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Globalization of Management Education - AACSB International 2011-02-09
In this comprehensive report, the AACSB Task Force explores broad globalization trends in management education that command the attention of any individual or institution striving to navigate in today's environment.
Flow Cytometry and Cell Sorting - Andreas Radbruch 2013-06-29
The practical aspects of flow cytometry and sorting are emphasized in this book which introduces the beginner to the technology and provides tips and tricks for the advanced user. The clear structure makes it easy to address specific problems fast. The chapters cover the modern applications of these procedures, with emphasis on immunofluorescence (antibody-fluorochrome conjugation, staining principles and data evaluation); the isolation of specific chromosomes, cells and fragile, large particles by magnetic and fluorescence-activated sorting; cellular biochemistry; and the dynamics of proliferation. The methods have been field-tested in recent EMBO courses on flow cytometry.
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
Pharma's Prescription - Kamal Biswas 2013-10-21
The pharmaceutical industry needs a shot in the arm – and not a moment too soon. The executive suite is mired in a bygone era, a time when extensive, well-funded pharmaceutical R&D produced blockbuster drugs, kept everything in-house and reaped the financial rewards. But that way of working needs to change. Executives now need to know what the technologists in their companies are doing in order to survive the next decade. Written for those new to industry, as well as for experienced professionals or specialists looking to expand their knowledge, this book is a must-read for business executives and information technologists alike. Pharma’s Prescription bridges the knowledge gap between current business practices and the most valuable technologies today. This book is filled with practical, real-life examples from industry and is a straightforward guide for all pharmaceutical and information technology executives who need to improve their businesses. Focuses on practical solutions that are easily incorporated in your day-to-day work Integrates business operations and information technology Highlights the industry's top turn-around stories Discusses pharmaceutical industry trends,

growth opportunities, innovation drivers, regulatory complexities, and emerging market operations

Validation of Pharmaceutical Processes - James P. Agalloco 2007-09-25

Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations, this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and competitive. The many chapters added to the prior compilation examine va

Chemical Engineering Progress - 2003

Ensuring Quality to Gain Access to Global Markets - Martin Kellermann 2019-04-09

In a modern world with rapidly growing international trade, countries compete less based on the availability of natural resources, geographical advantages, and lower labor costs and more on factors related to firms' ability to enter and compete in new markets. One such factor is the ability to demonstrate the quality and safety of goods and services expected by consumers and confirm compliance with international standards. To assure such compliance, a sound quality infrastructure (QI) ecosystem is essential. Jointly developed by the World Bank Group and the National Metrology Institute of Germany, this guide is designed to help development partners and governments analyze a country's quality infrastructure ecosystems and provide recommendations to design and implement reforms and enhance the capacity of their QI institutions.

Product Development with SAP PLM - Eudes Canuto 2017-04

Looking for better control over your product development? With this guide to SAP Product Lifecycle Management (SAP PLM), you'll get in-depth instructions and configuration information for all stages! Set up and use SAP Portfolio and Project Management (PPM), variant configuration, Product Structure Management, and more. Then integrate with R&D, manufacturing, and authoring systems. From product visualization to collaborative development--get all the tools you need to succeed with SAP PLM! Highlights: -SAP Innovation Management -SAP Portfolio and Project Management (PPM) -Requirements and target management -Variant configuration -Product structures -Product validation -Processes management -Change, release, and configuration management -Product visualization -Collaboration product developme

BIM Handbook - Rafael Sacks 2018-07-03

Discover BIM: A better way to build better buildings Building Information Modeling (BIM) offers a novel approach to design, construction, and facility management in which a digital representation of the building product and process is used to facilitate the exchange and interoperability of information in digital format. BIM is beginning to change the way buildings look, the way they function, and the ways in which they are designed and built. The BIM Handbook, Third Edition provides an in-depth understanding of BIM technologies, the business and organizational issues associated with its implementation, and the profound advantages that effective use of BIM can provide to all members of a project team. Updates to this edition include: Information on the ways in which professionals should use BIM to gain maximum value New topics such as collaborative working, national and major construction clients, BIM standards and guides A discussion on how various professional roles have expanded through the widespread use and the new avenues of BIM practices and services A wealth of new case studies that clearly illustrate exactly how BIM is applied in a wide variety of conditions Painting a colorful and thorough picture of the state of the art in building information modeling, the BIM Handbook, Third Edition guides readers to successful implementations, helping them to avoid needless frustration and costs and take full advantage of this paradigm-shifting approach to construct better buildings that consume fewer materials and require less time, labor, and capital resources.

Supply Chain Management with SAP APOTM - Jörg Thomas Dickersbach 2009-06-18

The Advanced Planner and Optimiser (APO) is the software from SAP dedicated to supply chain management. This book addresses the question of how to implement APO in a company. It is written from a long years'

experience in implementation projects and provides project managers and team members with the necessary know-how for a successful implementation project. The focus is on introducing modeling approaches and explaining the structure and interdependencies of systems, modules and entities of APO. Another concern is the integration with the R/3 system(s), both technically and from a process point of view. Since APO projects differ significantly from other SAP projects, some key issues and common mistakes concerning project management are covered.

GMP Compliance, Productivity, and Quality - Vinay Bhatt 1998-06-30

Written by twenty-eight experts, filled with recommendations that can immediately be put into action, this book provides the strategies and tactics required to link and harmonize manufacturing processes with GMP to achieve optimum operability and cost-effective regulatory compliance. Drawn from name brand and generic companies and regulatory and contract organizations across the globe, the contributing authors bring readers a combined 450+ years of hands-on experience. They offer thought-provoking questions to help readers diagnose their company's challenges, needs, and available options, all with the single purpose of achieving their ultimate goals: quality, high productivity, and profitability.

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.

Information Technology Control and Audit, Fifth Edition - Angel R. Otero 2018-07-27

The new fifth edition of Information Technology Control and Audit has been significantly revised to include a comprehensive overview of the IT environment, including revolutionizing technologies, legislation, audit process, governance, strategy, and outsourcing, among others. This new edition also outlines common IT audit risks, procedures, and involvement associated with major IT audit areas. It further provides cases featuring practical IT audit scenarios, as well as sample documentation to design and perform actual IT audit work. Filled with up-to-date audit concepts, tools, techniques, and references for further reading, this revised edition promotes the mastery of concepts, as well as the effective implementation and assessment of IT controls by organizations and auditors. For instructors and lecturers there are an instructor’s manual, sample syllabi and course schedules, PowerPoint lecture slides, and test questions. For students there are flashcards to test their knowledge of key terms and recommended further readings. Go to http://routledgetextbooks.com/textbooks/9781498752282/ for more information.

Handbook of Research on Emerging Technologies for Effective Project Management - Jamil, George Leal 2019-09-13

Driven by such tools as big data, cognitive computing, new business models, and the internet of things, the overall demand for innovation is becoming more critical for competitiveness and emerging technologies. These technologies have become real alternatives for the market and offer new perspectives for modern project management applications. The Handbook of Research on Emerging Technologies for Effective Project Management is an essential research publication that proposes innovations for firms and markets through the exploration of project management principles and methods and the effective integration of

knowledge and innovation. It encompasses academic and scientific propositions, reviews for conceptual bases, applications of theories in new market solutions, and cases of successful insertion of disruptive technologies and business models in new competitive market offers. Featuring a range of topics such as innovation management, business administration, and marketing, this book is ideal for project managers, IT specialists, software developers, executives, practitioners, managers, marketers, researchers, and industry professionals.

Clinical Trials in Neurology - Bernard Ravina 2012-04-12

Translating laboratory discoveries into successful therapeutics can be difficult. Clinical Trials in Neurology aims to improve the efficiency of clinical trials and the development of interventions in order to enhance the development of new treatments for neurologic diseases. It introduces the reader to the key concepts underpinning trials in the neurosciences. This volume tackles the challenges of developing therapies for neurologic disorders from measurement of agents in the nervous system to the progression of clinical signs and symptoms through illustrating specific study designs and their applications to different therapeutic areas. Clinical Trials in Neurology covers key issues in Phase I, II and III clinical trials, as well as post-marketing safety surveillance. Topics addressed include regulatory and implementation issues, outcome measures and common problems in drug development. Written by a multidisciplinary team, this comprehensive guide is essential reading for neurologists, psychiatrists, neurosurgeons, neuroscientists, statisticians and clinical researchers in the pharmaceutical industry.

WHO Global Model Regulatory Framework for Medical Devices Including in Vitro Diagnostic Medical Devices - World Health Organization 2017-05-09

The Model recommends guiding principles and harmonized definitions and specifies the attributes of effective and efficient regulation to be embodied within binding and enforceable law. Its main elements refer to international harmonization guidance documents developed by the Global Harmonization Task Force (GHTF) and its successor, the International Medical Device Regulators Forum (IMDRF). The Model is particularly relevant for WHO Member States with little or no regulation for medical devices currently in place but with the ambition to improve this situation. It foresees that such countries will progress from basic regulatory controls towards an expanded level to the extent that their resources allow. The Model is written for the legislative, executive, and regulatory branches of government as they develop and establish a system of medical devices regulation. It describes the role and responsibilities of a country's regulatory authority for implementing and enforcing the regulations. Also, it describes circumstances in which a regulatory authority may either "rely on" or "recognize" the work products from trusted regulatory sources (such as scientific assessments, audit, and inspection reports) or from the WHO Prequalification Team. Section 2 of this document recommends definitions of the terms "medical devices" and IVDs. It describes how they may be grouped according to their potential for harm to the patient or user and specifies principles of safety and performance that the device manufacturer must adhere to. It explains how the manufacturer must demonstrate to a regulatory authority that its medical device has been designed and manufactured to be safe and to perform as intended during its lifetime. Section 3 presents the principles of good regulatory practice and enabling conditions for effectively regulating medical devices. It then introduces essential tools for regulation, explaining the function of the regulatory entity and the resources required. Section 4 presents a stepwise approach to implementing and enforcing regulatory controls for medical devices as the regulation progresses from a basic to an expanded level. It describes elements from which a country may choose according to national priorities and challenges. Also, it provides information on when the techniques of reliance and recognition may be considered and on the importance of international convergence of regulatory practice.Section 5 provides a list of additional topics to be considered when developing and implementing regulations for medical devices. It explains the relevance of these topics and provides guidance for regulatory authorities to ensure that they are addressed appropriately. The Model outlines a general approach but cannot provide country-specific guidance on

implementation. While it does not offer detailed guidance on regulatory topics, it contains references to relevant documents where further information may be found. It does not detail the responsibilities of other stakeholders such as manufacturers, distributors, procurement agencies, and health-care professionals, all of whom have roles in assuring the quality, safety, and performance of medical devices.

Auditing and GRC Automation in SAP - Maxim Chuprunov 2013-04-09

Over the last few years, financial statement scandals, cases of fraud and corruption, data protection violations, and other legal violations have led to numerous liability cases, damages claims, and losses of reputation. As a reaction to these developments, several regulations have been issued: Corporate Governance, the Sarbanes-Oxley Act, IFRS, Basel II and III, Solvency II and BilMoG, to name just a few. In this book, compliance is understood as the process, mapped not only in an internal control system, that is intended to guarantee conformity with legal requirements but also with internal policies and enterprise objectives (in particular, efficiency and profitability). The current literature primarily confines itself to mapping controls in SAP ERP and auditing SAP systems. Maxim Chuprunov not only addresses this subject but extends the aim of internal controls from legal compliance to include efficiency and profitability and then well beyond, because a basic understanding of the processes involved in IT-supported compliance management processes are not delivered along with the software. Starting with the requirements for compliance (Part I), he not only answers compliance-relevant questions in the form of an audit guide for an SAP ERP system and in the form of risks and control descriptions (Part II), but also shows how to automate the compliance management process based on SAP GRC (Part III). He thus addresses the current need for solutions for implementing an integrated GRC system in an organization, especially focusing on the continuous control monitoring topics. Maxim Chuprunov mainly targets compliance experts, auditors, SAP project managers and consultants responsible for GRC products as readers for his book. They will find indispensable information for their daily work from the first to the last page. In addition, MBA, management information system students as well as senior managers like CIOs and CFOs will find a wealth of valuable information on compliance in the SAP ERP environment, on GRC in general and its implementation in particular.

Global Legislation for Food Packaging Materials - Rinus Rijk 2010-03-19

Providing a truly global overview of legislation in all major countries, this practical volume contains the information vital for manufactures of food contact materials and food producers, facilitating a comparison of the requirements and making mutual requirements easier to identify. It covers not only plastics but also other food contact materials, such as paper, board, coatings, ceramics, cork, rubber, and textiles.

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.

Medicines from Animal Cell Culture - Glyn N. Stacey 2007-06-29

Medicines from Animal Cell Culture focuses on the use of animal cell culture, which has been used to produce human and veterinary vaccines, interferon, monoclonal antibodies and genetically engineered products such as tPA and erythropoietin. It also addresses the recent dramatic expansion in cell-based therapies, including the use of live cells for tissue regeneration and the culture of stem cells. Medicines from Animal Cell Culture: Provides comprehensive descriptions of methods for cell culture and nutrition as well as the technologies for the preservation and characterisation of both the cells and the derived products Describes the preparation of stem cells and others for use in cell-based therapies – an area of burgeoning research Includes experimental examples to indicate expected results Covers regulatory issues from the UK, the EU and the USA and reviews how these are developing around the world Addresses the key issues of standardisation and validation with chapters on GLP and GMP for cell culture processes Delivering insight into the exciting world of biological medicines and directions for further investigation into specific topics, Medicines from Animal Cell Culture is an essential resource for researchers and technicians at all levels using cell culture within the pharmaceutical, biotechnology and biomedical industries. It is of value to laboratory managers in these industries and to all those interested in this topic alike.

Guideline on General Principles of Process Validation - 1987

GAMP 5 - 2008

Quality Management with SAP - Jawad Akhtar 2015-04-01

Supply Chain Management Based on SAP Systems - Gerhard F. Knolmayer 2009-02-11

Since SAP is emphasizing recent developments in operations management in its SCM initiative, this book describes the methodological background from the viewpoint of a company using SAP systems. It describes order processing both in an intra- and interorganizational perspective, as well as future developments and system enhancements.

GAMP Good Practice Guide - 2005-01-01

Testing SAP R/3 - Jose Fajardo 2007-04-10

Testing SAP R/3: A Manager's Step-by-Step Guide shows how to implement a disciplined, efficient, and proven approach for testing SAP R/3 correctly from the beginning of the SAP implementation through post-production support. The book also shows SAP professionals how to efficiently provide testing coverage for all SAP objects before they are moved into a production environment.

Good Design Practices for GMP Pharmaceutical Facilities - Terry Jacobs 2016-08-19

This revised publication serves as a handy and current reference for professionals engaged in planning, designing, building, validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U.S. and internationally. The new edition expands on facility planning, with a focus on the ever-growing need to modify existing legacy facilities, and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings. All chapters have been re-examined with a fresh outlook on current good design practices.

Validation Standard Operating Procedures - Syed Imtiaz Haider 2006-05-30

Spanning every critical element of validation for any pharmaceutical, diagnostic, medical device or equipment, and biotech product, this Second Edition guides readers through each step in the correct execution of validating processes required for non-aseptic and aseptic pharmaceutical production. With 14 exclusive environmental performance evaluati

Latest Research into Quality Control - Isin Akyar 2012-12-12

Quality control has an emerging importance in every field of life. Quality control is a process that is used to guarantee a certain level of quality in a product or service. It might include whatever actions a business deems necessary to provide for the control and verification of certain

characteristics of a product or service. With the improvement of technology everyday we meet new and complicated devices and methods in different fields. Quality control should be performed in all of those new techniques. In this book "Latest Research Into Quality Control" our aim was to collect information about quality control in many different fields. The aim of this book is to share useful and practical knowledge about quality control in several fields with the people who want to improve their knowledge.

Process Architecture in Biomanufacturing Facility Design - Jeffery Odum 2018-01-26

Essential information for architects, designers, engineers, equipment suppliers, and other professionals who are working in or entering the biopharmaceutical manufacturing field Biomanufacturing facilities that are designed and built today are radically different than in the past. The vital information and knowledge needed to design and construct these increasingly sophisticated biopharmaceutical manufacturing facilities is difficult to find in published literature—and it's rarely taught in architecture or design schools. This is the first book for architects and designers that fills this void. Process Architecture in Biomanufacturing Facility Design provides information on design principles of biopharmaceutical manufacturing facilities that support emerging innovative processes and technologies, use state-of-the-art equipment, are energy efficient and sustainable, and meet regulatory requirements. Relying on their many years of hands-on design and operations experience, the authors emphasize concepts and practical approaches toward design, construction, and operation of biomanufacturing facilities, including product-process-facility relationships, closed systems and single use equipment, aseptic manufacturing considerations, design of biocontainment facility and process based laboratory, and sustainability considerations, as well as an outlook on the facility of the future. Provides guidelines for meeting licensing and regulatory requirements for biomanufacturing facilities in the U.S.A and WHO—especially in emerging global markets in India, China, Latin America, and the Asia/Pacific regions Focuses on innovative design and equipment, to speed construction and time to market, increase energy efficiency, and reduce footprint, construction and operational costs, as well as the financial risks associated with construction of a new facility prior to the approval of the manufactured products by regulatory agencies Includes many diagrams that clarify the design approach Process Architecture in Biomanufacturing Facility Design is an ideal text for professionals involved in the design of facilities for manufacturing of biopharmaceuticals and vaccines, biotechnology, and life-science industry, including architects and designers of industrial facilities, construction, equipment vendors, and mechanical engineers. It is also recommended for university instructors, advanced undergraduates, and graduate students in architecture, industrial engineering, mechanical engineering, industrial design, and industrial interior design.

Department of Defense Dictionary of Military and Associated Terms - United States. Joint Chiefs of Staff 1994

Zero Acceptance Number Sampling Plans - Nicholas L. Squeglia 2008-01-01

This book provides a set of attribute plans for lot-by-lot inspection with the acceptance number in all cases as zero. After years of extensive application by government contractors, commercial manufacturing, and service industries, these c=0 sampling plans are now considered stand alone sampling plans. They have continually gained in popularity for more than 45 years, and today are the norm. The zero acceptance number plans developed by the author were originally designed and used to provide equal or greater consumer protection with less overall inspection than the corresponding MIL-STD-105-E sampling plans. In 2000, the Department of Defense declared MIL-STD-105-E obsolete and recommended the c=0 plans in this book for use in place of them. In addition to the economic advantages, the plans in this book are also simple to use and administer.

New Scientist - 2000

Fundamental and Applied Aspects of Animal Cell Cultivation - J. P.

Barford 1995
The advent of modern, biological techniques such as hybridoma technology, recombinant DNA techniques and viral transformation of cells has made the continuous production of a wide variety of biologicals possible using animal cells. The use of such products is well established in many diagnostic and (increasingly) therapeutic applications - the U.S. market for antibodies, for example, has been projected to increase from a 1991 level of US$0.33 billion to 1998 level of US$3.8 billion. Total sales of such products in 1992 was US$4.2 billion. The increasing application of this technology depends on increasing the efficiency of production and bioseparation and addressing various safety issues. This book examines the fundamental and applied aspects of animal cell cultivation.
ISO 9001:2000 Quality Management System Design - Jay J. Schlickman 2003
"The book describes the design rules required to document, implement, and demonstrate quality management system effectiveness in compliance with the latest version of the ISO 9000 International Standard. This systematic and engineering approach simplifies the many complexities in maintaining compliance with ISO standards. This hands-on guide is packed with tips and insights the author has garnered from personally designing quality management systems that integrate organizational strategy with quality management. Moreover, the book helps professionals create meaningful documentation and a user-friendly, informative quality manual that together form the core of an effective and responsive quality management system."--Jacket.
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
Validation of Product Shelf-Life (Revision 1) - Food Safety Authority of Ireland 2011

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
Practical Approaches to Risk Minimisation for Medicinal Products - World Health Organization 2015-03-02
Risk management of medicines is a wide and rapidly evolving concept and practice, following a medicine throughout its lifecycle, from first administration in humans through clinical studies and then marketing in the patient population at large. Previous reports from CIOMS I - VIII provided practical guidance in some essential components of risk management such as terminology and reporting of adverse drug reactions, management of safety information from clinical trials, and safety signal detection. Beyond the detection, identification, and characterization of risk, "risk minimization" is used as an umbrella term for the prevention or mitigation of an undesirable outcome. Risk management always includes tools for "routine risk minimization" such as product information, the format depending on the jurisdiction, to inform the patient and the prescriber, all of which serve to prevent or mitigate adverse effects. Until this current CIOMS IX document, limited guidance has been available on how to determine which risks need "additional risk minimization," select the appropriate tools, apply and implement such tools globally and locally, and measure if they are effective and valuable. Included in the report is a CIOMS framework for the evaluation of effectiveness of risk minimization, a discussion of future trends and developments, an annex specifically addressing vaccines, and examples from real life.
Accounts Payable Best Practices - Mary S. Schaeffer 2004-06-04

Have you ever wondered where your processes stand against industryleaders or how you can take your services and organizationalprocedures to state of the art levels? Are you frustratedbecause you don't think you have the finanical or human resourcesneeded to employ 'best' practices? This handy resource providesdocumented strategies and tactics for accounts payable used byseveral highly admired companies. You'll gain practicalknowledge you can turn into "Best" (or Almost Best) Practices aswell as examples of practices to avoid. Order your copy today!