

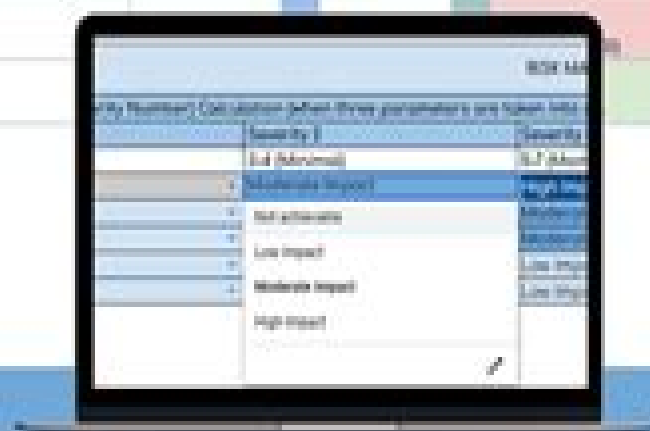
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Sl. No.	System	Sub-system	Component / Step / Function	Potential Failure	Potential effect / consequences	Sensitivity (1-10)	Potential Cause	Current controls in place	Undesired / Occurrence (1-10)	Current controls for detectability	Consequence (1-10)	Risk Level	Risk Acceptable?	Reason for acceptance	Sl.	
1	Ready Business Launch	Product Development	Product Formulation	Ingredient Contamination	Allergic reactions, product recalls	10	Wrong ingredient supplier	regular quality checks	6	random product testing	6	High Impact (240)	Yes			10
2	Ready Business Launch	Product Development	Packaging design	Inadequate protection	Product damage	8	Cheap material selection	Use of standard packaging	5	Visual inspection and ensure there	5	Moderate Impact (24)	Yes	If that hazard should be eliminated at this point		10
3	Ready Business Launch	Go-to-market campaign	Investment targeting	Statistical spend vs. engagement	False demographic selection	6	Analytics tracking	Campaign performance metrics	4	Reports	4	Moderate Impact (22)	Yes			10
4	Ready Business Launch		Supplier relationships			10			3		3	High Impact (70)				10
5	Ready Business Launch		Staffing			10										10
6	Ready Business Launch		Influencer partnership			5										10



Gmp Quality Risk Assessment Template

**Minal Ghante, Manohar Potdar, Vidhya
Bhusari**



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Quality Risk Management in the FDA-Regulated Industry José Rodríguez-Pérez, 2017-02-21 The purpose of this new edition is to offer an updated view of the risk management field as it applies to medical products Since the publication of the first edition 2012 the emphasis on risk based processes has grown exponentially across all sectors and risk management is now considered as significant as quality management ISO 9001 was revised and now requires that top management promote the use of risk based thinking ISO 13485 2016 which specifies the requirements for a quality management system specific to the medical devices industry also now shows a greater emphasis on risk management and risk based decision making In addition the FDA Food Safety Modernization Act FSMA is the most important reform of U S food safety laws in more than 70 years This indispensable book presents a systematic and 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 practice or good laboratory practice All chapters have been updated and revised and a new chapter has been added to discuss some of the most common pitfalls and misunderstandings regarding risk management specifically those related to the use of FMEA as the only element of risk management programs One of the appendices includes 12 case studies and the companion CD ROM contains dozens of U S FDA and European guidance documents as well as international harmonization documents ICH and GHTF IMDRF related to risk management activities as well as a 30 question exam with answers on the material discussed in the book

Quality Risk Management in the FDA-Regulated Industry Jose (Pepe) Rodriguez-Perez, 2024-04-18 For quality professionals and manufacturers in the food safety and medical device industries risk management is essential to ensuring organizations meet FDA regulations and requirements Without these recognized standards the lives of patients and consumers are placed in jeopardy In this third edition of *Quality Risk Management in the FDA Regulated Industry* Jose Rodriguez Perez provides an updated view of the risk management field as it applies to FDA regulated products using risk based thinking

Modern Aspects of Pharmaceutical Quality Assurance Minal Ghante, Manohar Potdar, Vidhya Bhusari, 2024-03-11 The pharmaceutical quality system ensures that the process performance is suitably achieved the product quality is regularly met improved opportunities are identified and evaluated and the knowledge is constantly expanded Auditing also plays a crucial role within the pharmaceutical industry It helps to assess and review quality to improve and build a better system for the benefit of companies This book aims to develop a tool that will substantially decrease the number of Inspectional Observations and Warning letters thus eliminating Import Alerts and Consent Decree This book targets the Pharmaceutical Industry and students of Pharmaceutical Quality Assurance so they can get in hand ready consolidated information on Pharmaceutical Quality guidelines Quality metrics and implementation of

simplified SOP guidelines plant layouts to implement Quality metrics for Pharmaceutical Manufacturing systems in tablets capsules liquid orals and semi solid dosage forms The chapters cover the various aspects of Pharmaceutical Quality Assurance The selection of topics is mainly based on the requirements of Pharmaceutical regulatory guidelines of India the UK the USA Australia and South Africa Each chapter includes the abstract detailed explanation implementation guidelines flowcharts layouts and Standard Operating Procedure of quality metrics for the Pharmaceutical Manufacturing System

Endotoxins Kevin L. Williams,2007-02-23 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

Analytical Testing for the Pharmaceutical GMP Laboratory Kim Huynh-Ba,2022-04-19 Provides practical guidance on pharmaceutical analysis written by leading experts with extensive industry experience Analytical Testing for the Pharmaceutical GMP Laboratory presents a thorough overview of the pharmaceutical regulations working processes and drug development best practices used to maintain the quality and integrity of medicines With a focus on smaller molecular weight drug substances and products the book provides the knowledge necessary for establishing the pharmaceutical laboratory to support Quality Systems while maintaining compliance with Good Manufacturing Practices GMP regulations Concise yet comprehensive chapters contain up to date coverage of drug regulations pharmaceutical analysis methodologies control strategies testing development and validation method transfer electronic data documentation and more Each chapter includes a table of contents definitions of acronyms a reference list and ample tables and figures Addressing the principal activities and regulatory challenges of analytical testing in the development and manufacturing of pharmaceutical drug products this authoritative resource Describes the structure roles core guidelines and GMP regulations of the FDA and ICH Covers the common analytical technologies used in pharmaceutical laboratories including examples of analytical techniques used for the release and stability testing of drugs Examines control strategies established from quality systems supported by real world case studies Explains the use of dissolution testing for products such as extended release capsules aerosols and inhalers Discusses good documentation and data reporting practices stability programs and the Laboratory Information Management System LIMS to maintain compliance Includes calculations application examples and illustrations to assist readers in day to day laboratory operations Contains practical information and templates to structure internal processes or common Standard Operating Procedures SOPs Analytical Testing for the Pharmaceutical GMP Laboratory is a must have reference for both early career and experienced pharmaceutical scientists analytical chemists pharmacists and quality control professionals It is also both a resource for GMP laboratory training programs and an excellent textbook for undergraduate and graduate courses of analytical chemistry in pharmaceutical sciences or regulatory compliance programs

Practical Pharmaceutics Yvonne Bouwman-Boer,V'Iain Fenton-May,Paul Le Brun,2015-08-24

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

Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Volume 2. Good manufacturing practices and inspection World Health Organization,2024-01-31 The GMP Compendium for Medical Products is a valuable resource for manufacturers regulators and other stakeholders involved in producing and distributing medical products It covers various topics from quality management systems to personnel hygiene equipment validation and complaint handling The guidance provided is based on the latest scientific and technical knowledge and considers the evolving regulatory landscape and the challenges faced by the industry

Quality Assurance of Pharmaceuticals World Health Organization,2007 Quality assurance of pharmaceutical products is a continuing concern of WHO Despite efforts made around the world to ensure a supply of quality and effective medicines substandard spurious and counterfeit products still compromise health care delivery in many countries To respond to the global need for adequate quality assurance of pharmaceuticals WHO s Expert Committee on Specifications for Pharmaceutical Preparations has over the years made numerous recommendations to establish standards and guidelines and to promote the effective functioning of national regulatory and control systems and the implementation of internationally agreed standards by trained personnel Many of the relevant documents endorsed by the Committee are reproduced in this volume providing guidance covering all aspects of good manufacturing practices GMP Important texts on inspection are also included Most of the material has been published separately in the Expert Committee s reports This compendium brings it together to make it more accessible and of greater practical value to those working in faculties of pharmacy in medicines regulation and control and in the pharmaceutical industry This is the second updated edition of the compendium and includes texts published in 2005 and 2006 in the WHO Technical Report Series

Advances In Pharmaceutical Cell Therapy: Principles Of Cell-based Biopharmaceuticals Christine Guenther,Andrea Josefine Hauser,Ralf Huss,2015-09-23 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

Enhancing compliance to good manufacturing practices and pharmaceutical quality system requirements in vaccine production World Health Organization,2024-06-25 **Handbook of Pharmaceutical Manufacturing Formulations**

Sarfaraz K. Niazi,2016-04-19 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

Pharmaceutical Manufacturing Formulations Dr. Priyanka Gupta Manglik,2024-08-15 This book provides detailed insight into the various aspects of pharmaceutical manufacturing covering formulations process design technology and regulatory requirements essential for professionals in the pharma industry **Quality Management and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy** Mahmoud Aljurf,John A.

Snowden,Patrick Hayden,Kim H. Orchard,Eoin McGrath,2021-02-19 This open access book provides a concise yet comprehensive overview on how to build a quality management program for hematopoietic stem cell transplantation HSCT and cellular therapy The text reviews all the essential steps and elements necessary for establishing a quality management program and achieving accreditation in HSCT and cellular therapy Specific areas of focus include document development and implementation audits and validation performance measurement writing a quality management plan the accreditation process data management and maintaining a quality management program Written by experts in the field Quality Management and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy A Practical Guide is a valuable resource for physicians healthcare professionals and laboratory staff involved in the creation and maintenance of a state of the art HSCT and cellular therapy program **ICH Quality Guidelines** Andrew Teasdale,David Elder,Raymond W.

Nims,2017-10-09 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 **Emerging Nanotechnologies in Immunology** Ranjita Shegokar, Eliana B. Souto, 2018-05-17 Emerging Nanotechnologies in Immunology aims to deliver a systematic and comprehensive review of data concerning the nature of interaction and nano related risks between the nanopharmaceuticals currently in the pipeline of S T development for skin ocular and nasal drug delivery including absorption toxicity and the ability to distribute after systemic exposure The scientific development of manufactured nanomaterials for drug delivery is increasing rapidly One of the most prominent applications is topical drug delivery where cutaneous ocular and nasal exposure becomes even more relevant These targets are the first barrier that nanoparticles encounter when in contact with the human body The contributors addresses a representative set of the broad spectrum of nanopharmaceuticals currently being used including cationic lipid nanoparticles polymeric PLGA PLA nanoparticles biomacromolecules based nanoparticles and other scaffolds tissue engineered skin substitutes Regulation and risk is also covered since the safety of these nanopharmaceuticals still represents a barrier to their wide innovative use Provides the reader with a thorough knowledge of the safety aspects of nanopharmaceuticals which are currently under research Focuses on the characterization and quantification of the nanopharmaceuticals Allows readers to understand the correlation between the nature of the materials and their potential nanotoxicological effects Includes an overview of regulatory aspects related to the R D of nanopharmaceuticals Risk Assessment and Risk Management in the Pharmaceutical Industry James L. Vesper, 2006

Pharmaceutical Microbiological Quality Assurance and Control David Roesti, Marcel Goverde, 2020-01-02 Relying on practical examples from the authors experience this book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non sterile pharmaceuticals Offers a comprehensive guidance for non sterile pharmaceuticals microbiological QA QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors experience in globalized pharmaceutical companies and expert networks Equine Applied and Clinical Nutrition Raymond J. Geor, Patricia Harris, Manfred Coenen, 2013-01-31 Equine Applied and Clinical Nutrition is a comprehensive text resource on the nutrition and feeding management of horses Over 20 experts from around the world share their wisdom on a topic of central relevance to all equine practitioners and the equine community generally Both basic and applied including healthy and diseased animals nutrition and feeding management of horses and other equids i e ponies donkeys wild equids are covered The book will appeal to a wide audience undergraduate and post graduate students in equine science and veterinary medicine veterinarians equine nutritionists horse trainers and owners The clinical component will strengthen the appeal for equine veterinarians

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Data Integrity and Compliance José Rodríguez-Pérez, 2019-05-08 Data integrity is a global mandatory requirement for the regulated healthcare industry It is more than a mere expectation it s a basic element of good documentation practices one of the most fundamental pillars of a quality management system Robustness and accuracy of the data submitted by manufacturers to regulatory authorities when bringing a medical product to market are crucial The purpose of this book is to consolidate existing data integrity principles and expectations from several regulatory sources including the U S Food and Drug Administration World Health Organization and European Medicines Agency into a single and handy document that provides detailed illustrative implementation guidance It serves as a means of understanding regulatory agencies position on good data management and the minimum expectation for how medical product manufacturers can achieve compliance

International IT Regulations and Compliance Siri H. Segalstad, 2008-11-20 Standards technologies and requirements for computer validation have changed dramatically in recent years and so have the interpretation of the standards and the understanding of the processes involved International IT Regulations and Compliance brings together current thinking on the implementation of standards and regulations in relation to IT for a wide variety of industries The book provides professionals in pharmaceutical and semiconductor industries with an updated overview of requirements for handling IT systems according to various Quality Standards and how to translate these requirements in the regulations

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