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ISPE GAMP® Good Practice Guide-Ispe 2010-03-24
GAMP Good Practice Guide- 2005
A Risk-based Approach to Operation of GxP Computerized Systems- 2009
Data Integrity and Data Governance-R D McDowall 2018-11-06 Data integrity is the hottest topic in the pharmaceutical industry. Global regulatory agencies have issued guidance, after guidance after guidance in the past few years, most of which does not offer practical advice on how to implement policies, procedures and processes to ensure integrity. These guidances state what but not how. Additionally, key stages of analysis that impact data integrity are omitted entirely. The aim of this book is to provide practical and detailed help on how to implement data integrity and data governance for regulated analytical laboratories working in or for the pharmaceutical industry. It provides clarification of the regulatory issues and trends, and gives practical methods for meeting regulatory requirements and guidance. Using a data integrity model as a basis, the principles of data integrity and data governance are expanded into practical steps for regulated laboratories to implement. The author uses case study examples to illustrate his points and provides instructions for applying the principles of data integrity and data governance to individual laboratory needs. This book is a useful reference for analytical chemists and scientists, management and senior management working in regulated laboratories requiring either an understanding about data integrity or help in implementing practical solutions. Consultants will also benefit from the practical guidance provided.
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 r
Practical Pharmaceutical Engineering-Gary Prager 2018-12-18 A practical guide to all key the elements of pharmaceuticals and biotech manufacturing and design Engineers working in the pharmaceutical and biotech industries are routinely called upon to handle operational issues outside of their fields of expertise. Traditionally the competencies required to fulfill those tasks were achieved piecemeal, through years of self-teaching and on-the-job experience—until now. Practical Pharmaceutical Engineering provides readers with the technical information and tools needed to deal with most common engineering issues that can arise in the course of day-to-day operations of pharmaceutical/biotech research and manufacturing. Engineers working in pharma/biotech wear many hats. They are involved in the conception, design, construction, and operation of research facilities and manufacturing plants, as well as the scale-up, manufacturing, packaging, and labeling processes. They have to implement FDA regulations, validation assurance, quality control, and Good Manufacturing Practices (GMP) compliance measures, and to maintain a high level of personal and environmental safety. This book provides readers from a range of engineering specialties with a detailed blueprint and the technical knowledge needed to tackle those critical responsibilities with confidence. At minimum, after reading this book, readers will have the knowledge needed to constructively participate in contractor/user briefings. Provides pharmaceutical industry professionals with an overview of how all the parts fit together and a level of expertise that can take years of on-the-job experience to acquire Addresses topics not covered in university courses but which are crucial to working effectively in the pharma/biotech industry Fills a gap in the literature, providing important information on pharmaceutical operation issues required for meeting regulatory guidelines, plant support design, and project engineering Covers the basics of HVAC systems, water systems, electric systems, reliability, maintainability, and quality assurance, relevant to pharmaceutical engineering Practical Pharmaceutical Engineering is an indispensable “tool of the trade” for chemical engineers, mechanical engineers, and pharmaceutical engineers employed by pharmaceutical and biotech companies, engineering firms, and consulting firms. It also is a must-read for engineering students, pharmacy students, chemistry students, and others considering a career in pharmaceuticals.
Method Validation in Pharmaceutical Analysis-Joachim Ermer 2006-03-06 Adopting a practical approach, the authors provide a detailed interpretation of the existing regulations (GMP, ICH), while also discussing the appropriate calculations, parameters and tests. The book thus allows readers to validate the analysis of pharmaceutical compounds while complying with both the regulations as well as the industry demands for robustness and cost effectiveness. Following an introduction to the basic parameters and tests in pharmaceutical validation, including specificity, linearity, range, precision, accuracy, detection and quantitation limits, the text focuses on a life-cycle approach to validation and the integration of validation into the whole analytical quality assurance system. The whole is rounded off with a look at future trends. With its first-hand knowledge of the industry as well as regulating bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmaceutists, QA officers, and public authorities.
Practical Pharmaceutics-Yvonne Bouwman-Boer 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.
Good Computer Validation Practices-Teri Stokes 1994-05-31 This sensible text on computer systems validation examines the regulatory and practical issues of computer validation from a global perspective and provides a common-sense approach to getting the job done. Combining the insights of an internationally respected group of computer systems specialists, healthcare industry professionals, and a regulator, it provides SOPs, checklists, and tips to make global computer validation an obtainable goal. Topics and concerns detailed in the text span the breadth of issues and influences imposed upon computer validation by worldwide GCP, GLP, and GMP requirements and provide an approach that meets the regulatory and real-world needs of the healthcare manufacturing and research industries.
WHO Expert Committee on Specifications for Pharmaceutical Preparations-WHO Expert Committee on Specifications for Pharmaceutical Preparations. Meeting 2016 The World Health Organization (WHO) Expert Committee on Specifications for Pharmaceutical Preparations advises the Director-General of WHO in the area of medicines quality assurance. It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality, safety and efficacy in all WHO Member States. Its advice is developed through a broad consensus-building process and covers all areas of quality assurance of medicines, from their development to their distribution to patients. In the area of quality control, the Expert Committee reviewed new and revised specifications and general texts for inclusion in The International Pharmacopoeia, and received the annual report of the European Directorate for the Quality of Medicines &

HealthCare (EDQM), the custodian centre for International Chemical Reference Substances (ICRS). The Committee adopted a number of monographs, general texts and ICRS. It noted the report on Phase 6 of the External Quality Assurance Assessment Scheme (EQAAS) and on new approaches to ensure sustainability of this scheme through user fees. The Committee further acknowledged the progress of good pharmacopoeial practices (GPhP), and adopted the document on GPhP which was prepared by the consecutive international meetings of world pharmacopoeias. In the various quality assurance-related areas the Expert Committee was presented with a number of new and revised guidelines related to good manufacturing practices (GMP), distribution and trade of pharmaceuticals and regulatory practice. It adopted 10 guidelines as listed below as well as 22 new specifications and general texts for inclusion in The International Pharmacopoeia. The Committee took note of ongoing work to promote collaboration and information exchange through the good regulatory practice project and welcomed the development of a comprehensive set of guidelines for all national regulatory authorities through this project.
The Theory and Practice of Hell-Eugen Kogon 2006-09-19 By the spring of 1945, the Second World War was drawing to a close in Europe. Allied troops were sweeping through Nazi Germany and discovering the atrocities of SS concentration camps. The first to be reached intact was Buchenwald, in central Germany. American soldiers struggled to make sense of the shocking scenes they witnessed inside. They asked a small group of former inmates to draft a report on the camp. It was led by Eugen Kogon, a German political prisoner who had been an inmate since 1939. The Theory and Practice of Hell is his classic account of life inside. Unlike many other books by survivors who published immediately after the war, The Theory and Practice of Hell is more than a personal account. It is a horrific examination of life and death inside a Nazi concentration camp, a brutal world of a state within state, and a society without law. But Kogon maintains a dispassionate and critical perspective. He tries to understand how the camp works, to uncover its structure and social organization. He knew that the book would shock some readers and provide others with gruesome fascination. But he firmly believed that he had to show the camp in honest, unflinching detail. The result is a unique historical document--a complete picture of the society, morality, and politics that fueled the systematic torture of six million human beings. For many years, The Theory and Practice of Hell remained the seminal work on the concentration camps, particularly in Germany. Reissued with an introduction by Nikolaus Waschmann, a leading Holocaust scholar and author of Hilter's Prisons, this important work now demands to be re-read.
Validation of Chromatography Data Systems-Robert D. McDowall 2016-11-25 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.
Validation of Chromatography Data Systems-Robert 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.
ISPE Good Practice Guide-Ispe 2019-03-25
Fundamentals of Clinical Data Science-Pieter Kubben 2018-12-21 This open access book comprehensively covers the fundamentals of clinical data science, focusing on data collection, modelling and clinical applications. Topics covered in the first section on data collection include: data sources, data at scale (big data), data stewardship (FAIR data) and related privacy concerns. Aspects of predictive modelling using techniques such as classification, regression or clustering, and prediction model validation will be covered in the second section. The third section covers aspects of (mobile) clinical decision support systems, operational excellence and value-based healthcare. Fundamentals of Clinical Data Science is an essential resource for healthcare professionals and IT consultants intending to develop and refine their skills in personalized medicine, using solutions based on large datasets from electronic health records or telemonitoring programmes. The book’s promise is “no math, no code”and will explain the topics in a style that is optimized for a healthcare audience.
Pharmaceutical Isolators-Brian Midcalf 2004 Pharmaceutical Isolators is a new indispensable guide to the design, construction, commissioning, maintenance, use and monitoring of pharmaceutical isolators. The current validation protocols are explained and the book includes some useful technical appendices. Written through the combined technical expertise of the Isolator Working Party, this new title will assist both experienced and new users to understand and manage this technology. The book will also be a useful reference source for auditors, inspectors and all those involved in standard setting and monitoring.
Process Validation in Manufacturing of Biopharmaceuticals, Third Edition-Anurag S. Rathore 2012-05-09 Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in final form on January 24, 2011. The book also provides guidelines and current practices, as well as industrial case studies illustrating the different approaches that can be taken for successful validation of biopharmaceutical processes. Case studies include Process validation for membrane chromatography Leveraging multivariate analysis tools to qualify scale-down models A matrix approach for process validation of a multivalent bacterial vaccine Purification validation for a therapeutic monoclonal antibody expressed and secreted by Chinese Hamster Ovary (CHO) cells Viral clearance validation studies for a product produced in a human cell line A much-needed resource, this book presents process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing, including chromatography, chemical modification reactions, ultrafiltration, and microfiltration. It also provides practical methods to test raw materials and in-process samples. Stressing the importance of taking a risk-based approach towards computerized system compliance, this book will help you and your team ascertain process validation is carried out and exceeds expectations.
Pharmaceutical Manufacturing Handbook-Shayne Cox Gad 2008-04-04 With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.
Analytical Method Validation and Instrument Performance Verification-Chung Chow Chan 2004-04-23 Validation describes the procedures used to analyze pharmaceutical products so that the data generated will comply with the requirements of regulatory bodies of the US, Canada, Europe and Japan. Calibration of Instruments describes the process of fixing, checking or correcting the graduations of instruments so that they comply with those regulatory bodies. This book provides a thorough explanation of both the fundamental and practical aspects of biopharmaceutical and bioanalytical methods validation. It teaches the proper procedures for using the tools and analysis methods in a regulated lab setting. Readers will learn the appropriate procedures for calibration of laboratory instrumentation and validation of analytical methods of analysis. These procedures must be executed properly in all regulated laboratories, including pharmaceutical and biopharmaceutical laboratories, clinical testing laboratories (hospitals, medical offices) and in food and cosmetic testing laboratories.
Practical Approaches to Method Validation and Essential Instrument Qualification-Chung Chow Chan 2011-03-01 Practical approaches to ensure that analytical methods and instruments meet GMP standards and requirements Complementing the authors' first book, Analytical Method Validation and Instrument Performance Verification, this new volume provides coverage of more advanced topics, focusing on additional and supplemental methods, instruments, and electronic systems that are used in pharmaceutical, biopharmaceutical, and clinical testing. Readers will gain new and valuable insights that enable them to avoid common pitfalls in order to seamlessly conduct analytical method validation as well as instrument operation qualification and performance verification. Part 1, Method Validation, begins with an overview of the book's risk-based approach to phase appropriate validation and instrument qualification; it then focuses on the strategies and requirements for early phase drug development, including validation of specific techniques and functions such as process analytical technology, cleaning validation, and validation of laboratory information management systems Part 2, Instrument Performance Verification, explores the underlying principles and techniques for verifying instrument performance—coverage includes analytical instruments that are increasingly important to the pharmaceutical industry, such as NIR spectrometers and particle size analyzers—and offers readers a variety of alternative approaches for the successful verification of instrument performance based on the needs of their labs At the end of each chapter, the authors examine important practical problems and share their solutions. All the methods covered in this book follow Good Analytical Practices (GAP) to ensure that reliable data are generated in compliance with

current Good Manufacturing Practices (cGMP). Analysts, scientists, engineers, technologists, and technical managers should turn to this book to ensure that analytical methods and instruments are accurate and meet GMP standards and requirements.
ISPE Baseline Guide-ISPE 1998-02-01
ISPE Good Practice Guide-Ispe 2019-01-24
OECD Series on Testing and Assessment Guidance Document on Good In Vitro Method Practices (GIVIMP)-OECD 2018-12-10 In the past several decades, there has been a substantial increase in the availability of in vitro test methods for evaluating chemical safety in an international regulatory context. To foster confidence in in vitro alternatives to animal testing, the test methods and conditions under which ...
Martin Chuzzlewit-Charles Dickens 1844
Becoming a Midwife in the 21st Century-Professor Ian Peate, OBE 2013-03-19 The NMC have produced standards of proficiency for pre registration midwifery education and those standards have been written in an “academic” language, for higher education institutions. Each student prior to being admitted to the profession must have achieved the proficiencies stated in the NMC publication. The purpose of this book is to provide students with material related to the standards of midwifery education. The students will be able to use the contents of this text and relate it to their own approved programme of midwifery study, as their programme of study would have had to comply with NMC’s requirements. It will help student midwives appreciate how their own programmes have been designed, and why they are required to study and understand some of the subjects they are, or will be studying.
ISPE Good Practice Guide-International Society for Pharmaceutical Engineering 2008
ISPE Good Practice Guide- 2011
Data Integrity and Data Governance-R D McDowall 2018-11-06 Data integrity is the hottest topic in the pharmaceutical industry. Global regulatory agencies have issued guidance, after guidance after guidance in the past few years, most of which does not offer practical advice on how to implement policies, procedures and processes to ensure integrity. These guidances state what but not how. Additionally, key stages of analysis that impact data integrity are omitted entirely. The aim of this book is to provide practical and detailed help on how to implement data integrity and data governance for regulated analytical laboratories working in or for the pharmaceutical industry. It provides clarification of the regulatory issues and trends, and gives practical methods for meeting regulatory requirements and guidance. Using a data integrity model as a basis, the principles of data integrity and data governance are expanded into practical steps for regulated laboratories to implement. The author uses case study examples to illustrate his points and provides instructions for applying the principles of data integrity and data governance to individual laboratory needs. This book is a useful reference for analytical chemists and scientists, management and senior management working in regulated laboratories requiring either an understanding about data integrity or help in implementing practical solutions. Consultants will also benefit from the practical guidance provided.
21 CFR Part 11-Orlando López 2004-01-15 Covering regulatory requirements stipulated by the FDA, this book delineates the organization, planning, verification, and documentation activities and procedural controls required for compliance with worldwide computer systems validation regulations. The author introduces supporting technologies such as encryption and digital signatures and places
Sheet Metal Workers' Manual-Louis Broemel 1918
Handbook of Computer and Computerized System Validation for the Pharmaceutical Industry-Stephen Robert Goldman 2003 The Curse is a tale of horror and suspense. It tells the story of a group of common people fleeing from their daunting past, and their struggle for survival. It shows how man's evil transgression and guilty conscience will literally follow him to his death, and perhaps even cause it. It also tells of how one man's fault could not only lead to his suffering, but also to those he holds dear. The tale begins when a group of six daring, young teenage boys plan an upcoming Halloween prank. The mastermind of the six, Jack Boomer, decides to try something different and more dangerous than the previous years. He plans to blow up the shack with a pile of firecrackers. Four of his cronies immediately agree with his plan; however, Ted Dot, the pessimistic, redheaded teenager, is reluctant. He tries to explain to them the consequences of being caught. The other five are not dissuaded from the idea, and they somehow talk Ted into going along with them. Once all six confirm their new idea, they gather their materials. On Halloween night, they set out to execute their plan. Everything works out perfectly for them, and the shack soon erupts into a blazing fury. Their celebration is short-lived, though. From out of the forest appears a mysterious old woman. Her ethnicity is unknown, her origin is unknown, why she is bald, wears a polka-dotted skullcap, wraps her feet in construction paper for shoes, and wears a mud-stained, dark brown dress is all unknown, and it remains unknown throughout the story. The entire time she is simply referred to as the "old woman." In her hand she carries a long, gnarled staff the most significant figure in the entire piece. This stranger claims that the destroyed shack was her home, and she doesn't give the six teenagers a chance to explain. She unleashes her fury and invokes a horrible curse upon them. From then on, it is the ultimate survival story for the six boys. Not only do they suffer the consequences, but also their family members and other best friends are part of the ordeal. And, the "old woman" claims, the terrible conflict does not cease until all six of them have been wiped out.

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