Deviation Handling And Quality Risk Management

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Leading Six Sigma OECD Publishing
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
Guidance for Preparing Standard Operating Procedures (SOPs). CRC Press
This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.
John P. Kotter on what Leaders Really Do National Academies Press
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
Practical Engineering, Process, and Reliability Statistics CRC Press
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.
Modern Aspects of Pharmaceutical Quality Assurance Government Printing Office
Implementing safety practices in healthcare saves lives and improves the quality of care: it is therefore vital to apply good clinical practices, such as the WHO surgical checklist, to adopt the most appropriate measures for the prevention of assistance-related risks, and to identify the potential ones using tools such as reporting & learning systems. The culture of safety in the care environment and of human factors influencing it should be developed from the beginning of medical studies and in the first years of professional practice, in order to have the maximum impact on clinicians' and nurses' behavior. Medical errors tend to vary with the level of proficiency and experience, and this must be taken into account in adverse events prevention. Human factors assume a decisive importance in resilient organizations, and an understanding of risk control and containment is fundamental for all medical and surgical specialties. This open access book offers recommendations and examples of how to improve patient safety by changing practices, introducing organizational and technological innovations, and creating effective, patient-centered, timely, efficient, and equitable care systems, in order to spread the quality and patient safety culture among the new generation of healthcare professionals, and is intended for residents and young professionals in different clinical specialties.
Improving Healthcare Quality in Europe Characteristics, Effectiveness and Implementation of Different Strategies Academic Press
Effective risk management is essential for the success of large projects built and operated by the Department of Energy (DOE), particularly for the one-of-a-kind projects that characterize much of its mission. To enhance DOE's risk management efforts, the department asked the NRC to prepare a summary of the most effective practices used by leading owner organizations. The study's primary objective was to provide DOE project managers with a basic understanding of both the project owner's risk management role and effective oversight of those risk management activities delegated to contractors.
Practical Approaches to Risk Minimisation for Medicinal Products Quality Press
FDA Regulatory Affairs is a roadmap to prescription drug, biologics, and medical device development in the United States. Written in plain English, the concise and jargon-free text demystifies the inner workings of the US Food and Drug Administration (FDA) and facilitates an understanding of how the agency operates with respect to compliance and product approval, including clinical trial exemptions, fast track status, advisory committee procedures, and more. The Third Edition of this highly successful publication: Examines the harmonization of the US Federal Food, Drug, and Cosmetic Act with international regulations on human drug, biologics and device development, research, manufacturing, and marketing Includes contributions from experts at organizations such as the FDA, National Institutes of Health (NIH), and PAREXEL Focuses on the new drug application

(NDA) process, cGMPs, GCPs, quality system compliance, and corresponding documentation requirements Provides updates to the FDA Safety and Innovation Act (FDASIA), incorporating pediatric guidelines and follow-on biologics regulations from the 2012 Prescription Drug User Fee Act (PDUFA) V Explains current FDA inspection processes, enforcement options, and how to handle FDA meetings and required submissions Co-edited by an industry leader (Mantus) and a respected academic (Pisano), FDA Regulatory Affairs, Third Edition delivers a compilation of the selected US laws and regulations as well as a straightforward commentary on the FDA product approval process that's broadly useful to both business and academia.

Principles of Parenteral Solution Validation Springer Nature

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. The first edition of the book covered many of the aspects of the strategy, but the new official guidance signals that a roadmap is required to fully comply with its requirements. Completely updated with the newest version of the EU-GPM (EN17141) the new edition expands the coverage of quality risk management and new complete examples to help professionals bridge the gap between regulation and implementation. Biocontamination Control for Pharmaceuticals and Healthcare offers professionals in pharma quality control and related areas guidance on building a complete biocontamination strategy. Includes the most current regulations Contains three new chapters, including Application of Quality Risk Management and its Application in Biocontamination Control, Designing an Environmental Monitoring Programme, and Synthesis: An Anatomy of a Contamination Control Strategy Offers practical guidance on building a complete biocontamination strategy

Predictive Modeling of Pharmaceutical Unit Operations Pencil

Quality Assurance of Aseptic Preparation Services Standards Handbook (also known as the Yellow Guide) provides standards for unlicensed aseptic preparation in the UK, as well as practical information to aid implementation of the standards. The handbook delivers essential standards in a practical way and in a format that will be useful for pharmacy management, staff working in aseptic preparation units and those whose role it is to audit the services. The accompanying support resources help with understanding the complexities of relevant topics including microbiology, radiopharmaceuticals, advanced therapy medicinal products, technical (quality) agreements and capacity planning. All the standards have been revised and updated for this 5th edition. The text is produced on behalf of the Royal Pharmaceutical Society (RPS) and the NHS Pharmaceutical Quality Assurance Committee. New in this edition: Replaces the 4th edition standards and forms the basis for an ongoing audit program in the NHS Many new and revised standards Greater emphasis on Pharmaceutical Quality Systems; the responsibilities of pharmacy management, Chief Pharmacists (or equivalent), has been expanded in line with developments in Good Manufacturing Practice Reformatted into 2 parts: standards and support resources. This is a new collaboration between the RPS and NHS. Since the previous edition the RPS has become the professional body for pharmacists and pharmaceutical scientists. RPS launched these standards as part of a library of professional standards and a programme of work to create standards for all areas of pharmacy. The Handbook is essential for pharmacists, hospital pharmacy management and technical services teams, and auditors of unlicensed NHS hospital pharmacy aseptic preparation services in the UK, pharmacists and regulators. The text is used to inform standards used in several other countries.

Usp38-Nf33 Routledge

A quality product or service is the successful and profitable outcome of organising resources, as judged by the final customer. Every business unit needs processes in order to do this effectively; and all processes must be documented so that achievements can be measured and future improvements planned and implemented. Pharmaceutical Process Design and Management takes a step-wise approach to process management. It presents the various elements comprising a process (man, machine, materials, method and environment); it looks at quality control and quality assurance, tools for quality improvements and ways of structuring a process into discrete, fully accountable elements; it proposes that for processes to run successfully, all operators must be the initial problem-solvers; finally, it illustrates how, with the right tools, every problem can be broken down into solvable elements. Learn how to deploy a science and risk-based approach to pharmaceutical manufacturing, by taking a fundamental approach to process design and management and, as a consequence, keep your customers satisfied and your profits healthy.

HAZOP: Guide to Best Practice FT Press

Author D. H. Stamatis has updated his comprehensive reference book on failure mode and effect analysis (FMEA). This is one of the most comprehensive guides to FMEA and is excellent for professionals with any level of understanding.!--nl--This book explains the process of conducting system, design, process, service, and machine FMEAs, and provides the rationale for doing so. Readers will understand what FMEA is, the different types of FMEA, how to construct an FMEA, and the linkages between FMEA and other tools. Stamatis offer a summary of tools/methodologies used in FMEA along with a glossary to explain key terms and principles. The updated edition includes information about the new ISO 9000:2000 standard, the Six Sigma approach to FMEA, a special section on automotive requirements related to ISO/TS 16949, the "robustness" concept, and TE 9000 and the requirements for reliability and maintainability. Also includes FMEA forms and samples, design review checklist, criteria for evaluation, basic reliability formulae and conversion failure factors, guidelines for RPN calculations and designing a reasonable safe product, and diagrams, and examples of FMEAs with linkages to robustness.

Biocontamination Control for Pharmaceuticals and Healthcare World Health Organization

Policymakers and program managers are continually seeking ways to improve accountability in achieving an entity's mission. A key factor in improving accountability in achieving an entity's mission is to implement an effective internal control system. An effective internal control system helps an entity adapt to shifting environments, evolving demands, changing risks, and new priorities. As programs change and entities strive to improve operational processes and implement new technology, management continually evaluates its internal control system so that it is effective and updated when necessary. Section 3512 (c) and (d) of Title 31 of the United States Code (commonly known as the Federal Managers? Financial Integrity Act (FMFIA)) requires the Comptroller General to issue standards for internal control in the federal government.

The Standard for Risk Management in Portfolios, Programs, and Projects Springer Science & Business Media

Compaction of powder constituents—both active ingredient and excipients—is examined to ensure consistent and reproducible disintegration and dispersion profiles. Revised to reflect modern pharmaceutical compacting techniques, this second edition of Pharmaceutical Powder Compaction Technology guides pharmaceutical engineers, formulation scientists, and product development and quality assurance personnel through the compaction formulation process and application. This unique reference covers: The physical structure of pharmaceutical compacts Bonding phenomena that occur during powder compaction Compression mechanisms of pharmaceutical particles Theories and basic principles of powder compaction New topics include: Compaction data analysis techniques The migration of powder constituents into commercial manufacture Instrumentation for compaction Compaction functionality testing, which is likely to become a USP requirement Design space for compaction Metrics required for scalability in tablet compression Interactive compaction and preformulation database for commonly used excipients

Foundations of Quality Risk Management ASQ Quality Press

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

Pharmaceutical Quality by Design Elsevier

A collection of test procedures for assessing the identity, purity, and content of medicinal plant materials, including determination of pesticide residues, arsenic and heavy metals. Intended to assist national laboratories engaged in drug quality control, the manual responds to the growing use of medicinal plants, the special quality problems they pose, and the corresponding need for international guidance on reliable methods for quality control. Recommended procedures - whether involving visual inspection or the use of thin-layer chromatography for the qualitative determination of impurities - should also prove useful to the pharmaceutical industry and pharmacists working with these materials.

Quality Management and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy Academic Press

This book is a convenient and comprehensive guide to statistics. A resource for quality technicians and engineers in any industry, this second edition provides even more equations and examples for the reader—with a continued focus on algebra-based math. Those preparing for ASQ certification examinations, such as the Certified Quality Technician (CQT), Certified Six Sigma Green Belt (CSSGB), Certified Quality Engineer (CQE), Certified Six Sigma Black Belt (CSSBB), Certified Reliability Engineer (CRE), and Certified Supplier Quality Professional (CSQP), will find this book helpful as well. Inside you'll find: • Complete calculations for determining confidence intervals, tolerances, sample size, outliers, process capability, and system reliability • Newly added equations for hypothesis tests (such as the Kruskal-Wallis test and Levene's test for equality of variances), the Taguchi method, and Weibull and log-normal distributions • Hundreds of completed examples to demonstrate practical use of each equation • 20+ appendices, including distribution tables, critical values tables, control charts, sampling plans, and a beta table

Guideline on General Principles of Process Validation John Wiley & Sons

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

Failure Mode and Effect Analysis Woodhead Publishing

This volume, developed by the Observatory together with OECD, provides an overall conceptual framework for understanding and applying strategies aimed at improving quality of care. Crucially, it summarizes available evidence on different quality strategies and provides recommendations for their implementation. This book is intended to help policy-makers to understand concepts of quality and to support them to evaluate single strategies and combinations of strategies.

The Owner's Role in Project Risk Management Springer Nature

The Public Health Foundation (PHF) in partnership with the Centers for Disease Control and Prevention (CDC) is pleased to announce the availability of Epidemiology and Prevention of Vaccine-Preventable Diseases, 13th Edition or "The Pink Book" E-Book. This resource provides the most current, comprehensive, and credible information on vaccine-preventable diseases, and contains updated content on immunization and vaccine information for public health practitioners, healthcare providers, health educators, pharmacists, nurses, and others involved in administering vaccines. "The Pink Book E-Book" allows you, your staff, and others to have quick access to features such as keyword search and chapter links. Online schedules and sources can also be accessed directly through e-readers with internet access. Current, credible, and comprehensive, "The Pink Book E-Book" contains information on each vaccine-preventable disease and delivers immunization providers with the latest information on: Principles of vaccination General recommendations on immunization Vaccine safety Child/adult immunization schedules International vaccines/Foreign language terms Vaccination data and statistics The E-Book format contains all of the information and updates that are in the print version, including: · New vaccine administration chapter · New recommendations regarding selection of storage units and temperature monitoring tools · New recommendations for vaccine transport · Updated information on available influenza vaccine products · Use of Tdap in pregnancy · Use of Tdap in persons 65 years of age or older · Use of PCV13 and PPSV23 in adults with immunocompromising conditions · New licensure information for varicella-zoster immune globulin Contact bookstore@phf.org for more information. For more news and specials on immunization and vaccines visit the Pink Book's Facebook fan page

Risk Assessment and Risk Management in the Pharmaceutical Industry Simon and Schuster

When a pharmaceutical company decides to build a Quality System, it has to face the fact that there aren't any guideline that define exactly how such a system has to be built. With terms such as quality system, quality assurance, and quality management used interchangeably, even defining the system's objectives is a problem. This book provides a pr

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