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TY AVILA

Principles of Parenteral Solution Validation CRC Press
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.
Industrial Metrology for Medical Products and Devices PHI Learning Pvt. Ltd.
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.
Guidance for Implementation Springer Nobody likes to lose good employees. But sometimes the loss of a key employee can be disruptive to the business at best, and completely disastrous at worst. Organizations that don’t take steps to address future talent needs at all levels will face some major obstacles or even near collapse when undervalued key employees get burned out and leave you to fend for yourself.The most comprehensive book on the subject, the fifth edition of the bestselling Effective Succession Planning covers every base of how to address future talent needs before a crisis hits, including how to:• Identify competencies and clarify organizational values• Plan for and quickly fill crucial vacancies at all levels• Develop and retain top talent• Assess current needs and future resources for seamless succession planning• And moreUpdated with current best practices, trends, and technology, the latest edition also includes: succession planning for small businesses and nonprofits; replacement planning; transition management; downsizing; international issues; mergers and acquisitions as a talent strategy; and succession planning for technical positions as well as roles built on longstanding social relationships.Don’t risk the loss of your most valued employees and their accumulated wisdom and experience that has been key to your company’s success for many years. Effective Succession Planning is your go-to indispensable guide for avoiding the catastrophe that losing them would bring.
The Cinema of Economic Miracles John Wiley & Sons
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.
Data Integrity and Compliance Springer Science & Business Media
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.
Manufacturing Science Springer Nature
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.

Modern Pharmaceutical Industry DIANE Publishing

Principles of Parenteral Solution Validation: A Practical Lifecycle Approach covers all aspects involved in the development and process validation of a parenteral product. By using a lifecycle approach, this book discusses the latest technology, compliance developments, and regulatory considerations and trends, from process design, to divesting. As part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin, this book incorporates numerous case studies and real-world examples that address timely problems and offer solutions to the daily challenges facing practitioners in this area. Discusses international and domestic regulatory considerations in every section Features callout boxes that contain points-of-interest for each segment of the audience so readers can quickly find their interests and needs Contains important topics, including risk management, the preparation and execution of properly designed studies, scale-up and technology transfer activities, problem-solving, and more

Validation of Chromatography Data Systems Pragati Books Pvt. Ltd.

Medical progress is associated with innovative product developments in medical technology, e.g. for different implants and instruments. The developments are also characterized by increasing miniaturization and precision. Hence the demands on the geometric and surface characteristics of the usually complex form elements are growing. Consequently, the need for highly-accurate dimensional inspection for the verification of these characteristics is rapidly increasing. ZEISS successfully and reliably faces these challenges. Being a leading manufacturer of medical technology as well as of measurement and inspection technology, the company ZEISS has a high level of know-how in the industrial production of medical devices and products. This book presents the metrological solutions for the medical technology and explains their application. The required measuring machines and the task-based sensors are addressed to the same extent as the challenges regarding automated 100 % checks. Methods for checking the reliability of measuring results and evaluating the inspection process quality are presented and the required procedures are described in detail. The extended regulations for medical devices and products, e.g. by FDA and MDR, place high demands on the measurement technology used and on the electronic documentation of measurement results. This is addressed in detail at the end of the book; in the appendix, easy-to-use checklists for the regulations according to 21 CFR Part 11 are provided.

A Handbook of Job Aids Pfeiffer

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.

A Primer Ispe Headquarters

What is global citizenship, exactly? Are we all global citizens? In The Practices of Global Citizenship, Hans Schattle provides a striking account of how global citizenship is taking on much greater significance in everyday life. This lively book includes many fascinating conversations with global citizens all around the world. Their personal stories and reflections illustrate how global citizenship relates to important concepts such as awareness, responsibility, participation, cross-cultural empathy, international mobility, and achievement. Now more than ever, global citizenship is being put into practice by schools, universities, corporations, community organizations, and government institutions. This book is a must-read for everyone who participates in global events-all of us.

Llyn Foulkes Lippincott Williams & Wilkins

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.

Practical Implementation in Regulated Laboratories Academic Press

The Italian art cinema of the 1960s is known worldwide for its brilliance and vitality. Yet rarely has this cinema been considered in relation to the profound economic and cultural changes that transformed Italy during the sixties--described as the “economic miracle.” Angelo Restivo argues for a completely new understanding of that cinema as a negotiation between a national aesthetic tradition of realism and a nascent postmodern image culture. Restivo studies numerous films of the period, focusing mainly on the works of Pier Paolo Pasolini and Michelangelo Antonioni. He finds that these auteurs’ films reworked the neorealist aesthetic developed in the 1940s and 1950s, explored issues brought to the fore by the subsequent consumer boom, and presaged developments central to both critical theory and the visual arts in the 1980s and 1990s. Drawing on the theories of Lacan, Zizek, Benjamin, Foucault, Jameson, and Deleuze, he shines new light on such films as Pasolini’s Accattone and Teorema, and Antonioni’s Red Desert and Blow-Up. Restivo’s model for understanding the relationship of the 1960s Italian art film to its cultural contexts also has implications that extend to the developing national cinemas of countries such as Brazil and Taiwan. The Cinema of Economic Miracles will interest scholars and students in all areas of film studies, especially those studying theories of the image, national cinema theory, and Italian cinema, and to those engaged in poststructuralist theory, philosophy, and comparative literature.

Visuality and Modernization in the Italian Art Film Duke University Press

Modern Pharmaceutical Industry: A Primer comprehensively explains the broad range of divisions in the complex pharmaceutical industry. Experts actively involved in each component discuss their own contribution to a pharmaceutical company's work and success. Divisions include regulatory affairs, research and development, intellectual property, pricing, marketing, generics, OTC, and more. The seventeen chapters included in this resource offer a wide range of topics, from discovery and formulation to post-approval and legal. Readers will be given a detailed look at the structure of a contemporary drug company and a thorough understanding of what goes on behind the scenes. Modern Pharmaceutical Industry: A Primer is a valuable resource for all pharmacy students, new hires at pharmaceutical companies, drug company management, and academic health center libraries. No other text provides a comprehensive look at one of the most dynamic industries related to the modern healthcare system.

GCP Auditing CRC Press

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.

ISPE Baseline® Guide Carl Zeiss AG

Basic Laboratory Methods for Biotechnology, Third Edition is a versatile textbook that provides students with a solid foundation to pursue employment in the biotech industry and can later serve as a practical reference to ensure success at each stage in their career. The authors focus on basic principles and methods while skillfully including recent innovations and industry trends throughout. Fundamental laboratory skills are emphasized, and boxed content provides step by step laboratory method instructions for ease of reference at any point in the students' progress. Worked through examples and practice problems and solutions assist student comprehension. Coverage includes safety practices and instructions on using common laboratory instruments. Key Features: Provides a valuable reference for laboratory professionals at all stages of their careers. Focuses on basic principles and methods to provide students with the knowledge needed to begin a career in the Biotechnology industry. Describes fundamental laboratory skills. Includes laboratory scenario-based questions that require students to write or discuss their answers to ensure they have mastered the chapter content. Updates reflect recent innovations and regulatory requirements to ensure students stay up to date. Tables, a detailed glossary, practice problems and solutions, case studies and anecdotes provide students with the tools needed to master the content.

A Practical Lifecycle Approach John Wiley & Sons

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.

Pharmaceutical Analysis for Small Molecules LexisNexis

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.

Volume 3 - Sterile Product Manufacturing Facilities Jones & Bartlett Publishers

The International Conference of Harmonization (ICH) has worked on har-nizing 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.

Contextualizing Data Governance Drivers, Technologies, and Tools IGI Global

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 Implementation in Regulated Laboratories John Wiley & Sons

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.

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