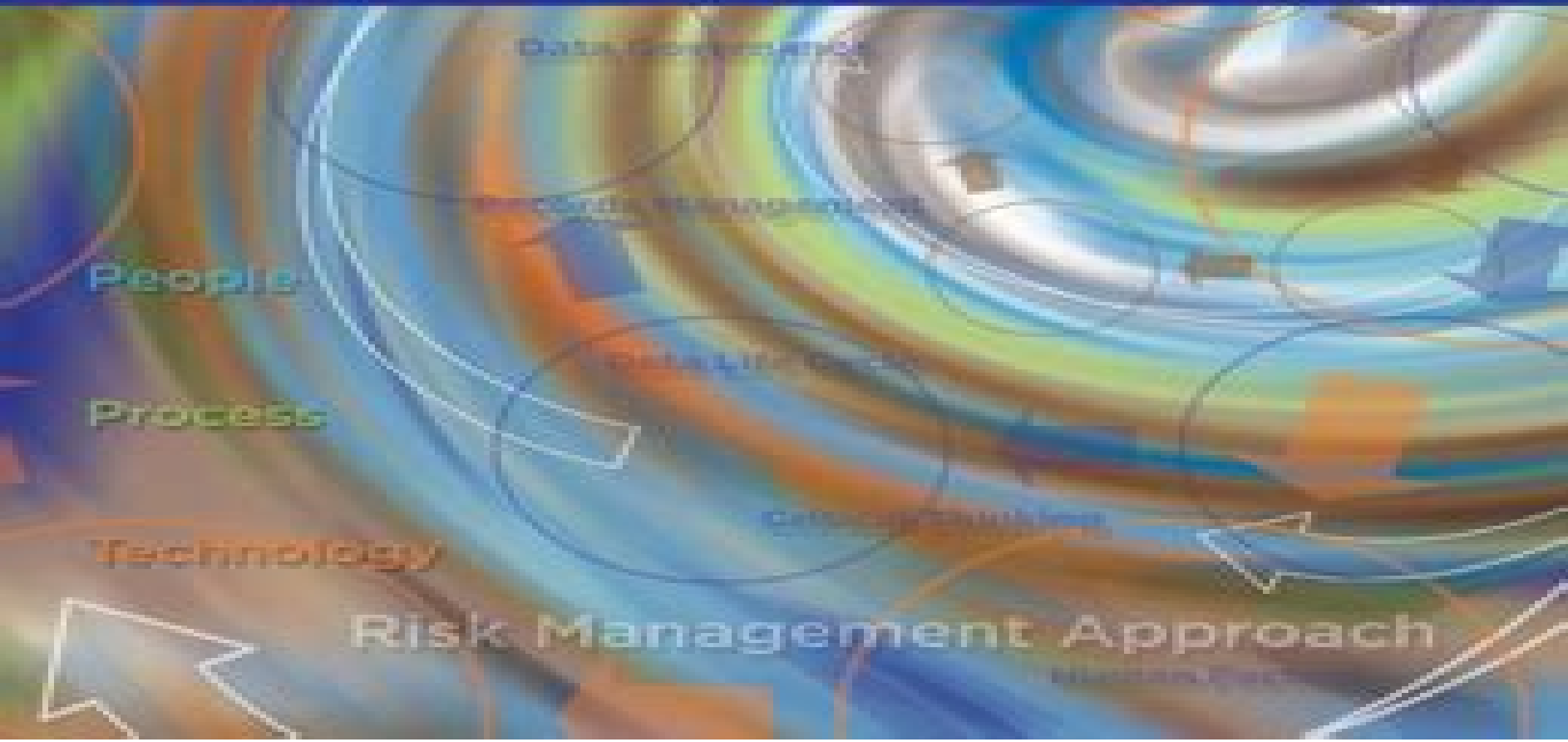


Records and Data Integrity GUIDE



Gamp Records Data Integrity Ispe

Orlando López

A red circular graphic with a gradient, appearing as a semi-circle or a partial circle, located to the right of the name bar.

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ISPE GAMP Records and Data Integrity Guide ,2017 ISPE GAMP Records and Data Integrity Guide ,2017 ISPE GAMP® RDI Good Practice Guide Ispe,2019-06-07 *Ensuring the Integrity of Electronic Health Records* Orlando López,2020-12-21 Data integrity is a critical aspect to the design implementation and usage of any system which stores processes or retrieves data The overall intent of any data integrity technique is the same ensure data is recorded exactly as intended and upon later retrieval ensure the data is the same as it was when originally recorded Any alternation to the data is then traced to the person who made the modification The integrity of data in a patient s electronic health record is critical to ensuring the safety of the patient This book is relevant to production systems and quality control systems associated with the manufacture of pharmaceuticals and medical device products and updates the practical information to enable better understanding of the controls applicable to e records The book highlights the e records suitability implementation and associated risk assessed controls and e records handling The book also provides updated regulatory standards from global regulatory organizations such as MHRA Medicines and Healthcare Products Regulatory Agency UK FDA Food and Drug Administration US National Medical Products Association China TGA Therapeutic Goods Administration Australia SIMGP Russia State Institute of Medicines and Good Practices and the World Health Organization to name a few **Data Integrity in Pharmaceutical and Medical Devices Regulation Operations** Orlando Lopez,2016-11-03 Data integrity is fundamental in a pharmaceutical and medical devices quality system This book provides practical information to enable compliance with data integrity while highlighting and efficiently integrating worldwide regulation into the subject The ideas presented in this book are based on many years experience in regulated industries in various computer systems development maintenance and quality functions In addition to case studies a practical approach will be presented to increase efficiency and to ensure that the design and testing of the data integrity controls are correctly achieved **Good Manufacturing Practices for Pharmaceuticals, Seventh Edition** Graham P. Bunn,2019-02-04 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 Data Integrity and Data Governance R. D. McDowall,2018-11-09 This book provides practical and detailed advice on how to implement data governance and data integrity for regulated analytical laboratories working in the pharmaceutical and allied industries 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.

GMP im Labor Nadine Frankenberg, 2022-07-15

GMP im Labor: Der perfekte Leitfaden für Neulinge und Quereinsteigerinnen zur Etablierung eines GMP-konformen Qualitätssystems mit besonderem Augenmerk auf die speziellen Bedürfnisse im Labor. Good Manufacturing Practice (GMP) oder gute Herstellungspraxis ist ein System zur Qualitätssicherung von Herstellungsprozessen und Produkten basierend auf nationalen und internationalen Gesetzen. Dabei beziehen sich die Richtlinien auf Produktionsabläufe und Umgebung in der Herstellung von Arzneimitteln und Wirkstoffen, aber auch bei Kosmetika, Lebens- und Futtermitteln. GMP im Labor beschäftigt sich mit der Umsetzung von GMP-Anforderungen in der Laborpraxis und präsentiert eine Grundlage für die Etablierung eines GMP-konformen Qualitätssystems. Besonders nützlich für Einsteigerinnen werden die speziellen Bedürfnisse im Laboralltag detailliert beleuchtet und praktische Lösungsvorschläge geboten. Dabei wird genauer auf die gesetzlichen Grundlagen und Abgrenzung zu anderen Systemen (GLP, GCP, ISO etc.) eingegangen und die verschiedenen Punkte eines Qualitätssystems wie etwa Dokumentation, Validierung und Risikomanagement beleuchtet. Des Weiteren werden die fundamentalen Prozesse in einem GMP-konformen Qualitätssystem wie etwa Gerätequalifizierung, Abweichungen und Selbstinspektionen behandelt und mit praktischen Lösungsvorschlägen präsentiert. Dringend benötigt: Das einzige Buch, das einen umfassenden und doch komprimierten Einblick in die komplexe GMP-Thematik bietet. Praxisnah. Es wird besondere Rücksicht auf die speziellen Bedürfnisse im Labor genommen und bietet praktische Lösungsvorschläge. Leitfaden, der die notwendigen Grundlagen und dient als Leitfaden zur Etablierung eines GMP-konformen Qualitätssystems. GMP im Labor richtet sich an Studierende in Bachelor- und Masterstudiengängen, Doktorandinnen, Naturwissenschaftlerinnen sowie Mitarbeiterinnen in Laboratorien und in der Industrie.

Validation of Chromatography Data Systems Robert D McDowall, 2016-11-23

Guiding chromatographers working in regulated industries and helping them to validate their chromatography data systems to meet data integrity, business and regulatory needs. This book is a detailed look at the life cycle and documented evidence required to ensure a system is fit for purpose throughout the lifecycle. Initially providing the regulatory data integrity and system life cycle requirements for computerised system validation, the book then develops into a guide on planning, specifying, managing risk, configuring and testing a chromatography data system before release. This is followed by operational aspects such as training, integration and IT support, and finally retirement. All areas are discussed in detail with case studies and practical examples provided as appropriate. The book has been carefully written and is right up to date, including recently released FDA data integrity

guidance It provides detailed guidance on good practice and expands on the first edition making it an invaluable addition to a chromatographer's book shelf **EU Annex 11 Guide to Computer Validation Compliance for the Worldwide Health Agency GMP** Orlando Lopez, 2015-04-06 Good Manufacturing Practice GMP ensures medicinal products are produced consistently and controlled to the quality standards appropriate for their intended use and as required by product specifications or marketing authorization Annex 11 details the European Medicines Agency EMA GMP requirements for computer systems The purpose of Annex 11 is **Understanding Pharmaceutical Standards and Regulations** Navneet Sharma, Vikesh Kumar Shukla, Sandeep Arora, 2025-06-24 This unique resource provides a comprehensive guide to the evolving regulations and standards which govern the international pharmaceutical industry Featuring clear explanations of the latest regulations as well as insights and strategies to maintain compliance the book covers the key principles of best practice for laboratory research manufacturing and distribution It also offers strategies to navigate the intricacies of different regulatory environments so that pharmaceutical companies can operate internationally avoiding the potentially costly risk of violations Detailed and holistic the book is an essential resource to pharmaceutical researchers and manufacturers as well as an important resource for students and scholars in the field **Pharmaceutical Computer Systems Validation** Guy Wingate, 2016-04-19 Thoroughly revised to include the latest industry developments the Second Edition presents a comprehensive overview of computer validation and verification principles and how to put them into practice To provide the current best practice and guidance on identifying and implementing improvements for computer systems the text extensively reviews regulations of pharmaceuticals healthcare products blood processing medical devices clinical systems and biotechnology Ensuring that organizations transition smoothly to the new system this guide explains how to implement the new GMP paradigm while maintaining continuity with current practices In addition all 24 case studies from the previous edition have been revised to reflect the new system **Pharmaceutical Regulatory Affairs** Nimisha Srivastava, Neeraj Mishra, Sumel Ashique, Bharanitharan Rajendran, 2025-12-26 This book provides concepts procedures guidelines and regulatory affairs in drug development Pharmaceutical Regulatory Affairs Principles and Practices begins with a detailed overview of the drug development life cycle from initial discovery and preclinical research to clinical trials and market approval addressing scientific regulatory and ethical considerations at each stage The book covers the evolution of global trade agreements like the General Agreement on Tariffs and Trade GATT and the World Trade Organization's WTO impact on pharmaceuticals highlighting issues surrounding pharmaceutical patents and intellectual property rights It discusses the importance of the Scale Up and Post Approval Changes SUPAC guidelines in ensuring quality and consistency in drug manufacturing post approval and examines the World Health Organization's WHO guidelines on technology development and transfer The fundamentals of regulatory affairs are covered emphasizing the roles and responsibilities of regulatory professionals The book provides an in depth look at regulatory frameworks of major agencies worldwide including the

Central Drugs Standard Control Organization CDSCO in India the Food and Drug Administration FDA in the US the European Medicines Agency EMA in the EU the Therapeutic Goods Administration TGA in Australia the Pharmaceuticals and Medical Devices Agency PMDA in Japan Health Canada and regulatory authorities in emerging markets It also addresses the international regulatory landscape for medical devices and reviews foundational pharmaceutical regulations Additionally the text explores regulatory guidelines for clinical testing including the roles and responsibilities under pharmaceutical legislation principles of bioethics and biosafety the digital transformation in clinical trials and the critical role of pharmacovigilance The book concludes with an examination of the global regulatory scenario for pharmaceutical excipients providing a detailed roadmap through the complexities of drug development regulatory compliance and global standards This book is valuable for professionals researchers and students of pharmaceutical sciences

WHO Expert Committee on Specifications for Pharmaceutical Preparations World Health Organization, 2024-04-26 The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines and provision of global regulatory tools The Expert Committee develops standards through worldwide consultation and an international consensus building process The following new guidance texts were adopted and recommended for use WHO good manufacturing practices for excipients used in pharmaceutical products revision IAEA WHO good manufacturing practices for in house cold kits for radiopharmaceutical preparations new WHO good practices for pharmaceutical quality control laboratories revision WHO UNFPA female condom generic specification new WHO Biowaiver List proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate release updated solid oral dosage forms WHO guideline on Biopharmaceutics Classification System based biowaivers revision and Multisource generic pharmaceutical products guidelines on registration requirements to establish interchangeability republished All of the above are included in this report and recommended for implementation

Quality assurance of pharmaceuticals: a compendium of guidelines and related materials, tenth edition. Volume 1. Good practices and related regulatory guidance World Health Organization, 2024-10-24 This publication represents a significant achievement in our ongoing effort to ensure that everyone can reach the highest possible level of health Over the last three decades we have seen the transformation of the pharmaceutical industry and the increasing intricacy of the product life cycle The challenges we face today are very different from those we faced when the first edition of this Compendium was published in 1997 However our mission remains the same to promote health keep the world safe and serve the vulnerable The new edition reflects the collective knowledge and expertise of countless professionals who have worked diligently to develop revise and implement WHO guidelines for pharmaceuticals This includes experts from WHO Member States our Expert Advisory Panels and Expert Committees on Specifications for Pharmaceutical Preparations and other organizations and has undergone extensive consultation with stakeholders worldwide This Compendium covers development through manufacturing and

quality control to post marketing surveillance It provides a comprehensive framework for quality assurance that is both strong and flexible capable of meeting the requirements of a rapidly changing global health landscape The 10th edition is a collection of knowledge and tools for empowerment enabling all stakeholders in the pharmaceutical industry to make informed decisions that prioritize patient safety and well being

Pharmaceutical and Medical Devices Manufacturing

Computer Systems Validation Orlando Lopez,2018-10-02 Validation of computer systems is the process that assures the formal assessment and report of quality and performance measures for all the life cycle stages of software and system development its implementation qualification and acceptance operation modification requalification maintenance and retirement PICS CSV PI 011 3 It is a process that demonstrates the compliance of computer systems functional and non functional requirements data integrity regulated company procedures and safety requirements industry standards and applicable regulatory authority s requirements Compliance is a state of being in adherence to application related standards or conventions or regulations in laws and similar prescriptions This book which is relevant to the pharmaceutical and medical devices regulated operations provides practical information to assist in the computer validation to production systems while highlighting and efficiently integrating worldwide regulation into the subject A practical approach is presented to increase efficiency and to ensure that the validation of computer systems is correctly achieved

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

Handbook of Validation in Pharmaceutical Processes, Fourth Edition James Agalloco, Phil DeSantis, Anthony Grilli, Anthony Pavell, 2021-10-28 Revised to reflect significant advances in pharmaceutical production and regulatory expectations Handbook of Validation in Pharmaceutical Processes Fourth Edition examines and blueprints every step of the validation process needed to remain compliant and competitive This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions As the industry's leading source for validation of sterile pharmaceutical processes for more than 10 years this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio pharmaceutical production processes Handbook of Validation in Pharmaceutical Processes Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals Key Features Provides an in depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program and suggests the newest and most advanced solutions Explores distinctive and specific process steps and identifies critical process control points to reach acceptable results New chapters include disposable systems combination products nano technology rapid microbial methods contamination control in non sterile products liquid chemical sterilization and medical device manufacture

Computer Systems Validation Guy Wingate, 2003-12-18 Both pervasive and ubiquitous computerized systems are now an integral component of every corporate strategy in pharmaceutical and healthcare companies However when technology is combined with high risk public safety projects or the production and control of life saving medicines or devices it is necessary to ensure that it is reliable quality

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