Deviation Handling And Quality Risk Management Who

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Principles of Parenteral Solution Validation
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Quality Assurance of Aseptic Preparation Services Standards Handbook
Water Quality
Predictive Modeling of Pharmaceutical Unit Operations
Forty-seventh Report
The Owner's Role in Project Risk Management
How to Validate a Pharmaceutical Process
Detection and Handling of Deviations in Process-centered Software Engineering Environments
An Effective Tool for Improving Transfusion Safety
Towards a Better Management of Risks
fifty-fourth report
Regulations and Quality
Guidelines for Failure Modes and Effects Analysis for Medical Devices
The FDA and Worldwide Current Good Manufacturing Practices and Quality System Requirements Guidebook for Finished Pharmaceuticals
Frontier Discoveries and Innovations in Interdisciplinary Microbiology
Quantitative Risk Management: Concepts, Techniques, and Tools
Who Expert Committee on Specifications for Pharmaceutical Preparations
Application of Usability Engineering to Medical Devices
Biocontamination Control for Pharmaceuticals and Healthcare
Failure Mode and Effect Analysis
Production and Processes
Quality Management and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy
A Step-by-step Guide Based on Experience with GE and Other Six Sigma Companies

JONATHAN ANNABEL

Special Report of the Intergovernmental Panel on Climate Change Lulu.com
This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.
Process Control, Intensification, and Digitalisation in Continuous Biomanufacturing Quality 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. 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 orobustnesso concept, and TE 9000 and the requirements for reliability and maintainability. the accompanying CD-ROM offers 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.
Risk Management in Regulatory Frameworks American Psychiatric Pub
Recent years have been marked by many catastrophic events both natural and man-made. Close interconnections mean that the impact of these crises has been felt throughout the world.

Although many tools have been developed to manage risks successfully, there can be no doubt that many of the losses we have recently witnessed could have been prevented or minimized, in the context of an effective and well-balanced regulatory system. The goal of this publication is to provide insights and recommendations for policymakers on designing regulatory systems that result in an efficient, effective and transparent management of risks. It introduces a holistic model of a regulatory system, function by function and with real-life examples, which is based on the objective of managing risks effectively.

The JACIE Guide Biocontamination Control for Pharmaceuticals and Healthcare

Software Processes aim at improving the quality and productivity of software development by encoding sets of well-know practices for realizing them. When encoded in the form of Software Process Models (SPM) they can be analyzed, improved and automated. This third activity is the focus of this work. More specifically, we deal with a particular piece of software that is in charge of the automatization of the execution of SPMs: the Process-centered Software Engineering Environment (PSEE). They consist of process-aware software development environments that allow process agents to enact a SPM while having the conformance of their actions to the SPM verified by the PSEE. In this work, we are interested in the actions performed by the agents that do not conform to the SPM, we call these actions deviations. As a starting point of this work, we evaluated the existing PSEEs and realized that they do not provide the necessary support for detecting and handling deviations. This work intends to provide PSEEs the necessary support for detecting deviations and guiding process agents in handling them. In terms of detection, our approach reduces the level of prescriptiveness of PSEEs, by allowing them to detect deviations as early as possible (Early Deviation Detection) and to classify deviations according to their impact to the process objectives (Risk Assessment) In terms of guidance, we want our approach to allow the PSEE to delay the effective handling of deviations for as long as possible (Late Deviation Handling) and to provide correction plans that help process agents to reduce the overall risk represented by the detected deviations (Correction Guidance).

WHO Expert Committee on Specifications for Pharmaceutical Preparations John Wiley & Sons

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

A User’s Guide John Wiley & Sons

"Nurses play a vital role in improving the safety and quality of patient car -- not only in the hospital or ambulatory treatment facility, but also of community-based care and the care performed by family members. Nurses need know what proven techniques and interventions they can use to enhance patient outcomes. To address this need, the Agency for Healthcare Research and Quality (AHRQ), with additional funding from the Robert Wood Johnson Foundation, has prepared this comprehensive, 1,400-page, handbook for nurses on patient safety and quality -- Patient Safety and Quality: An Evidence-Based Handbook for Nurses. (AHRQ Publication No. 08-0043)."--Online AHRQ blurb, http://www.ahrq.gov/qual/nurseshdbk.

Patient Safety and Quality CRC 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

Pharmaceutical Powder Compaction Technology, Second Edition

Project Management Institute

Alcohol use disorder (AUD) is a major public health problem in the United States. The estimated 12-month and lifetime prevalence values for AUD are 13.9% and 29.1%, respectively, with approximately half of individuals with lifetime AUD having a severe disorder. AUD and its sequelae also account for significant excess mortality and cost the United States more than $200 billion annually. Despite its high prevalence and numerous negative consequences, AUD remains undertreated. In fact, fewer than 1 in 10 individuals in the United States with a 12-month diagnosis of AUD receive any treatment. Nevertheless, effective and evidence-based interventions are available, and treatment is associated with reductions in the risk of relapse and AUD-associated mortality. The American Psychiatric Association Practice Guideline for the Pharmacological Treatment of Patients With Alcohol Use Disorder seeks to reduce these substantial psychosocial and public health consequences of AUD for millions of affected individuals. The guideline focuses specifically on evidence-based pharmacological treatments for AUD in outpatient settings and includes additional information on assessment and treatment planning, which are an integral part of using pharmacotherapy to treat AUD. In addition to reviewing the available evidence on the use of AUD pharmacotherapy, the guideline offers clear, concise, and actionable recommendation statements, each of which is given a rating that reflects the level of confidence that potential benefits of an intervention outweigh potential harms. The guideline provides guidance on implementing these recommendations into clinical practice, with the goal of improving quality of care and treatment outcomes of

AUD.
FMEA from Theory to Execution Cambridge University Press
This excellent book covers wide-ranging topics in interdisciplinary microbiology, addressing various research aspects and highlighting advanced discoveries and innovations. It presents the fascinating topic of modern biotechnology, including agricultural microbiology, microalgae biotechnology, bio-energy, bioinformatics and metagenomics, environmental microbiology, enzyme technology and marine biology. It presents the most up-to-date areas of microbiology with an emphasis on shedding light on biotechnological advancements and integrating these interdisciplinary microbiology research topics into other biotechnology sub-disciplines. The book raises awareness of the industrial relevance of microbiology, which is key component of this unique collection. The topics include production of antioxidant-glutathione, enzyme-engineering methods, probiotic microbiology and features of microbial xylanases. It also covers some other remarkable aspects of microbiology, like potential health hazards in recreational water and fullerene nanocomposites, which are vital for biotechnological interventions. This book will be valuable resource for senior undergraduate and graduate students, researchers and other interested professionals or groups working in the interdisciplinary areas of microbiology and biotechnology.
The American Psychiatric Association Practice Guideline for the Pharmacological Treatment of Patients With Alcohol Use Disorder Springer Nature
A comprehensive, one-stop reference for cutting-edge research in integrated risk management, modern applications, and best practices In the field of business, the ever-growing dependency on global supply chains has created new challenges that traditional risk management must be equipped to handle. Handbook of Integrated Risk Management in Global Supply Chains uses a multi-disciplinary approach to present an effective way to manage complex, diverse, and interconnected global supply chain risks. Contributions from leading academics and researchers provide an action-based framework that captures real issues, implementation challenges, and concepts emerging from industry studies.The handbook is divided into five parts: Foundations and Overview introduces risk management and discusses the impact of supply chain disruptions on corporate performance Integrated Risk Management: Operations and Finance Interface explores the joint use of operational and financial hedging of commodity price uncertainties Supply Chain Finance discusses financing alternatives and the role of financial services in procurement contracts; inventory management and capital structure; and bank financing of inventories Operational Risk Management Strategies outlines supply risks and challenges in decentralized supply chains, such as competition and misalignment of incentives between buyers and suppliers Industrial Applications presents examples and case studies that showcase the discussed methodologies Each topic's presentation includes an introduction, key theories, formulas, and applications. Discussions conclude with a summary of the main concepts, a real-world example, and professional insights into common challenges and best practices. Handbook of Integrated Risk Management in Global Supply Chains is an essential reference for academics and practitioners in the areas of supply chain management, global logistics, management science, and industrial engineering who gather, analyze, and draw results from data. The handbook is also a suitable supplement for operations research, risk management, and financial engineering courses at the upper-undergraduate and graduate levels.
The Basics of FMEA John Wiley & Sons
This Intergovernmental Panel on Climate Change Special Report (IPCC-SREX) explores the challenge of understanding and managing the risks of climate extremes to advance climate change adaptation. Extreme weather and climate events, interacting with exposed and vulnerable human and natural systems, can lead to disasters. Changes in the frequency and severity of the physical events affect disaster risk, but so do the spatially diverse and temporally dynamic patterns of exposure and vulnerability. Some types of extreme weather and climate events have increased in frequency or magnitude, but populations and assets at risk have also increased, with consequences for disaster risk. Opportunities for managing risks of weather- and climate-related disasters exist or can be developed at any scale, local to international. Prepared following strict IPCC procedures, SREX is an invaluable assessment for anyone interested in climate extremes, environmental disasters and adaptation to climate change, including policymakers, the private sector and academic researchers.
Principles of Parenteral Solution Validation John Wiley & Sons
The field of occupational health and safety constantly changes, especially as it pertains to biomedical research. New infectious hazards are of particular importance at nonhuman-primate facilities. For example, the discovery that B virus can be transmitted via a splash on a mucous membrane raises new concerns that must be addressed, as does the discovery of the Reston strain of Ebola virus in import quarantine facilities in the U.S. The risk of such infectious hazards is best managed through a flexible and comprehensive Occupational Health and Safety Program (OHSP) that can identify and mitigate potential hazards. Occupational Health and Safety in the Care and Use of Nonhuman Primates is intended as a reference for vivarium managers, veterinarians, researchers, safety professionals, and others who are involved in developing or implementing an OHSP that deals with nonhuman primates. The book lists the important features of an OHSP and provides the tools necessary for informed decision-making in developing an optimal program that meets all particular institutional needs.
Occupational Health and Safety in the Care and Use of Nonhuman Primates CRC 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
The Pink Book Government Printing Office
This guidance book is meant as a resource to manufacturers of pharmaceuticals, providing up-to-date information concerning required and recommended quality system practices. It should be used as a companion to the regulations/standards themselves and texts on the specific processes and activities contained within the QMS. This book includes chapters on US current Good Manufacturing Practice (GMP); international GMP; global GMP guides and harmonization; detailed analysis of the requirements and guidances; missing subparts; what inspectors are looking for;

and the price of noncompliance. It also includes an appendix with two tabulated comparisons: the first compares US, European-PIC/S, Canadian, and WHO cGMPs, while the second compares US cGMPs with effective quality system elements. The companion CD contains cGMP regulations for sterile products produced by aseptic processing; it also includes updated data of statistical enforcement by the FDA, both domestically and abroad; a detailed glossary; and dozens of FDA guidance documents as well as international regulations (EU and Canada) and harmonization documents (WHO, PIC/S, and ICH). A very comprehensive checklist for a cGMP audit that is based on risk management criteria is also included. Finally, a comprehensive GMP exam is also included.

Strategies for Small Manufacturers Academic Press

This User’s Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User’s Guide was created by researchers affiliated with AHRQ’s Effective Health Care Program, particularly those who participated in AHRQ’s DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

Pharmaceutical Quality Systems Academic Press

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

Practice Standard for Project Risk Management Academic Press

Aimed at experts who are dedicated to software testing, The Software Testing Process: Test Management addresses the major issues related to advanced, state-of-the-art test management. This book covers the syllabus required to pass the Certified Tester Examination - Advanced Level as defined by the International Software Testing Qualifications Board (ISTQB). Software developers, project managers, quality managers, and team leaders will benefit from the comprehensive coverage of risk oriented management and the way testing is shown to be an integral, though independent part of software development. Included are best practices in the field of testing, as well as detailed descriptions of involved tasks, roles, and responsibilities. Well suited for self-study, the reader is "taken by the hand" and guided through the key concepts and terminology of software testing in a variety of scenarios and case studies (as featured in the first book in this series, Software Testing Foundations). Not only will testers and test managers find this a must-read, but anyone requiring advanced professional knowledge and skills in this field, anyone wanting to become a true testing professional, will find this book a must for a successful, well-founded education in advanced test management. Topics include: Test process and test toolsTesting in the software life cycleTest policy and test manualTest plan and test planningTest controlIncident managementRisk management/risk-based testingStaff qualificationsTest metrics

National Academies Press

The managed flow of goods and information from raw material to final sale also known as a "supply chain" affects everything--from the U.S. gross domestic product to where you can buy your jeans. The nature of a company's supply chain has a significant effect on its success or failure--as in the success of Dell Computer's make-to-order system and the failure of General Motor's vertical integration during the 1998 United Auto Workers strike. Supply Chain Integration looks at this crucial component of business at a time when product design, manufacture, and delivery are changing radically and globally. This book explores the benefits of continuously improving the relationship between the firm, its suppliers, and its customers to ensure the highest added value. This book identifies the state-of-the-art developments that contribute to the success of vertical tiers of suppliers and relates these developments to the capabilities that small and medium-sized manufacturers must have to be viable participants in this system. Strategies for attaining these capabilities through manufacturing extension centers and other technical assistance providers at the national, state, and local level are suggested. This book identifies action steps for small and medium-sized manufacturers--the "seed corn" of business start-up and development--to improve supply chain management. The book examines supply chain models from consultant firms, universities, manufacturers, and associations. Topics include the roles of suppliers and other supply chain participants, the rise of outsourcing, the importance of information management, the natural tension between buyer and seller, sources of assistance to small and medium-sized firms, and a host of other issues. Supply Chain Integration will be of interest to industry policymakers, economists, researchers, business leaders, and forward-thinking executives.

Quality Assurance of Aseptic Preparation Services Standards Handbook CRC Press

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

Water Quality John Wiley & Sons

The quality of water, whether it is used for drinking, irrigation or recreational purposes, is significant for health in both developing and developed countries worldwide. This book is based on a programme of work undertaken by an international group of experts during 1999-2001. The aim was to develop a harmonised framework of effective and affordable guidelines and standards to improve the risk assessment and management of water-related microbial hazards. This book will be useful to all those concerned with issues relating to microbial water quality and health, including environmental and public health scientists, water scientists, policy makers and those responsible for developing standards and regulations.