Gamp 5 As A Suitable Framework For Validation Of

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Instrument Engineers' Handbook, Volume 3 - Bela G. Liptak 2016-04-19
Instrument Engineers' Handbook – Volume 3: Process Software and Digital Networks, Fourth Edition is the latest addition to an enduring collection that industrial automation (AT) professionals often refer to as the "bible." First published in 1970, the entire handbook is approximately 5,000 pages, designed as standalone volumes that cover the measurement (Volume 1), control (Volume 2), and software (Volume 3) aspects of automation. This fourth edition of the third volume provides an in-depth, state-of-the-art review of control software packages used in plant optimization, control, maintenance, and safety. Each updated volume of this renowned reference requires about ten years to prepare, so revised installments have been issued every decade, taking into account the numerous developments that occur from one publication to the next. Assessing the rapid evolution of automation and optimization in control systems used in all types of industrial plants, this book details the wired/wireless communications and software used. This includes the ever-increasing number of applications for intelligent instruments, enhanced networks, Internet use, virtual private networks, and integration of control systems with the main networks used by management, all of which operate in a linked global environment. Topics covered include: Advances in new displays, which help operators to more quickly assess and respond to plant conditions Software and networks that help monitor, control, and optimize industrial processes, to determine the efficiency, energy consumption, and profitability of operations Strategies to counteract changes in market conditions and energy and raw material costs Techniques to fortify the safety of plant operations and the security of digital communications systems This volume explores why the holistic approach to integrating process and enterprise networks is convenient and efficient, despite associated problems involving cyber and local network security, energy conservation, and other issues. It shows how firewalls must separate the business (IT) and the operation (automation technology, or AT) domains to guarantee the safe function of all industrial plants. This book illustrates how these concerns must be addressed using effective technical solutions and proper management policies and practices. Reinforcing the fact that all industrial control systems are, in general, critically interdependent, this handbook provides a wide range of software application examples from industries including: automotive, mining, renewable energy, steel, dairy, pharmaceutical, mineral processing, oil, gas, electric power, utility, and nuclear power.
Guideline on General Principles of Process Validation - 1987

WHO Expert Committee on Specifications for Pharmaceutical

Preparations - World Health Organization 2019-05-29
The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensusbuilding process. The following new guidelines were adopted and recommended for use: Procedure for development of the WHO medicines quality assurance guidelines; Guidelines on Good Manufacturing Practices (GMP) for heating ventilation and air-conditioning systems (HVAC) ? illustrative part; Guidance on GMP for Validation including the general main text analytical procedure validation validation of computerized systems and qualification; in the area of interchangeability of multisource medicines: the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification systembased classification of active pharmaceutical ingredients for biowaiver; Guidelines on Import Procedures for pharmaceutical products; and the Good Practice Guidance document on implementing the collaborative procedures. All of the above are included in this report and recommended for implementation.
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
Pharmaceutical Isothermal Calorimetry - Simon Gaisford 2019-08-30
Pharmaceutical Isothermal Calorimetry discusses the application of isothermal calorimetric techniques to challenges encountered during the rational design and development of novel drugs and drug delivery systems. Providing a comprehensive review of recent research and trends, this book contains an expert discussion of research and applications to pharmaceutical characterization and formulation.
Inner Bonding - Margaret Paul 2012-10-16
Inner bonding is the process of connecting our adult thoughts with our instinctual, gut feelings—the feelings of the "inner child"—so that we can minimize painful conflict within ourselves. Free of inner conflict, we feel peaceful, open to joy, and open to giving and receiving love. Margaret Paul, coauthor of Healing Your Aloneness, explores how abandonment of the inner child leads to increasingly negative and destructive feelings of low self-worth, codepenclence, addiction, shame, powerlessness, and withdrawal from relationships. Her breakthrough inner bonding process teaches us to heal past wounds through reparenting and clearly demonstrates how we can learn to parent in the present. Real-life examples illustrate the dynamics of the healing process and show the benefits we can expect in every facet of our lives and in all our relationships. Inner Bonding provides the tools we need to forge and maintain the inner unity that makes our family, sexual, work, and social relationships productive, honest, and joyful.
Solid State Development and Processing of Pharmaceutical Molecules - Michael Gruss 2021-09-14
Solid State Development and Processing of Pharmaceutical Molecules A guide to the lastest industry principles for optimizing the production of solid state active pharmaceutical ingredients Solid State Development and Processing of Pharmaceutical Molecules is an authoritative guide that covers the entire pharmaceutical value chain. The authors—noted experts on the topic—examine the importance of the solid state form of chemical and biological drugs and review the development, production, quality control, formulation, and stability of medicines. The book explores the most recent trends in the digitization and automation of the pharmaceutical production processes that reflect the need for consistent high quality. It also includes information on relevant regulatory and intellectual property considerations. This resource is aimed at professionals in the pharmaceutical industry and offers an in-depth examination of the commercially relevant issues facing developers, producers and distributors of drug substances. This important book: Provides a guide for the effective development of solid drug forms

Compares different characterization methods for solid state APIs Offers a resource for understanding efficient production methods for solid state forms of chemical and biological drugs Includes information on automation, process control, and machine learning as an integral part of the development and production workflows Covers in detail the regulatory and quality control aspects of drug development Written for medicinal chemists, pharmaceutical industry professionals, pharma engineers, solid state chemists, chemical engineers, Solid State Development and Processing of Pharmaceutical Molecules reviews information on the solid state of active pharmaceutical ingredients for their efficient development and production.

Object-Oriented Software Engineering Using UML, Patterns, and Java - Bernd Bruegge 2013-08-29

For courses in Software Engineering, Software Development, or Object-Oriented Design and Analysis at the Junior/Senior or Graduate level. This text can also be utilized in short technical courses or in short, intensive management courses. Shows students how to use both the principles of software engineering and the practices of various object-oriented tools, processes, and products. Using a step-by-step case study to illustrate the concepts and topics in each chapter, Bruegge and Dutoit emphasize learning object-oriented software engineer through practical experience: students can apply the techniques learned in class by implementing a real-world software project. The third edition addresses new trends, in particular agile project management (Chapter 14 Project Management) and agile methodologies (Chapter 16 Methodologies).

How to Validate a Pharmaceutical Process - Steven Ostrove 2016-06-07

How to Validate a Pharmaceutical Process provides a “how to approach to developing and implementing a sustainable pharmaceutical process validation program. The latest volume in the Expertise in Pharmaceutical Process Technology Series, this book illustrates the methods and reasoning behind processes and protocols. It also addresses practical problems and offers solutions to qualify and validate a pharmaceutical process. Understanding the “why is critical to a successful and defensible process validation, making this book an essential research companion for all practitioners engaged in pharmaceutical process validation. Thoroughly referenced and based on the latest research and literature Illustrates the most common issues related to developing and implementing a sustainable process validation program and provides examples on how to be successful Covers important topics such as the lifecycle approach, quality by design, risk assessment, critical process parameters, US and international regulatory guidelines, and more

GAMP 5 - 2008

Essentials of Nursing Leadership and Management - Ruth M. Tappen 2004-01

This new edition focuses on preparing your students to assume the role as a significant member of the health-care team and manager of care, and is designed to help your students transition to professional nursing practice. Developed as a user-friendly text, the content and style makes it a great tool for your students in or out of the classroom. (Midwest).

GAMP Good Practice Guide - 2005

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.

IT-Prüfung und IT-Revision - Matthias Knoll 2013-03-15

Einerseits erfordern gesetzliche und aufsichtsrechtliche Vorgaben für die IT eine immer stärkere Aufmerksamkeit, andererseits zwingt die steigende Abhängigkeit der Geschäftsabläufe von der IT Unternehmen zu einem sehr sorgfältigen Umgang mit der IT. Denn von ihr darf keine Gefahr für die Betriebskontinuität ausgehen: Vertraulichkeit, (Daten-)Integrität und Verfügbarkeit müssen ständig gewährleistet sein. Doch IT-Risiken sind vielfältig und allgegenwärtig. Um ebendiese Risiken für die IT und solche aus dem Einsatz der IT bestmöglich zu beherrschen, haben viele Unternehmen interne Kontrollsysteme (IKS) aufgebaut und Verfahren entwickelt, mit denen geprüft werden kann, ob diese Kontrollsysteme wirksam sind, sowie Prozesse definiert, wie sie verbessert werden könnten. HMD 289 berichtet über den aktuellen Stand und Trends in der IT-Prüfung und ITRevision. Neben theoretischen Überlegungen fließen Erfahrungen aus der Praxis in das Heft ein, beispielsweise mit Werkzeugen zur Unterstützung der IT-Revisions- und IT-Prüfungstätigkeiten oder mit bestimmten Prüfmethoden und -verfahren.

Quality Assurance of Aseptic Preparation Services Standards Handbook - Alison M. Beaney 2016-10-03

Standards for unlicensed aseptic preparation in the UK, as well as practical information for implementing the standards.

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.

24th European Symposium on Computer Aided Process Engineering - 2014-06-20

The 24th European Symposium on Computer Aided Process Engineering creates an international forum where scientific and industrial contributions of computer-aided techniques are presented with applications in process modeling and simulation, process synthesis and design, operation, and process optimization. The organizers have broadened the boundaries of Process Systems Engineering by inviting contributions at different scales of modeling and demonstrating vertical and horizontal integration. Contributions range from applications at the molecular level to the strategic level of the supply chain and sustainable development. They cover major classical themes, at the same time exploring a new range of applications that address the production of renewable forms of energy, environmental footprints and sustainable use of resources and water.

GAMP Good Practice Guide - ISPE 2002

Good Research Practice in Non-Clinical Pharmacology and Biomedicine - Anton Bespalov 2020-01-01

This open access book, published under a CC BY 4.0 license in the Pubmed indexed book series Handbook of Experimental Pharmacology, provides up-to-date information on best practice to improve experimental design and quality of research in non-clinical pharmacology and biomedicine.

SAP PI for Beginners - Rana Brata De 2018-05-20

The objective of this tutorial is to make you understand - what is SAP Process Integration? We will not go into the nitty-gritty of the subject but we will discuss the architecture and different features of SAP PI. We will cover the basic features only and will avoid discussing all features in this tutorial.Next there are a set of case studies which will give you an idea about the industry level utilization of SAP PI. Once you get more acquainted with the subject, you should try to solve them. The test cases are prepared in a manner so that it will take you down into the subject from simple to more complexes with each lesson and will give you an

overall idea of the subject.

Factfulness - Hans Rosling 2018-04-03

INSTANT NEW YORK TIMES BESTSELLER “One of the most important books I’ve ever read—an indispensable guide to thinking clearly about the world.” – Bill Gates “Hans Rosling tells the story of ‘the secret silent miracle of human progress’ as only he can. But Factfulness does much more than that. It also explains why progress is so often secret and silent and teaches readers how to see it clearly.” —Melinda Gates "Factfulness by Hans Rosling, an outstanding international public health expert, is a hopeful book about the potential for human progress when we work off facts rather than our inherent biases." - Former U.S. President Barack Obama Factfulness: The stress-reducing habit of only carrying opinions for which you have strong supporting facts. When asked simple questions about global trends—what percentage of the world’s population live in poverty; why the world’s population is increasing; how many girls finish school—we systematically get the answers wrong. So wrong that a chimpanzee choosing answers at random will consistently outguess teachers, journalists, Nobel laureates, and investment bankers. In Factfulness, Professor of International Health and global TED phenomenon Hans Rosling, together with his two long-time collaborators, Anna and Ola, offers a radical new explanation of why this happens. They reveal the ten instincts that distort our perspective—from our tendency to divide the world into two camps (usually some version of us and them) to the way we consume media (where fear rules) to how we perceive progress (believing that most things are getting worse). Our problem is that we don’t know what we don’t know, and even our guesses are informed by unconscious and predictable biases. It turns out that the world, for all its imperfections, is in a much better state than we might think. That doesn’t mean there aren’t real concerns. But when we worry about everything all the time instead of embracing a worldview based on facts, we can lose our ability to focus on the things that threaten us most. Inspiring and revelatory, filled with lively anecdotes and moving stories, Factfulness is an urgent and essential book that will change the way you see the world and empower you to respond to the crises and opportunities of the future. --- “This book is my last battle in my life-long mission to fight devastating ignorance…Previously I armed myself with huge data sets, eye-opening software, an energetic learning style and a Swedish bayonet for sword-swallowing. It wasn’t enough. But I hope this book will be.” Hans Rosling, February 2017.

Process Understanding - Ian Houson 2011-06-09

Process Understanding is the underpinning knowledge that allows the manufacture of chemical entities to be carried out routinely, robustly and to the required standard of quality. This area has gained in importance over the last few years, particularly due to the recent impetus from the USA`s Food and Drug Administration. This book covers the multidisciplinary aspects required for successful process design, safety, modeling, scale-up, PAT, pilot plant implementation, plant design as well the rapidly expanding area of outsourcing. In discussing what process understanding means to different disciplines and sectors throughout a product`s life cycle, this handbook and ready reference reveals the factors important to the development and manufacture of chemicals. The book focuses on the fundamental scientific understanding necessary. for a smoother technical transfer between the disciplines, leading to more effective and effi cient process development and manufacturing. A range of case studies are used to exemplify and illustrate the main issues raised. As a result, readers will appreciate that process understanding can deliver a real competitive advantage within the pharmaceuticals and fine chemicals industry. This book serves as an aid to meeting the stringent regulations required by the relevant authorities through demonstrable understanding of the underlying science.

Development of Distributed Systems from Design to Application and Maintenance - Bessis, Nik 2012-12-31

"This book is a collection of research on the strategies used in the design and development of distributed systems applications"--Provided by publisher.

The Paraphilias - J. Paul Fedoroff 2019-10-10

Of the thousands of papers and books about problematic sexual behaviors, most focus solely on sex crimes or so-called "hyper-sexuality"

or "sexual addiction." Together, these publications present a grim and pessimistic prognosis for anyone who has unusual sexual interests of any type. This book challenges that view by providing a more informed and balanced review of what is known and what is not known about unconventional sexual interests. It is based on approximately thirty years of experience by the author concerning the assessment and treatment of paraphilias and unconventional sexual interests. The Paraphilias: Changing Suits in the Evolution of Sexual Interest Paradigms examines current and past perspectives concerning unconventional sexual interests associated with both criminal and non-criminal activities. Extensively referenced, it challenges the dogma that sexual interests are immutably determined during a single critical period and are thereafter unchangeable. The book provides extensive case histories and tables summarizing over 100 paraphilias and the latest research regarding them. It also reviews diagnostic criteria for the paraphilias. Analyses of current and past paradigms are presented together with new ways to understand, investigate, and provide meaningful and effective assistance to people with paraphilias. It is written for mental health clinicians and specialists in the fields of sexology and forensic psychiatry and psychology.

From Spinster to Career Woman - Arlene Young 2019-05-30

The late Victorian period brought a radical change in cultural attitudes toward middle-class women and work. Anxiety over the growing disproportion between women and men in the population, combined with an awakening desire among young women for personal and financial freedom, led progressive thinkers to advocate for increased employment opportunities. The major stumbling block was the persistent conviction that middle-class women - "ladies" - could not work without relinquishing their social status. Through media reports, public lectures, and fictional portrayals of working women, From Spinster to Career Woman traces advocates' efforts to alter cultural perceptions of women, work, class, and the ideals of womanhood. Focusing on the archetypal figures of the hospital nurse and the typewriter, Arlene Young analyzes the strategies used to transform a job perceived as menial into a respected profession and to represent office work as progressive employment for educated women. This book goes beyond a standard examination of historical, social, and political realities, delving into the intense human elements of a cultural shift and the hopes and fears of young women seeking independence. Providing new insights into the Victorian period, From Spinster to Career Woman captures the voices of ordinary women caught up in the frustrations and excitements of a new era.

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.

GAMP Good Practice Guide - 2005-01-01

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.

Handbook of Validation in Pharmaceutical Processes, Fourth Edition - James Agalloco 2021-10-28

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

Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise - National Academies of Sciences, Engineering, and Medicine 2022-08-03

The U.S. medical countermeasures (MCMs) enterprise is interconnected, complex, and dynamic. It includes public and private entities that develop and manufacture new and existing MCMs, ensure procurement, storage, and distribution of MCMs, and administer, monitor, and evaluate MCMs. The interagency group known as the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) is the nation's sole coordinating body, responsible for ensuring end-to-end MCM preparedness and response. Ensuring an Effective Public Health Emergency Medical Countermeasures Enterprise provides recommendations from an expert committee for a re-envisioned PHEMCE. Four priority areas of improvement emerged from committee deliberations: (1) articulating PHEMCE's mission and role and explicating the principles guiding PHEMCE's operating principles and processes, (2) revising PHEMCE operations and processes, (3) collaborating more effectively with external public and private partners, and (4) navigating legal and policy issues.

Pharmaceutical Manufacturing Handbook - Shayne Cox Gad 2008-03-21

This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

Measuring Vulnerability to Natural Hazards - Birkmann 2007-01-01

Measuring Vulnerability to Natural Hazards presents a broad range of current approaches to measuring vulnerability. It provides a comprehensive overview of different concepts at the global, regional, national, and local levels, and explores various schools of thought. More than 40 distinguished academics and practitioners analyse quantitative and qualitative approaches, and examine their strengths and limitations. This book contains concrete experiences and examples from Africa, Asia, the Americas and Europe to illustrate the theoretical analyses.The

authors provide answers to some of the key questions on how to measure vulnerability and they draw attention to issues with insufficient coverage, such as the environmental and institutional dimensions of vulnerability and methods to combine different methodologies.This book is a unique compilation of state-of-the-art vulnerability assessment and is essential reading for academics, students, policy makers, practitioners, and anybody else interested in understanding the fundamentals of measuring vulnerability. It is a critical review that provides important conclusions which can serve as an orientation for future research towards more disaster resilient communities.

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.

Complex, Intelligent and Software Intensive Systems - Leonard Barolli 2020-06-10

This book explores three interwoven and challenging areas of research and development for future ICT-enabled applications: software intensive systems, complex systems and intelligent systems. Software intensive systems are systems that extensively interact with other systems, sensors, actuators, devices and users. More and more domains are now employing software intensive systems, e.g. the automotive sector, telecommunication systems, embedded systems in general, industrial automation systems and business applications. Moreover, the outcome of web services offers a new platform for enabling software intensive systems. Complex systems research is focused on the overall understanding of systems rather than their components. Complex systems are very much characterized by the changing environments in which they operate through their multiple internal and external interactions. They evolve and adapt through (internal and external) dynamic interactions. The development of intelligent systems and agents, which is increasingly characterized by the use of ontologies, can be beneficial for software intensive systems and complex systems alike. Accordingly, recent research in the areas of intelligent systems, robotics, neuroscience, artificial intelligence, and the cognitive sciences is essential to the future development of software intensive and complex systems.

Information Systems for Small and Medium-sized Enterprises - Jan Devos 2013-10-04

This book establishes and explores existing and emerging theories on Small and Medium-sized Enterprises (SMEs) and the adoption of IT/IS. It presents the latest empirical research findings in that area of IS research and explores new technologies and practices. The book is written for researchers and professionals working in the field of IS research or the research of SMEs. Moreover, the book will be a reference for researchers, professionals and students in management information systems science and related fields.

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

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

European Guide to Power System Testing - Thomas I. Strasser 2020-01-01

This book is an open access book. This book provides an overview of the ERIGrid validation methodology for validating CPES, a holistic power system testing method. It introduces readers to corresponding simulation and laboratory-based tools, including co-simulation, real-time simulation, and hardware-in-the-loop. Selected test cases and validation examples are provided, in order to support the theory discussed. The book begins with an introduction to current power system testing methods and an overview of the ERIGrid system-level validation approach. It then moves on to discuss various validation methods, concepts and tools, including simulation and laboratory-based assessment methods. The book presents test cases and validation examples of the proposed methodologies and summarises the lessons learned from the holistic validation approach. In the final section of the book, the educational aspects of these methods, the outlook for the future, and overall conclusions are discussed. Given its scope, the book will be of interest to researchers, engineers, and laboratory personnel in the fields of power systems and smart grids, as well as undergraduate and graduate students studying related engineering topics.

Continuous Manufacturing of Pharmaceuticals - Peter Kleinebudde 2017-09-05

A comprehensive look at existing technologies and processes for continuous manufacturing of pharmaceuticals As rising costs outpace new drug development, the pharmaceutical industry has come under intense pressure to improve the efficiency of its manufacturing processes. Continuous process manufacturing provides a proven solution. Among its many benefits are: minimized waste, energy consumption, and raw material use; the accelerated introduction of new drugs; the use of smaller production facilities with lower building and capital costs; the ability to monitor drug quality on a continuous basis; and enhanced process reliability and flexibility. Continuous Manufacturing of Pharmaceuticals prepares professionals to take advantage of that exciting new approach to improving drug manufacturing efficiency. This book covers key aspects of the continuous manufacturing of pharmaceuticals. The first part provides an overview of key chemical engineering principles and the current regulatory environment. The second covers existing technologies for manufacturing both small-molecule-based products and protein/peptide products. The following section is devoted to process analytical tools for continuously operating manufacturing environments. The final two sections treat the integration of several individual parts of processing into fully operating continuous process systems and summarize state-of-art approaches for innovative new manufacturing principles. Brings together the essential know-how for anyone working in drug manufacturing, as well as chemical, food, and pharmaceutical scientists working on continuous processing Covers chemical engineering principles, regulatory aspects, primary and secondary manufacturing, process analytical technology and quality-by-design Contains contributions from researchers in leading pharmaceutical companies, the FDA, and academic institutions Offers an extremely well-informed look at the most promising future approaches to continuous manufacturing of innovative pharmaceutical products Timely, comprehensive, and authoritative, Continuous Manufacturing of Pharmaceuticals is an important professional resource for researchers in industry and academe working in the fields of pharmaceuticals development and manufacturing.

Manual of Industrial Microbiology and Biotechnology - Richard H. Baltz 2010-03-25

A rich array of methods and discussions of productive microbial processes. • Reviews of the newest techniques, approaches, and options in the use of microorganisms and other cell culture systems for the manufacture of pharmaceuticals, industrial enzymes and proteins, foods and beverages, fuels and fine chemicals, and other products. • Focuses on the latest advances and findings on the current state of the art and science and features a new section on the microbial production of biofuels and fine chemicals, as well as a stronger emphasis on mammalian cell culture methods. • Covers new methods that enhance the capacity of microbes used for a wide range of purposes, from winemaking to pharmaceuticals to bioremediation, at volumes from micro- to industrial scale.