and statistical consultant with more than 30 years of experience in the pharmaceutical industry. He has published over 50 articles, technical reports, and book chapters besides serving as a referee for several journals. He has a PhD in Statistics from Southern Methodist University, Dallas, Texas and is a Fellow of the American Statistical Association. Dr. Fanni Natanegara has over 15 years of pharmaceutical experience and is currently Principal Research Scientist and Group Leader for the Early Phase Neuroscience Statistics team at Eli Lilly and Company. She played a key role in the Advanced Analytics team to provide Bayesian education and statistical consultation at Eli Lilly. Dr. Natanegara is the chair of the cross industry-regulatory-academic DIA BSWG to ensure that Bayesian methods are appropriately utilized for design and analysis throughout the drug-development process.

Manufacturing of Quality Oral Drug Products - Sam A. Hout 2022-07-07

 Downloaded from ricg.com on by guest

This book provides an understanding of what is required to engineer and manufacture drug products. It bridges established concepts and provides for a new outlook by concentrating and creating new linkages in the implementation of manufacturing, quality assurance, and business practices related to drug manufacturing and healthcare products. This book fills a gap by providing a connection between drug production and regulated applications. It focuses on drug manufacturing, quality techniques in oral solid dosage, and capsule filling including equipment and critical systems, to control production and the finished products. The book offers a correlation between design strategies and a step-by-step process to ensure the reliability, safety, and efficacy of healthcare products. Fundamentals of techniques, quality by design, risk assessment, and management are covered along with a scientific method approach to continuous improvement in the usage of computerized manufacturing and dependence on information technology and control operations through data and metrics. Manufacturing and Quality Assurance of Oral Pharmaceutical Products: Processing and Safe Handling of Active Pharmaceutical Ingredients (API) is of interest to professionals and engineers in the fields of manufacturing engineering, quality assurance, reliability, business management, process, and continuous improvement, life cycle management, healthcare products manufacturing, pharmaceutical processing, and computerized manufacturing.

Practical Approaches to Method Validation and Essential Instrument Qualification - Chung Chow Chan 2011-03-01

Practical approaches to ensure that analytical methods and instruments meet GMP standards and requirements Complementing the authors' first book, Analytical Method Validation and Instrument Performance Verification, this new volume provides coverage of more advanced topics, focusing on additional and supplemental

 Downloaded from ricg.com on by guest

methods, instruments, and electronic systems that are used in pharmaceutical, biopharmaceutical, and clinical testing. Readers will gain new and valuable insights that enable them to avoid common pitfalls in order to seamlessly conduct analytical method validation as well as instrument operation qualification and performance verification. Part 1, Method Validation, begins with an overview of the book's risk-based approach to phase appropriate validation and instrument qualification; it then focuses on the strategies and requirements for early phase drug development, including validation of specific techniques and functions such as process analytical technology, cleaning validation, and validation of laboratory information management systems Part 2, Instrument Performance Verification, explores the underlying principles and techniques for verifying instrument performance—coverage includes analytical instruments that are increasingly important to the pharmaceutical industry, such as NIR spectrometers and particle size analyzers—and offers readers a variety of alternative approaches for the successful verification of instrument performance based on the needs of their labs At the end of each chapter, the authors examine important practical problems and share their solutions. All the methods covered in this book follow Good Analytical Practices (GAP) to ensure that reliable data are generated in compliance with current Good Manufacturing Practices (cGMP). Analysts, scientists, engineers, technologists, and technical managers should turn to this book to ensure that analytical methods and instruments are accurate and meet GMP standards and requirements.

Pharmaceutical Process Validation - Bernard T. Loftus 1984

Pharmaceutical Product Development - Vandana B. Patravale 2016-05-25

Pharmaceutical product development is a

 Downloaded from ricg.com on by guest

multidisciplinary activity involving extensive efforts in systematic product development and optimization in compliance with regulatory authorities to ensure the quality, efficacy and safety of resulting products. Pharmaceutical Product Development equips the pharmaceutical formulation scientist with extensive and up-to-date knowledge of drug product development and covers all steps from the beginning of product conception to the final packaged form that enters the market and lifecycle management thereof. Applications of core scientific principles for product development are also thoroughly discussed in conjunction with the latest approaches involving design of experiment and quality by design with comprehensive illustrations based on practical case studies of several dosage forms. The book presents pharmaceutical product development information in an easy-to-read mode with simplified theories, case studies and guidelines for students, academicians and professionals in the pharmaceutical industry. It is an invaluable resource and hands-on guide covering managerial, regulatory and practical aspects of pharmaceutical product lifecycle management.

Method Validation in Pharmaceutical Analysis - Joachim Ermer 2006-03-06

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

 Downloaded from ricg.com on by guest

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.

Methodologies in Biosimilar Product Development - Sang Joon Lee 2021-09-30

Methodologies for Biosimilar Product Development covers the practical and challenging issues that are commonly encountered during the development, review, and approval of a proposed biosimilar product. These practical and challenging issues include, but are not limited to the mix-up use of interval hypotheses testing (i.e., the use of TOST) and confidence interval approach, a risk/benefit assessment for non-inferiority/similarity margin, PK/PD bridging studies with multiple references, the detection of possible reference product change over time, design and analysis of biosimilar switching studies, the assessment of sensitivity index for assessment of extrapolation across indications without collecting data from those indications not under study, and the feasibility and validation of non-medical switch post-approval. Key Features: Reviews withdrawn draft guidance on analytical similarity assessment. Evaluates various methods for analytical similarity evaluation based on FDA's current guidelines. Provides a general approach for the use of n-of-1 trial design for assessment of interchangeability. Discusses the feasibility and validity of the non-medical switch studies. Provides innovative thinking for detection of possible reference product change over time. This book embraces innovative thinking of design and analysis for biosimilar studies, which are required for review and approval of biosimilar regulatory submissions.

Developing Solid Oral Dosage Forms - Yihong Qiu 2016-11-08

Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice, Second Edition illustrates how to develop high-quality,

 Downloaded from ricg.com on by guest

safe, and effective pharmaceutical products by discussing the latest techniques, tools, and scientific advances in preformulation investigation, formulation, process design, characterization, scale-up, and production operations. This book covers the essential principles of physical pharmacy, biopharmaceutics, and industrial pharmacy, and their application to the research and development process of oral dosage forms. Chapters have been added, combined, deleted, and completely revised as necessary to produce a comprehensive, well-organized, valuable reference for industry professionals and academics engaged in all aspects of the development process. New and important topics include spray drying, amorphous solid dispersion using hot-melt extrusion, modeling and simulation, bioequivalence of complex modified-released dosage forms, biowaivers, and much more. Written and edited by an international team of leading experts with experience and knowledge across industry, academia, and regulatory settings Includes new chapters covering the pharmaceutical applications of surface phenomenon, predictive biopharmaceutics and pharmacokinetics, the development of formulations for drug discovery support, and much more Presents new case studies throughout, and a section completely devoted to regulatory aspects, including global product regulation and international perspectives

Principles of Parenteral Solution Validation - Igor Gorsky 2019-04-15

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

 Downloaded from ricg.com on by guest

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

Pharmaceutical Process Validation, Second Edition - Ira R. Berry 1993-01-29

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.

A Lifecycle Approach to Knowledge Excellence in the Biopharmaceutical Industry - Nuala Calnan 2017-06-26

This book addresses the rapidly emerging field of Knowledge Management in the pharmaceutical, medical devices and medical diagnostics industries. In particular, it explores the role that Knowledge Management can play in ensuring the delivery of safe and effective products to patients. The book also provides good practice examples of how the effective use of an organisation’s knowledge assets can provide a path towards business excellence.

Leading Pharmaceutical Operational Excellence - Thomas Friedli 2013-11-26

Achieving operational excellence is a challenge for the pharmaceutical industry, with many companies setting successful examples time and again. This book presents such leading practices for managing operational excellence throughout the pharmaceutical industry. Based on the

 Downloaded from ricg.com on by guest

St.Gallen OPEX Model the authors describe the current status of OPEX and the future challenges that have to be dealt with. The ample theoretical background is complemented hand-in-hand by case studies contributed by authors from leading pharmaceutical companies.

 Downloaded from ricg.com on by guest