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Embedded Systems and Software Validation - Abhik Roychoudhury 2009-04-29
Modern embedded systems require high performance, low cost and low power consumption. Such systems typically consist of a heterogeneous collection of processors, specialized memory subsystems, and partially programmable or fixed-function components. This heterogeneity, coupled with issues such as hardware/software partitioning, mapping, scheduling, etc., leads to a large number of design possibilities, making performance debugging and validation of such systems a difficult problem. Embedded systems are used to control safety critical applications such as flight control, automotive electronics and healthcare monitoring. Clearly, developing reliable software/systems for such applications is of utmost importance. This book describes a host of debugging and verification methods which can help to achieve this goal. Covers the major abstraction levels of embedded systems design, starting from software analysis and micro-architectural modeling, to modeling of resource sharing and communication at the system level Integrates formal techniques of validation for hardware/software with debugging and validation of embedded system design flows Includes practical case studies to answer the questions: does a design meet its requirements, if not, then which parts of the system are responsible for the violation, and once they are identified, then how should the design be suitably modified?
Process Validation in Manufacturing of Biopharmaceuticals - Anurag S. Rathore 2012-05-09
Process Validation in Manufacturing of

Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in

Handbook of Computer and Computerized System Validation for the Pharmaceutical Industry - Stephen Robert Goldman 2003

This handbook details methods for sustainable compliance with GxPs and 21 CFR Part 11 validation requirements regarding computerized systems in the pharmaceutical, biotechnology, and medical device industry. The handbook follows FDA guidelines and best industry practices in defining roles, responsib

The Role of the Study Director in Nonclinical Studies - William J. Brock 2014-06-03

A single-source reference with a broad and holistic overview of nonclinical studies, this book offers critical training material and describes regulations of nonclinical testing through guidelines, models, case studies, practical examples, and worldwide perspectives. The book: Provides a complete overview of nonclinical study organization, conduct, and reporting and describes the roles and responsibilities of a Study Director to manage an effective study Covers regulatory and scientific concepts, including international testing and Good Laboratory Practice (GLP), compliance with guidelines, and animal models Features a concluding chapter that compiles case studies / lessons learned from those that have served as a Study Director for many years Addresses the entire spectrum of nonclinical testing, making it applicable to those in the government, laboratories and those actively involved in in all sectors of industry

Methods and Applications of Statistics in Clinical Trials, Volume 1 - N. Balakrishnan 2014-03-05

A complete guide to the key statistical concepts essential for the design and construction of clinical trials As the newest major resource in the field of medical research, Methods and Applications of Statistics in Clinical Trials, Volume 1: Concepts, Principles, Trials, and Designs presents a timely and authoritative reviewof the central statistical concepts used to build clinical trials that obtain the best results. The referenceunveils modern approaches vital to understanding, creating, and evaluating data obtained throughoutthe various stages of clinical trial design and analysis. Accessible and comprehensive, the first volume in a two-part set includes newly-written articles as well as established literature from the Wiley Encyclopedia of Clinical Trials. Illustrating a variety of statistical concepts and principles such as longitudinal data, missing data, covariates, biased-coin randomization, repeated measurements, and simple randomization, the book also provides in-depth coverage of the various trial designs found within phase I-IV trials. Methods and Applications of Statistics in Clinical Trials, Volume 1: Concepts, Principles, Trials, and Designs also features: Detailed chapters on the type of trial designs, such as adaptive, crossover, group-randomized, multicenter, non-inferiority, non-randomized, open-labeled, preference, prevention, and superiority trials Over 100 contributions from leading academics, researchers, and practitioners An exploration of ongoing, cutting-edge clinical trials on early cancer and heart disease, mother-to-child human immunodeficiency virus transmission trials, and the AIDS

Clinical Trials Group Methods and Applications of Statistics in Clinical Trials, Volume 1: Concepts, Principles, Trials, and Designs is an excellent reference for researchers, practitioners, and students in the fields of clinicaltrials, pharmaceutics, biostatistics, medical research design, biology, biomedicine, epidemiology,and public health.

Quality Assurance in Analytical Chemistry - Elizabeth Prichard 2007-09-27

The issue of quality assurance in the analytical chemistry laboratory has become of great importance in recent years. Quality Assurance in Analytical Chemistry introduces the reader to the whole concept of quality assurance. It discusses how all aspects of chemical analysis, from sampling and method selection to choice of equipment and the taking and reporting of measurements affect the quality of analytical data. Finally, the implementation and use of quality systems are covered.

Scientific and Technical Aerospace Reports - 1992

Hearings, Reports and Prints of the Senate Select Committee on Small Business - United States. Congress. Senate. Select Committee on Small Business 1975

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.

NASA Technical Memorandum - 1981

Computer System Validation - Mindy Allport-Settle 2021-03-31

Pharmaceutical and Medical Devices Manufacturing Computer Systems Validation - Orlando Lopez 2018-10-02

Validation of computer systems is the process that assures the formal assessment and report of quality and performance measures for all the life-cycle stages of software and system development, its implementation, qualification and acceptance, operation, modification, requalification, maintenance and retirement (PICS CSV PI 011-3). It is a process that demonstrates the compliance of computer systems functional and non-functional requirements, data integrity, regulated company procedures and safety requirements, industry standards,

and applicable regulatory authority’s requirements. Compliance is a state of being in adherence to application-related standards or conventions or regulations in laws and similar prescriptions. This book, which is relevant to the pharmaceutical and medical devices regulated operations, provides practical information to assist in the computer validation to production systems, while highlighting and efficiently integrating worldwide regulation into the subject. A practical approach is presented to increase efficiency and to ensure that the validation of computer systems is correctly achieved.

Genetic Toxicology Testing - Ray Proudlock 2016-05-28
Genetic Toxicology Testing: A Laboratory Manual presents a practical guide to genetic toxicology testing of chemicals in a GLP environment. The most commonly used assays are described, from laboratory and test design to results analysis. In a methodical manner, individual test methods are described step-by-step, along with equipment, suggested suppliers, recipes for reagents, and evaluation criteria. An invaluable resource in the lab, this book will help to troubleshoot any assay problems you may encounter to optimise quality and efficiency in your genetic toxicology tests. Genetic Toxicology Testing: A Laboratory Manual is an essential reference for those new to the genetic toxicology laboratory, or anyone involved in setting up their own. Offers practical and consistent guidance on the most commonly-performed tests and procedures in a genetic toxicology lab Describes standard genetic toxicology assays, their methodology, reagents, suppliers, and analysis of their results Includes guidance on general approaches: formulation for in vitro assays, study monitoring, and Good Laboratory Practice (GLP) Serves as an essential reference for those new to the genetic toxicology laboratory, or anyone involved in setting up their own lab

Proceedings of Symposium on Simulation of Computer Systems, National Bureau of Standards, Boulder, Colorado, August 10-12, 1976 - Harold Joseph Highland 1976

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.

Handbook of Research on Scripting, Media Coverage, and Implementation of E-Learning Training in LMS Platforms - Khaldi, Mohamed 2023-02-20
Digital learning proves that the digital revolution has almost no limits in the world. The extension of e-learning to digital learning has completely changed training and learning habits. In universities and companies and even at home, anytime and anywhere, innovative e-learning tools, such as online videos, e-learning quizzes, interactive games, and digital

learning courses, can enhance knowledge exchange. The Handbook of Research on Scripting, Media Coverage, and Implementation of E-Learning Training in LMS Platforms considers the design and development of management systems, learner profiles, learning activities, and e-learning projects and discusses the design, development, and implementation in an LMS platform of e-learning projects based on educational engineering models. Covering key topics such as teaching practices, distance learning, and artificial intelligence, this reference work is ideal for industry professionals, administrators, policymakers, researchers, academicians, scholars, instructors, and students.

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

Good Manufacturing Practices for Pharmaceuticals, Seventh Edition - Graham P. Bunn 2019-02-04

This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task-oriented procedure-based cultures to truly integrated quality business systems that are self-detecting and correcting. Chapter flow has been changed to adopt a quality systems organization approach, and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends.

Handbook of Research on Distributed Medical Informatics and E-Health - Lazakidou, Athina A. 2008-08-31

Provides coverage of specific topics and issues in healthcare, highlighting recent trends and describing the latest advances in the field.

Handbook of LC-MS Bioanalysis - Wenkui Li 2013-09-03

Consolidates the information LC-MS bioanalytical scientistsneed to analyze small molecules and macromolecules The field of bioanalysis has advanced rapidly, propelled by newapproaches for developing bioanalytical methods, new liquidchromatographic (LC) techniques, and new mass spectrometric (MS)instruments. Moreover, there are a host of guidelines andregulations designed to ensure the quality of bioanalyticalresults. Presenting the best practices, experimental protocols, and thelatest understanding of regulations, this book offers acomprehensive review of LC-MS bioanalysis of small molecules andmacromolecules. It not only addresses the needs of bioanalyticalscientists working on routine projects, but also explores advancedand emerging technologies such as high-resolution mass spectrometryand dried blood spot microsampling. Handbook of LC-MS Bioanalysis features contributions froman international team of leading bioanalytical scientists. Theircontributions reflect a review of the latest findings, practices,and regulations as well as their own firsthand analyticallaboratory experience. The book thoroughly examines: Fundamentals of LC-MS bioanalysis in drug discovery, drugdevelopment, and therapeutic drug monitoring The current understanding of regulations governing LC-MSbioanalysis Best practices and detailed technical instructions for LC-MSbioanalysis method development, validation, and stabilityassessment of

analyte(s) of interest Experimental guidelines and protocols for quantitative LC-MSbioanalysis of challenging molecules, including pro-drugs, acylglucuronides, N-oxides, reactive compounds, and photosensitive andautooxidative compounds With its focus on current bioanalytical practice, Handbook ofLC-MS Bioanalysis enables bioanalytical scientists to developand validate robust LC-MS assay methods, all in compliance withcurrent regulations and standards.

Testing and Validation of Computer Simulation Models - David J. Murray-Smith 2015-10-08

This must-read text/reference provides a practical guide to processes involved in the development and application of dynamic simulation models, covering a wide range of issues relating to testing, verification and validation. Illustrative example problems in continuous system simulation are presented throughout the book, supported by extended case studies from a number of interdisciplinary applications. Topics and features: provides an emphasis on practical issues of model quality and validation, along with questions concerning the management of simulation models, the use of model libraries, and generic models; contains numerous step-by-step examples; presents detailed case studies, often with accompanying datasets; includes discussion of hybrid models, which involve a combination of continuous system and discrete-event descriptions; examines experimental modeling approaches that involve system identification and parameter estimation; offers supplementary material at an associated website.

Pharmaceutical Computer Validation Introduction Guidebook - Daniel Farb 2005

Pharmaceutical Computer Validation Introduction gives you a comprehensive introduction to computer systems validation as the computers come to life while the head of computer systems at a pharmaceutical company has to prepare for an FDA inspection. You will learn about regulations, the personnel responsible for computer validation, how to accomplish validation, examples of regulatory problems, and so on. It is also relevant for the medical device, food, and cosmetic industries. 86 pages in the guide include a handy printout of several relevant FDA documents. Those readers who wish to have an accompanying program with video and interactivity should also purchase the CD version.

Industrial Applications of Formal Methods to Model, Design and Analyze Computer Systems - Dan Craigen 2012-12-02

Formal methods are mathematically-based techniques, often supported by reasoning tools, that can offer a rigorous and effective way to model, design and analyze computer systems. The purpose of this study is to evaluate international industrial experience in using formal methods. The cases selected are representative of industrial-grade projects and span a variety of application domains. The study had three main objectives: · To better inform deliberations within industry and government on standards and regulations; · To provide an authoritative record on the practical experience of formal methods to date; and À To suggest areas where future research and technology development are needed. This study was undertaken by three experts in formal methods and software engineering: Dan Craigen of ORA Canada, Susan Gerhart of Applied Formal Methods, and Ted Ralston of Ralston Research Associates. Robin Bloomfield of Adelard was involved with the Darlington Nuclear Generating Station Shutdown System case. Support for this study was provided by organizations in Canada

and the United States. The Atomic Energy Control Board of Canada (AECB) provided support for Dan Craigen and for the technical editing provided by Karen Summerskill. The U.S. Naval Research Laboratories (NRL), Washington, DC, provided support for all three authors. The U.S. National Institute of Standards and Technology (NIST) provided support for Ted Ralston.

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.

The Computer System Risk Management and Validation Life Cycle - R. Timothy Stein 2006

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

Clinical Trials Handbook - Shayne Cox Gad 2009-06-17

Best practices for conducting effective and safe clinical trials Clinical trials are arguably the most important steps in proving drug effectiveness and safety for public use. They require intensive planning and organization and involve a wide range of disciplines: data management, biostatistics, pharmacology, toxicology, modeling and simulation, regulatory monitoring, ethics, and particular issues for given disease areas. Clinical Trials Handbook provides a comprehensive and thorough reference on the basics and practices of clinical trials. With contributions from a range of international authors, the book takes the reader through each trial phase, technique, and issue. Chapters cover every key aspect of preparing and conducting clinical trials, including: Interdisciplinary topics that have to be coordinated for a successful clinical trialData management (and adverse event reporting systems) Biostatistics, pharmacology, and toxicology Modeling and simulation Regulatory monitoring and ethics Particular issues for given disease areas-cardiology, oncology, cognitive, dementia, dermatology, neuroscience, and more With unique information on such current issues as adverse event reporting (AER) systems, adaptive trial designs, and crossover trial designs, Clinical Trials Handbook will be a ready reference for pharmaceutical scientists, statisticians, researchers, and the many other professionals involved in drug development.

Publications of the National Bureau of Standards 1977 Catalog - United States. National Bureau of Standards 1978

The Art of Computer Systems Performance Analysis - Raj Jain 1991

The Art of Computer Systems Performance Analysis "At last, a welcome and needed text for computer professionals who require practical, ready-to-apply techniques for performance analysis. Highly recommended!" -Dr. Leonard Kleinrock University of California, Los Angeles "An entirely refreshing text which has just the right mixture of theory and real world practice. The book is ideal for both classroom

instruction and self-study." -Dr. Raymond L. Pickholtz President, IEEE Communications Society "An extraordinarily comprehensive treatment of both theoretical and practical issues." -Dr. Jeffrey P. Buzen Internationally recognized performance analysis expert ". it is the most thorough book available to date" -Dr. Erol Gelenbe Université René Descartes, Paris ". an extraordinary book.. A worthy addition to the bookshelf of any practicing computer or communications engineer" -Dr. Vinton G. Cer??? Chairman, ACM SIGCOMM "This is an unusual object, a textbook that one wants to sit down and peruse. The prose is clear and fluent, but more important, it is witty." -Allison Mankin The Mitre Washington Networking Center Newsletter

Artificial Intelligence and Civil Engineering - B. H. V. Topping 1991

Included in this volume are papers presented at the Second International Conference on the Application of Artificial Intelligence to Civil & Structural Engineering, 3-5 September, 1991, Oxford.

Environmental Health Perspectives - 1993

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

Handbook of Research on Discrete Event Simulation Environments: Technologies and Applications - Abu-Taieh, Evon M. O. 2009-10-31

"This book provides a comprehensive overview of theory and practice in simulation systems focusing on major breakthroughs within the technological arena, with particular concentration on the accelerating principles, concepts and applications"--Provided by publisher.

Design for Validation: An Approach to Systems Validation - 1989

Every complex system built is validated in some manner. Computer validation began with one person reviewing the design of the system. As systems became too complicated for one person to review, validation began to rely on the application of adhoc methods by many individuals. As the cost of changes mounted and the expense of failures increased, more organized procedures became essential. Attempts at devising and carrying out those procedures showed that validation is indeed a difficult technical problem. The successful transformation of the validation process into a systematic series of formally sound, integrated steps is necessary if the liability inherent in future digital-system-based avionic and space systems is to be minimized. This report presents a suggested framework and timetable for that transformation. In sections two through four, we provide basic working definitions of two pivotal ideas--validation and system life-cycle, and show how the two concepts interact. Many examples are given of past and present validation activities by NASA and others. In section five, we present a conceptual framework for the validation process. Finally, in sections six and seven, we list important areas for ongoing development of the validation process at NASA Langley Research Center (NASA-LaRC).

GAMP 5 - Sion Wyn 2008

GAMP 5 provides pragmatic and practical industry

guidance to achieve compliant computerized systems fit for intended use in an efficient and effective manner. This technical document describes a flexible risk-based approach to compliant GxP regulated computerized systems, based on scalable specification and verification. It points to the future of computer systems compliance by centering on principles behind major industry developments such as PQLI; ICH Q8, Q9, Q10; and ASTM E2500. This revolutionary Guide addresses the entire lifecycle of an automated system and its applicability to a wide range of information systems, lab equipment, integrated manufacturing systems, and IT infrastructures. It contains new information on outsourcing, electronic batch recording, end user applications (such as spreadsheets and small database applications), and patch management.

Third NASA Langley Formal Methods Workshop - 1995

Biostatistics in the Study of Toxicology - 1994

Process Chromatography - Gail K. Sofer 2015-09-02

Research and development into biological products for therapeutic use has increased dramatically over the last 10 years. With this, strict regulatory requirements have been imposed by authorities such as the U.S. Food & Drug Administration, so that today validation has become a key issue in the biopharmaceutical industry. This concise book addresses validation issues in the chromatography of biotherapeutics. It covers process design, qualification and validation, including an overview of analytical techniques commonly used in the validation of processes. A concluding section comments on product changeover and presents four case studies.

Compendium of HHS Evaluations and Relevant Other Studies - HHS Policy Information Center (U.S.) 1990

Handbook of Research on Informatics in Healthcare and Biomedicine - Lazakidou, Athina A. 2006-06-30

Describes and analyzes recent breakthroughs in healthcare and biomedicine providing comprehensive coverage and definitions of important issues, concepts, new trends and advanced technologies.