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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.
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.
Validation, Verification, and Testing of Computer Software - W. Richards Adrion 1981

Drug Stability and Chemical Kinetics - Muhammad Sajid Hamid Akash

2020-11-01

This book comprehensively reviews drug stability and chemical kinetics: how external factors can influence the stability of drugs, and the reaction rates that trigger these effects. Explaining the important theoretical concepts of drug stability and chemical kinetics, and providing numerous examples in the form of illustrations, tables and calculations, the book helps readers gain a better understanding of the rates of reactions, order of reactions, types of degradation and how to prevent it, as well as types of stability studies. It also offers insights into the importance of the rate at which the drug is degraded and/or decomposed under various external and internal conditions, including temperature, pH, humidity and light. This book is intended for researchers, PhD students and scientists working in the field of pharmacy, pharmacology, pharmaceutical chemistry, medicinal chemistry and biopharmaceutics.

Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Orange Guide) 2017 - Medicines and Healthcare products Regulatory Agency 2017-01-06

Commonly known as the Orange Guide, this book remains an essential reference for all manufacturers and distributors of medicines in Europe. It provides a single authoritative source of European and UK guidance, information and legislation relating to the manufacture and distribution of human medicines.

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.

The Use of Drugs in Psychiatry - John Lewis Crammer 1978

New Antiepileptic Drug Development - Jacqueline A. French 1993

This volume represents the input of individuals involved in aspects of antiepileptic drug development and discusses how the process can be improved upon and drug evaluation made more effective. Topics range from the theoretical such as ethical issues, to the practical such as study budgets.

Handbook of Stability Testing in Pharmaceutical Development - Kim Huynh-Ba 2008-11-16
This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.
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.
Guidance for Preparing Standard Operating Procedures (SOPs). - 2001

Validation, Verification, and Testing for the Individual Programmer - Martha A. Branstad 1980

Handbook for Good Clinical Research Practice (GCP) - World Health Organization 2005

Contract Law in Australia - John W. Carter 1996

The Sentinel CEO - William G. Parrett 2007-08-17
A forward-thinking approach to addressing corporate security challenges after 9/11 The Sentinel CEO takes a proactive look-from the perspective of top executives-at the ways business has changed since 9/11. Filled with in-depth interviews with America's leading CEOs, security experts, public officials, and academics, this essential tool underscores how a business's core values can help it address and recover from unforeseen threats. A revealing examination of the subtle and profound ways in which American business has changed, The Sentinel CEO explores a variety of risks facing businesses of all sizes that operate in a global environment. This important book includes timely discussion of growing anti-American sentiments worldwide, the avian flu, and the impact of tougher immigration enforcement on the talent pool in the United States.
Pharmaceutical Quality Systems - Oliver Schmidt 2000-04-30
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
Pharmaceutical Analysis for Small Molecules - Behnam Davani 2017-08-01
A comprehensive introduction for scientists engaged in new drug development, analysis, and approvals Each year the pharmaceutical industry worldwide recruits thousands of recent science graduates—especially chemistry, analytical chemistry, pharmacy, and pharmaceutical majors—into its ranks. However, because of their limited background in pharmaceutical analysis most of those new recruits find making the transition from academia to industry very difficult. Designed to assist both recent graduates, as well as experienced chemists or scientists with limited regulatory, compendial or pharmaceutical analysis

background, make that transition, Pharmaceutical Analysis for Small Molecules is a concise, yet comprehensive introduction to the drug development process and analysis of chemically synthesized, small molecule drugs. It features contributions by distinguished experts in the field, including editor and author, Dr. Behnam Davani, an analytical chemist with decades of technical management and teaching experience in compendial, regulatory, and industry. This book provides an introduction to pharmaceutical analysis for small molecules (non-biologics) using commonly used techniques for drug characterization and performance tests. The driving force for industry to perform pharmaceutical analyses is submission of such data and supporting documents to regulatory bodies for drug approval in order to market their products. In addition, related required supporting studies including good laboratory/documentation practices including analytical instrument qualification are highlighted in this book. Topics covered include: Drug Approval Process and Regulatory Requirements (private standards) Pharmacopeias and Compendial Approval Process (public standards) Common methods in pharmaceutical analysis (typically compendial) Common Calculations for assays and impurities and other specific tests Analytical Method Validation, Verification, Transfer Specifications including how to handle out of specification (OOS) and out of trend (OOT) Impurities including organic, inorganic, residual solvents and elemental impurities Good Documentation Practices for regulatory environment Management of Analytical Laboratories Analytical Instrument Qualifications including IQ, OQ, PQ and VQ Due to global nature of pharmaceutical industry, other topics on both regulatory (ICH) and Compendial harmonization are also highlighted. Pharmaceutical Analysis for Small Molecules is a valuable working resource for scientists directly or indirectly involved with the drug development process, including analytical chemists, pharmaceutical scientists, pharmacists, and quality control/quality assurance professionals. It also is an excellent text/reference for graduate students in analytical chemistry, pharmacy, pharmaceutical and regulatory sciences.

A Handbook of Job Aids - Allison Rossett 1991-06-15

You can save time and money and improve work performance throughout your organization--with the help of job aids. Job aids make it easier to perform tasks by providing access to information, procedures, policies, and examples. These sources of information make it easier to perform tasks by providing access to information, examples, policies, and procedures. Paired with training and supervisory support, job aids play a key role in introducing new work technologies and systems. The authors clearly instruct you how to create seven job aid formats: step job aids worksheets arrays decision tables flow charts checklists combination job aids. Learn about every step of job aid implementation: Identifying the problem Choosing the format and the medium Preparing the job aid draft Piloting the job aid Making revisions to the job aid Managing the job aid With this guide, you will: Establish new and expanded ways of defining job aids Offer approaches that broaden opportunities to employ job aids Present strategies to improve the quality of the job aids that are developed...and much more! The authors reinforce each job aid with a case study that shows just how the job aid can be used. Without job aids, employees often don't know where to find information. They can waste their own time--and the time of others--seeking answers. With effective job aids in place, employees will stop wondering where to go: the job aids will provide the information they need. Job aids save huge amounts of time and money. Any trainer or manager seeking to improve organizational effectiveness should look no further--A Handbook of Job Aids is the most comprehensive job aid source available.

2185good automated laboratory practices principles and guidance to regulations for ensuring data integrity in automated laboratory operations with implementation guidance. -

Introduction to Pharmacokinetics and Pharmacodynamics - Thomas N. Tozer 2006

This unique text helps students and healthcare professionals master the fundamentals of pharmacokinetics and pharmacodynamics. Written by distinguished international experts, it provides readers with an introduction to the basic principles underlying the establishment and

individualization of dosage regimens and their optimal use in drug therapy. Up-to-date examples featuring currently prescribed drugs illustrate how pharmacokinetics and pharmacodynamics relate to contemporary drug therapy. Study problems at the end of each chapter help students and professionals gain a firm grasp of the material covered within the text.

Nanobiosensors - Alexandru Grumezescu 2016-12-20

Nanobiosensors: Nanotechnology in the Agri-Food Industry, Volume 8, provides the latest information on the increasing demand for robust, rapid, inexpensive, and safe alternative technologies that monitor, test, and detect harmful or potentially dangerous foods. Due to their high sensitivity and selectivity, nanobiosensors have attracted attention for their use in monitoring not only biological contaminants in food, but also potential chemical and physical hazards. This book offers a broad overview regarding the current progress made in the field of nanosensors, including cutting-edge technological progress and the impact of these devices on the food industry. Special attention is given to the detection of microbial contaminants and harmful metabolotes, such as toxins and hormones, which have a great impact on both humans and animal health and feed. Includes the most up-to-date information on nanoparticles based biosensors and quantum dots for biological detection Provides application methods and techniques for research analysis for bacteriological detection and food testing Presents studies using analytical tools to improve food safety and quality analysis

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.

Modern HPLC for Practicing Scientists - Michael W. Dong 2016-04-06

A comprehesive yet concise guide to Modern HPLC Written for practitioners by a practitioner, Modern HPLC for Practicing Scientists is a concise text which presents the most important High-Performance Liquid Chromatography (HPLC) fundamentals, applications, and developments. It describes basic theory and terminology for the novice, and reviews relevant concepts, best practices, and modern trends for the experienced practitioner. Moreover, the book serves well as an updated reference guide for busy laboratory analysts and researchers. Topics covered include: HPLC operation Method development Maintenance and troubleshooting Modern trends in HPLC such as quick-turnaround and "greener" methods Regulatory aspects While broad in scope, this book focuses particularly on reversed-phase HPLC, the most common separation mode, and on applications for the pharmaceutical industry, the largest user segment. Accessible to both novice and intermedate HPLC users, information is delivered in a straightforward manner illustrated with an abundance of diagrams, chromatograms, tables, and case studies, and supported with selected key references and Web resources. With intuitive explanations and clear figures, Modern HPLC for Practicing Scientists is an essential resource for practitioners of all levels who need to understand and utilize this versatile analytical technology.

Clinical Pharmacist's Guide to Biostatistics and Literature Evaluation - Robert DiCenzo 2011

Whether you are interpreting the medical literature to optimize patient care, improve health outcomes, or generate hypothesis for research, an understanding of biostatistics is essential for success. Despite exposure to biostatistics in undergraduate and professional education, pharmacists tend to be less confident in their knowledge of biostatistics and their ability to interpret the medical literature than in their clinical skills. This book was developed to bolster the pharmacist's knowledge and confidence for using biostatistical tools for interpreting the literature. With material drawn from ACCP's renowned Pharmacotherapy Self-Assessment Program (PSAP) and the live pharmacotherapy preparatory course Updates in Therapeutics, editor Robert DiCenzo, Pharm.D., FCCP, BCPS, has designed this review to support pharmacists' preparation for the Pharmacotherapy and Ambulatory Care Board of Pharmacy Specialties (BPS) examinations.

European Immigration - Anna Triandafyllidou 2016-07-22

Fully updated and containing chapters on the new EU member states and

the attempt to form a common EU migration policy, this new edition of European Immigration: A Sourcebook provides a comprehensive overview of the trends and developments in migration in all EU countries. With chapters following a common structure to facilitate direct international comparisons, it not only examines the internal affairs of each member state, but also explores both migratory trends within the EU itself and the implications for European immigration of wider global events, including the Arab Spring and the world financial crisis.

ISPE Good Practice Guide - Ispe 2019-01-24

Pharmaceutical Stability Testing to Support Global Markets - Kim Huynh-Ba 2012-02-25

The International Conference of Harmonization (ICH) has worked on harnizing the stability regulations in the US, Europe, and Japan since the early 1990s. Even though the Stability Guidelines Q1A (R2) was issued over a decade ago, issues surrounding this arena continue to surface as the principles described in the guideline are applied to different technical concentrations. As a result, the stability community has continued to discuss concerns and find ways of harmonizing regulatory requirements, streamlining practices, improving processes in order to bring safe and effective medical supplies to the patients around the world. In 2007, the American Association of Pharmaceutical Scientists (AAPS) Stability Focus Group organized two workshops – the Stability Workshop and the Degradation Mechanism Workshop. These meetings attracted many industry scientists as well as representatives from several regulatory agencies in the world to discuss important topics related to pharmaceutical stability practices. Recognizing the importance of documenting these discussions and with the permission of AAPS, I have worked with speakers to assemble a collection of 30 articles from presentations given at these two meetings, mainly the Stability Workshop. I trust that this book will be beneficial to all of you in providing guidance and up-to-date information for building quality stability programs. v Freedom of our mind is Mother of all inventions.

GAMP Good Practice Guide - 2005-01-01

Criminology in Africa - Mwene Mushanga 2004-12-29

Criminology in Africa has been produced with contributions from leading African authors who have focussed on the various problems facing Africa today regarding crime and criminal justice, and they have, at the same time, put forward their ideas and suggestions for coming to terms with these massive problems.

Measuring Scholarly Impact - Ying Ding 2014-11-06

This book is an authoritative handbook of current topics, technologies and methodological approaches that may be used for the study of scholarly impact. The included methods cover a range of fields such as statistical sciences, scientific visualization, network analysis, text mining, and information retrieval. The techniques and tools enable researchers to investigate metric phenomena and to assess scholarly impact in new ways. Each chapter offers an introduction to the selected topic and outlines how the topic, technology or methodological approach may be applied to metrics-related research. Comprehensive and up-to-date, Measuring Scholarly Impact: Methods and Practice is designed for researchers and scholars interested in informetrics, scientometrics, and text mining. The hands-on perspective is also beneficial to advanced-level students in fields from computer science and statistics to information science.

International Pharmaceutical Law and Practice - Adrian Zahl 2021-11-26

Covers key pharmaceutical law topics in all of the major industrial countries and for each country discusses in detail: • Treaties and international law principles affecting patents, data exclusivity and other rights relating to pharmaceutical manufacture and sales • Patent procurement and the scope of patent protection afforded pharmaceutical subject matter • Substantive patentability requirements of novelty, utility and inventiveness • New drug approval process and supplementary approvals • Government price controls on pharmaceuticals and government drug payment plans • Obtaining an approval for a generic version of a drug • Compulsory Licensing

WHO Expert Committee on Specifications for Pharmaceutical

Preparations - World Health Organization 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 Queensland Legislation Handbook - 2009
The Queensland Legislation Handbook outlines relevant policies, recommendations, information, and procedures for the realisation of policy in the form of Acts of Parliament or subordinate legislation. The handbook is particularly designed to help departmental policy or instructing officers to work effectively with the Office of the Queensland Parliamentary Counsel (OQPC). This handbook outlines what is needed in drafting instructions for Acts of Parliament and subordinate legislation. Various other procedural requirements associated with the legislative development process are also included.
Production, Quality Control and Clinical Applications of Radiosynovectomy Agents - International Atomic Energy Agency 2021-08-31
Therapeutic radiopharmaceuticals play a major role in today's nuclear medicine with a positive impact on the diagnosis and treatment of diseases. One area of application is radiation synovectomy (RSV).
GAMP 5 - 2008

Data Governance and Data Management - Rupa Mahanti 2021-09-08
This book delves into the concept of data as a critical enterprise asset needed for informed decision making, compliance, regulatory reporting and insights into trends, behaviors, performance and patterns. With good data being key to staying ahead in a competitive market, enterprises capture and store exponential volumes of data. Considering the business impact of data, there needs to be adequate management around it to derive the best value. Data governance is one of the core data management related functions. However, it is often overlooked, misunderstood or confused with other terminologies and data management functions. Given the pervasiveness of data and the importance of data, this book provides comprehensive understanding of the business drivers for data governance and benefits of data governance, the interactions of data governance function with other data management functions and various components and aspects of data governance that can be facilitated by technology and tools, the distinction between data management tools and data governance tools, the readiness checks to perform before exploring the market to purchase a data governance tool, the different aspects that must be considered

when comparing and selecting the appropriate data governance technologies and tools from large number of options available in the marketplace and the different market players that provide tools for supporting data governance. This book combines the data and data governance knowledge that the author has gained over years of working in different industrial and research programs and projects associated with data, processes and technologies with unique perspectives gained through interviews with thought leaders and data experts. This book is highly beneficial for IT students, academicians, information management and business professionals and researchers to enhance their knowledge and get guidance on implementing data governance in their own data initiatives.

Good Manufacturing Practices for Pharmaceuticals - Joseph D. Nally 2016-04-19

With global harmonization of regulatory requirements and quality standards and national and global business consolidations ongoing at a fast pace, pharmaceutical manufacturers, suppliers, contractors, and distributors are impacted by continual change. Offering a wide assortment of policy and guidance document references and interpretations, this Sixth Edition is significantly expanded to reflect the increase of information and changing practices in CGMP regulation and pharmaceutical manufacturing and control practices worldwide. An essential companion for every pharmaceutical professional, this guide is updated and expanded by a team of industry experts, each member with extensive experience in industry or academic settings.

Llyn Foulkes - 2011

Quality Control in the Production of Radiopharmaceuticals - International Atomic Energy Agency 2018-11-30

Advances have led to the production of new radiopharmaceuticals and availability of new production routes. Various new diagnostic agents in the field (such as Ga-68 radiopharmaceuticals and generators) as well as therapeutic agents (such as alpha emitters) have been added to the clinician's menu. It is essential that radiopharmaceuticals are prepared within a robust quality control system encompassing materials and personnel, with adequate documentation, and continuous review of ongoing results. This publication provides guidelines and best practices for the quality control of medical radioisotopes and radiopharmaceuticals. It was written by a group of experts with experience across a range of radiopharmaceuticals and is intended to support professionals in the preparation of good quality and safe products to be used in nuclear medicine procedures.

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