Q9 Quality Risk Management

The use of modeling and simulation tools is rapidly gaining prominence in the pharmaceutical industry covering a wide range of applications. This book focuses on modeling and simulation tools as they pertain to drug product manufacturing processes, although similar principles and tools may apply to many other areas. Modeling tools can improve fundamental process understanding and provide valuable insights into the manufacturing processes, which can result in significant process improvements and cost savings. With FDA mandating the use of Quality by Design (QbD) principles during manufacturing, reliable modeling techniques can help to alleviate the costs associated with such efforts, and be used to create in silico formulation and process design space. This book is geared toward detailing modeling techniques that are utilized for the various unit operations during drug product manufacturing. By way of examples that include case studies, various modeling principles are explained for the nonexpert end users. A discussion on the role of modeling in quality risk management for manufacturing and application of modeling for continuous manufacturing and biologics is also included. Explains the commonly used modeling and simulation tools Details the modeling of various unit operations commonly utilized in solid dosage drug product manufacturing Practical examples of the application of modeling tools through case studies Discussion of modeling techniques used for a risk-based approach to regulatory filings Explores the usage of modeling in upcoming areas such as continuous manufacturing and biologics manufacturingBullet points

With more restrictions upon animal experimentations, pharmaceutical industries are currently focusing on a new generation of experiments and technologies that are considerably more efficient and less controversial. The integration of computational and experimental strategies has led to the identification and development of promising compounds. Computer Applications in Drug Discovery and Development is a pivotal reference source that provides innovative research on the application of computers for discovering and designing new drugs in modern molecular biology and medicinal chemistry. While highlighting topics such as chemical structure databases and dataset utilization, this publication delves into the current panorama of drug discovery, where high drug failure rates are a major concern and properly designed virtual screening strategies can be a time-saving, cost-effective, and productive alternative. This book is ideally designed for chemical engineers, pharmacists, molecular biologists, students, researchers, and academicians seeking current research on the unexplored avenues and future perspectives of drug design.

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 and high quality products.

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 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.

Pharmaceutical Quality by Design

The Development of a Quality Risk Management Solution Designed to Facilitate Compliance with the Risk-based Qualification, Validation and Change Control GMP Requirement of the EU.

Good Design Practices for GMP Pharmaceutical Facilities

Pyrogens, LAL Testing and Depyrogenation

Problem Solving and Training Strategies for Success in the Pharmaceutical and Life Science Industries

An International Guideline for the Preparation, Care and Use of Medicinal Products

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.

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

Vaccine Manufacturing and Production is an invaluable reference on how to produce a vaccine - from beginning to end - addressing all classes of vaccines from a processing, production, and regulatory viewpoint. It will provide comprehensive information on the various fields involved in the production of vaccines, from fermentation, purification, formulation, to regulatory filing and facility designs. In recent years, there have been tremendous advances in all aspects of vaccine manufacturing. Improved technology and growth media have been developed for the production of cell culture with high cell density or fermentation. Vaccine Manufacturing and Production will serve as a reference on all aspects of vaccine production by providing an in-depth description of the available technologies for making different types of vaccines and the current thinking in facility designs and supply issues. This book will provide insight to the issues scientists face when producing a vaccine, the steps that are involved, and will serve as a reference tool regarding state-of-the-art vaccine manufacturing technologies and facility set-up. Highlights include: Comprehensive coverage of vaccine production : from a process point of view- fermentation to purification to formulation developments; from a production point of view - from facility design to manufacturing; and from a regulatory point of view - requirements from government agencies Authors from different major pharmaceutical and biotechnology companies Describes the challenges and issues involved in vaccine production and manufacturing of the different classes of vaccines, an area not covered by other books currently on the market

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)

Special Topics in Drug Discovery

Managing Difficult Projects

Guidance for Industry

Good Clinical Practice eRegs & Guides - For Your Reference Book 3

Semisolid Products

A Practical Lifecycle Approach

This research work was concerned with investigating the risk-based regulatory requirements that are currently in place in the European Union governing the manufacture of medicinal products. The main goal of this research was to develop a practical Quality Risk Management methodology that served as a solution for facilitating compliance with the EU GMP requirements in the area of risk-based Qualification, Validation and Change Control, and which was fully in line with the principles and guidance of ICH Q9, on Quality Risk Management. Following extensive testing and evaluation activities with a range of key stakeholders including the pharmaceutical manufacturing sector in Ireland, the UK and the US, and GMP Inspectors from a wide range of countries, this work resulted in a formal, readily usable, rigorous and complete Quality Risk Management Methodology. It is designed to facilitate compliance with the risk based qualification, validation and change control GMP requirements of the EU, and is fully in line with ICH Quality Risk Management principles and guidelines. A practical and detailed training programme on the use of this methodology is also presented. This provides comprehensive training materials for facilitating training activities, as well as a documented strategy for the provision of such training in a timely and resource-efficient manner. In a comprehensive benchmarking exercise, this approach to Quality Risk Management was compared with the application of Risk Management in two industries that are considered mature and advanced in their application of Risk Management principles and methodologies. These were the US aeronautics industry, as represented by the work of the National Aeronautics Space Administration (NASA) and the US nuclear power generation industry, as represented by the work of the US Nuclear Regulatory Commission (NRC). The methodology performed very favourably in this benchmarking exercise, and many examples of common best practices were ide.

Biopharmaceuticals (i.e., biological medicines sourced from genetically-engineered living systems) for treatment of human diseases have become a significant percentage of the pharmaceutical industry. And not just the recombinant DNA-derived proteins and monoclonal antibodies (both from the innovators and biosimilars); but now, an increasing awareness of the importance of gene therapy and genetically engineered cellular medicinal products. These biopharmaceuticals are being developed by many companies whose Chemistry, Manufacturing & Control (CMC) teams have varying degrees of familiarity or experience with the CMC strategy and regulatory compliance requirements for these challenging products. Companies clearly plan out the strategy for their clinical study plans, but frequently, the development of a strategy for CMC is an afterthought. Coupled with the complexity of the biopharmaceutical manufacturing processes and products, and this can be a recipe for disaster. The third edition of this book provides insights and practical guidance for the CMC teams to develop an acceptable cost-effective, risk-based CMC regulatory compliance strategy for all biopharmaceuticals (recombinant proteins, monoclonal antibodies, genetically engineered viruses and genetically engineered human cells) from early clinical stage development through market approval. The third edition of this book provides added coverage for the biosimilars, antibody drug conjugates (ADCs), bispecific antibodies, genetically engineered viruses, and genetically engineered cells. This third edition of the book also addresses the heightened pressure on CMC regulatory compliance timelines due to the introduction of expedited clinical pathways moving the clinical development closer to a seamless phase process (e.g., FDA Breakthrough Therapy designation, CBER Regenerative Medicine Advanced Therapy (RMAT) designation, EMA Priority Medicines (PRIME) designation). The Challenge of CMC Regulatory Compliance for Biopharmaceuticals is essential, practical information for all pharmaceutical development scientists, Manufacturing and Quality Unit staff, Regulatory Affairs personnel, and senior management involved in the manufacture of biopharmaceuticals.

Quality assurance is necessary to maintain quality and services in the pharmaceutical and life science industries. Quality assurance demonstrates that the logic and practice of problem solving can integrate both program efficacy and regulatory compliance. This title is divided into three parts; the first part discusses the process by which a problem in regulated industry is identified, for example a manufacturing deviation that leads to an adulterated drug product, and reviews the decision-making steps involved in remedying the problem. The second part delves into the staff training requirements of procedures that are thereby revised. The third part expands on this discussion by considering piloting the proposed training module, preparing assessments of trainee proficiency, evaluating the training module, including integrating rigorous evaluative designs with formative program improvement, and documenting the entire effort. Presents a comprehensive view of the field of quality assurance An approach grounded in direct experience Uses diagrams and figures to clarify analytical points

With global harmonization of regulatory requirements and quality standards and national and global business consolidations ongoing at a fast pace, pharmaceutical manufacturers, suppliers, contractors, and distributors are impacted by continual change. Offering a wide assortment of policy and guidance document references and interpretations, this Sixth Edition is significantly expanded to reflect the increase of information and changing practices in CGMP regulation and pharmaceutical manufacturing and control practices worldwide. An essential companion for every pharmaceutical professional, this guide is updated and expanded by a team of industry experts, each member with extensive experience in industry or academic settings.

Vaccine Development and Manufacturing

Quality Assurance

Drugs

importance de la gestion du risque dans le cycle de la vie d'un projet au sein d'une industrie pharmaceutique

A Practical Approach

Quality Risk Management in the FDA-Regulated Industry

The third edition of this best-selling book continues to offer a user-friendly, step-by-step introduction to all the key processes involved in bringing a drug to the market, including the performance of pre-clinical studies, the conduct of human clinical trials, regulatory controls, and even the manufacturing processes for pharmaceutical products. Concise and easy to read, Drugs: From Discovery to Approval, Third Edition quickly introduces basic concepts, then moves on to discuss target selection and the drug discovery process for both small and large molecular drugs. The third edition incorporates the latest developments and updates in the pharmaceutical community, provides more comprehensive coverage of topics, and includes more materials and case studies suited to college and university use.

Biotechnology is a dynamic field with changes across R&D, clinical trials, manufacturing and regulatory processes, and the third edition of the text provides timely updates for those in this rapidly growing field.

This revised publication serves as a handy and current reference for professionals engaged in planning, designing, building, validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U.S. and internationally. The new edition expands on facility planning, with a focus on the ever-growing need to modify existing legacy facilities, and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings. All chapters have been re-examined with a fresh outlook on current good design practices.

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

Risk management principles are effectively utilized in many areas of business and government, including finance, insurance, occupational safety, and public health, and by agencies regulating these industries. The U.S. Food and Drug Administration (FDA) and its worldwide counterparts are responsible for protecting public health by ensuring the safety and effectiveness of the drugs and medical devices. Regulators must decide whether the benefits of a specific product for patients and users outweigh its risk, while recognizing that "absolute safety" (or zero risk) is not achievable. Every product and every process has an associated risk. Although there are some examples of the use of quality risk management in the FDA-regulated industry today, they are limited and do not represent the full contribution that risk management has to offer. The present FDA focus on risk-based determination is requiring that the regulated industries improve dramatically their understanding and capability of hazard control concepts. In addition, the importance of quality systems has been recognized in the life sciences industry, and it is becoming evident that quality risk management is a valuable component of an effective quality system. The purpose of this book is to offer a systematic and very comprehensive approach to quality risk management. It will assist medical and food product manufacturers with the integration of a risk management system or risk management principles and activities into their existing quality management system by providing practical explanations and examples. The appropriate use of quality risk management can facilitate compliance with regulatory requirements such as good manufacturing practices or good laboratory practices. The content of this book will provide FDA-regulated manufacturers with a framework within which experience, insight, and judgment are applied systematically to manage the risks associated with their products. Manufacturers in other industries may use it as an informative guidance in developing and maintaining a risk management system and process. The two appendices add even more insight: Appendix A contains general examples of risk management, while Appendix B includes 10 case studies illustrating real examples of the quality risk management process across the medical product arena.

Advances In Pharmaceutical Cell Therapy: Principles Of Cell-based Biopharmaceuticals

Handbook of Pharmaceutical Manufacturing Formulations

Computer Applications in Drug Discovery and Development

Pharmaceutical Manufacturing Handbook

Endotoxins

Biocontamination Control for Pharmaceuticals and Healthcare

This book contains essential knowledge on the preparation, control, logistics, dispensing and use of medicines. It features chapters written by experienced pharmacists working in hospitals and academia throughout Europe, complete with practical examples as well as information on current EU-legislation. From prescription to production, from usage instructions to procurement and the impact of medicines on the environment, the book provides step-by-step coverage that will help a wide range of readers. It offers product knowledge for all pharmacists working directly with patients and it will enable them to make the appropriate medicine available, to store medicines properly, to adapt medicines if necessary and to dispense medicines with the appropriate information to inform patients and caregivers about product care and how to maintain their quality. This basic knowledge will also be of help to industrial pharmacists to remind and focus them on the application of the medicines manufactured. The basic and practical knowledge on the design, preparation and quality management of medicines can directly be applied by the pharmacists whose main duty is production in community and hospital pharmacies and industries. Undergraduate as well as graduate pharmacy students will find knowledge and backgrounds in a fully coherent way and fully supported with examples.

Managing Difficult Projects pulls together the principles and practice of project management and presents useful diagnostic approaches, tools and structures in a clear and practical way. The book focuses on the diagnosis and resolution of "difficult" problems whether in large or small complex projects. The intent is to help corporate executives and project management practitioners apply proven processes, methodologies, systems, structures and tools to rally the information and the resources required for better decisions, faster delivery and improved results. This essential book shows how to plan effectively and to reduce risk at every step of project delivery, particulary vital during project implementation when 90% of project funding is spent. It covers new ground by proposing the use of the project management process as an integral part of setting and updating corporate strategy. In projects, context is everything! The text is amply illustrated with international case studies, charts, photos, graphs and data tables.

The fourth volume in the series covers the techniques and technologies involved in the preparation of semisolid products such as ointments, creams, gels, suppositories, and special topical dosage forms. Drug manufacturers need a thorough understanding of the specific requirements that regulatory agencies impose on the formulation and efficacy deter

Good Clinical Practice eRegs & Guides provides a reference to key US FDA Guides and regulations via your electronic reader. An excellent way to access the reference documents on your e-reader. No need to carry paper books and you can search for key terms. In this issue you will find: ICH Q8 Pharmaceutical Development ICH Q9 Quality Risk Management ICH Q10 Pharmaceutical Quality System

Practical Pharmaceutics

Regulations and Quality

ICH Quality Guidelines

International Journal of Drug Development and Research : Volume 10

The Certified Pharmaceutical GMP Professional Handbook, Second Edition

Proceedings of 8th Edition of International Conference on Mass Spectrometry 2018

The merging of different basic and clinical science disciplines towards the common goal of fighting against cancer has long ago called for the establishment of a comprehensive reference source both as a tool to close the language gap between clinical and basic science investigators and as a platform of information for students and informed laymen alike. The Encyclopedia of Cancer provides rapid access to focused information on all topics of cancer research for clinicians, research scientists and advanced students. Given the overwhelming success of the Second Edition, which appeared in 2009, and fast recent development in the different fields of cancer research, it has been decided to publish a third fully revised and expanded edition, following the principal concept of the first edition that has proven so successful. Recent developments are seeing a dynamic progress in basic and clinical cancer science, with translational research increasingly becoming a new paradigm in cancer research. In particular, new approaches to both Personalized Cancer Medicine and Targeted Therapies have made promising progress. While the Second Edition featured scholarly contributions from approximately 1.000 scientists/clinicians in four Volumes, the Third Edition includes 1.300 contributors in 7 Volumes with an A-Z format of approx. 7000 entries. It provides definitions of common acronyms and short definitions of related terms and processes in the form of keyword entries. In addition, there are detailed essays, which provide comprehensive information on syndromes, genes and molecules, and processes and methods. Each essay is well-structured, with extensive cross-referencing between all entries. In the Third Edition, topical Essays present a comprehensive picture of major cancers, such as Breast Cancer, Colorectal Cancer, Prostate Cancer, Ovarian Cancer, Renal Cancer, Lung Cancer, and Hematological Maligancies, Leukemias and Lymphomas. For each of these cancers, different authoritative Essays are included that cover topics ranging from Pathology, to Clinical Oncology and Targeted Therapies. This new feature should meet the expectance that a wide community has towards a major cancer reference works. The Encyclopedia of Cancer will be accessible both in print and online, and this information source should be of value to both the clinical and basic scientific community as well as to the public.

This source expertly examines the discovery, biological structure, control, and continued clarification of endotoxin from a parenteral manufacturing perspective, with in-depth discussion of state-of-the-art technologies involving Limulus amebocyte lysate (LAL) such as assay development, automation, depyrogenation. Completely revised and exp

The submersed cultivation of organisms in sterile containments or fermenters has become the standard manufacturing procedure, and will remain the gold standard for some time to come. This book thus addresses submersed cell culture and fermentation and its importance for the manufacturing industry. It goes beyond expression systems and integrally investigates all those factors relevant for manufacturing using suspension cultures. In so doing, the contributions cover all industrial cultivation methods in a comprehensive and comparative manner, with most of the authors coming from the industry itself. Depending on the maturity of the technology, the chapters address in turn the expression system, basic process design, key factors affecting process economics, plant and bioreactor design, and regulatory aspects.

Fundamentals of Biologicals Regulation: Vaccines and Biotechnology Medicines serves as an introduction to the international regulatory arena in which biologicals are developed and offers an overview of the processes and insight into the scientific concepts underpinning global regulations. This book will provide multiple levels of readership with guidance on basic concepts, a detailed look at regulatory challenges, and practical insight into how regulators consider regulatory science and regulatory process issues across various regions. With numerous case studies, learning activities, and real-world examples across several classes of biotechnological products, this book is a valuable and comprehensive resource for graduate students, professors, regulatory officials, and industry scientists working with biologicals. Provides a broad overview and introduction to the regulatory processes, from product development pathways, through clinical trials and product development stages and beyond Includes FDA, EMA, ICH, and WHO recommendations and guidelines so readers can compare and contrast the different regulatory regions with their expectations and understand why they are different Contains chapters on some of the exceptions to the process including how biosimilars and in vitro diagnostics are regulated Includes numerous case studies, learning activities, and real-world examples across several classes of biotechnological products

From Discovery to Approval

An Implementation Guide

draft step 2 on 22 March 2005

The Basics, Volume 1

Prediction and Assessment, Second Edition

Application de l'ICH Q9 quality risk management à un nouveau procédé de remplissage d'un dispositif de poudre pour inhalation

Biocontamination Control for Pharmaceuticals and Healthcare outlines a biocontamination strategy that tracks bio-burden control and reduction at each transition in classified areas of a facility. This key part of controlling risk escalation can lead to the contamination of medicinal products, hence necessary tracking precautions are essential. Regulatory authorities have challenged pharmaceutical companies, healthcare providers, and those in manufacturing practice to adopt a holistic approach to contamination control. New technologies are needed to introduce barriers between personnel and the environment, and to provide a rapid and more accurate assessment of risk. This book offers guidance on building a complete biocontamination strategy. Provides the information necessary for a facility to build a complete biocontamination strategy Helps facilities understand the main biocontamination risks to medicinal products Assists the reader in navigating regulatory requirements Provides insight into developing an environmental monitoring program Covers the types of rapid microbiological monitoring methods now available, as well as current legislation

This textbook is a comprehensive overview of the development of cell-based biopharmaceuticals. Beginning with the underlying biology of stem cell and cell-based products, it traces the long and complex journey from preclinical concept to initiation of a pivotal clinical trial and the potential business model behind it.The book also takes into consideration the different regulatory landscapes and their continuous evolution in Europe, North America and other parts of the world. The authors describe a path to manufacture a clinical grade therapeutic that passes all necessary quality measures as a robust and marketable product including an outlook on next generation products and innovative strategies.This reference book is a must-have guide for any professional already active in biopharmaceuticals and anyone interested in getting involved in a scientific, medical or business capacity.

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.

Drug discovery involves multiple disciplines, technologies, and approaches. This book selects important topics related to drug discovery, including emerging tool (Chapter 1), cutting-edge approaches (Chapters 2, 3, and 4), examples of specific therapeutic area (Chapter 5), quality control in drug development (Chapter 6), and job and career opportunities in the pharmaceutical sector, a topic rarely covered by other books (Chapter 7). This book draws knowledge from experts actively involved in different areas of drug discovery from both industrial and academic settings. We hope that this book will facilitate your efforts in drug discovery.

Solid Oral Dose Process Validation

Q9 Quality Risk Management

The Challenge of CMC Regulatory Compliance for Biopharmaceuticals

ICH Q9, quality risk management - Qualitäts-Risikomanagement

ICH Q8 Pharmaceutical Development, ICH Q9 Quality Risk Management, ICH Q10 Pharmaceutical Quality System

Principles of Parenteral Solution Validation

Oral Drug Absorption, Second Edition thoroughly examines the special equipment and methods used to test whether drugs are released adequately when administered orally. The contributors discuss methods for accurately establishing and validating in vitro/in vivo correlations for both MR and IR formulations, as well as alternative approaches for MR an

March 12-13, 2018 London, UK Key Topics : New Advances And Development In Mass Spectrometry, Mass Spectrometry Applications, Mass Spectrometry In Pharmaceutical Industry, Spectroscopy, Mass Spectrometry Applications In Clinical Diagnostics, Capillary Electrophoresis, Tandem Mass Spectrometry, Environmental Analysis, Protein Mass Spectrometry, Ionization Techniques Mass Spectrometry, Forensic Analysis, Mass Spectrometry In Medicine, Imaging Mass Spectrometry, Analytical Chemistry, Molecular Mass Spectrometry

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.

Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is 'current good manufacturing practice (CGMP)'', which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.

Application de l'ICH Q9 "Quality Risk Management" par la méthode de l'Analyse des Modes de Défaillances, de leurs effets et de leur Criticité, au processus de distribution du talimogène laherparepvec

Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing

Principles and Applications

Encyclopedia of Cancer

Good Manufacturing Practices for Pharmaceuticals, Seventh Edition

Pharmaceutical Quality by Design: Principles and Applications discusses the Quality by Design (QbD) concept implemented by regulatory agencies to ensure the development of a consistent and high-quality pharmaceutical product that safely provides the maximum therapeutic benefit to patients. The book walks readers through the QbD framework by covering the fundamental principles of QbD, the current regulatory requirements, and the applications of QbD at various stages of pharmaceutical product development, including drug substance and excipient development, analytical development, formulation development, dissolution testing, manufacturing, stability studies, bioequivalence testing, risk and assessment, and clinical trials. Contributions from global leaders in QbD provide specific insight in its application in a diversity of pharmaceutical products, including nanopharmaceuticals, biopharmaceuticals, and vaccines. The inclusion of illustrations, practical examples, and case studies makes this book a useful reference guide to pharmaceutical scientists and researchers who are engaged in the formulation of various delivery systems and the analysis of pharmaceutical product development and drug manufacturing process. Discusses vital QbD precepts and fundamental aspects of QbD implementation in the pharma, biopharma and biotechnology industries Provides helpful illustrations, practical examples and research case studies to explain QbD concepts to readers Includes contributions from global leaders and experts from academia, industry and regulatory agencies

With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

La gestion du risque qualité est une problématique de plus en plus présente dans l'industrie pharmaceutique et notamment lors de la mise en place de nouveaux procédés de production. Le procédé considéré dans ce travail est un procédé de remplissage d'une poudre pour inhalation. La démarche utilisée pour gérer les risques qualité de ce procédé suit une méthodologie définie par l'ICH Q9. Elle prend en compte trois grandes phases (appréciation, maîtrise et revue des risques) et utilise un vocabulaire spécifique. L'application de cette démarche est facilitée par l'ICH Q9 qui donne des exemples d'outils : l'AMEDEC (analyse des modes de défaillance, de leurs effets et de leur criticité). L'ensemble de ces outils permet une prise de décision justifiée. La gestion du risque est présentée à travers une étude détaillée qui utilise une méthodologie de cartographie du procédé et une analyse de risques approfondie de type AMDEC. Les actions correctives pertinentes mises en oeuvres suite à cette analyse permettent de démontrer la maîtrise du procédé de remplissage, et d'assurer la qualité

Good Manufacturing Practices for Pharmaceuticals

Fundamentals of Biologicals Regulation

Industrial Scale Suspension Culture of Living Cells

Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook

Process Validation in Manufacturing of Biopharmaceuticals

Vaccines and Biotechnology Medicines