

Computer Validation Compliance

A Quality Assurance Perspective



**Mary Ellen Double
Maryann McKendry**



Interpharm/CRC

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Orlando Lopez

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Computer Validation Compliance Mary Ellen Double, Maryann McKendry, 1994-01-31 Computer Validation Compliance takes a systematic Quality Assurance QA approach to computer validation in a regulated environment. Built on the authors' experiences at major multinational pharmaceutical companies, this book presents a complete step-by-step guide covering the QA role from early development to final completion from a compliance/regulatory perspective. Topics include responsibilities of the user, the developer, and QA vendor assessment, contract facilities, end user computing, and implementing a quality assurance program. Appendices include useful computer system validation sample documentation, a case study, and checklists.

Validation Compliance Annual International Validation Forum, 2024-11-15 Offers an overview of validation and the current regulatory climate and provides a compendium of the regulations, guidance documents, issues, compliance tools, terminology, and literature involved in computer systems validation. Thoroughly examines regulations issued by the U.S. Food and Drug Administration, the U.S. Environmental Protection Agency, and the European Union. Furnishes case studies of real-world situations.

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 regulations of pharmaceuticals, healthcare products, blood processing, medical devices, clinical systems, and biotechnology. Ensuring that organizations transition smoothly to the new system, this guide explains how to implement the new GMP paradigm while maintaining continuity with current practices. In addition, all 24 case studies from the previous edition have been revised to reflect the new system.

Computer Systems Validation Guy Wingate, 2003-12-18 Both pervasive and ubiquitous computerized systems are now an integral component of every corporate strategy in pharmaceutical and healthcare companies. However, when technology is combined with high-risk public safety projects or the production and control of life-saving medicines or devices, it is necessary to ensure that it is reliable quality.

Practical Guide to Clinical Data Management Susanne Prokscha, 1999-01-31 Clinical data management (CDM) has changed from being an essentially clerical task in the late 1970s and early 1980s to a highly computerized, highly specialized field today. And clinical data managers have had to adapt their data management systems and processes accordingly. Practical Guide to Clinical Data Management steers you through a basic understanding of the role of data management in clinical trials and includes more advanced topics such as CDM systems, SOPs, and quality assurance. This book helps you ensure GCP, manage laboratory data, and deal with the kinds of clinical data that can cause difficulties in database applications. With the tools this book provides, you'll learn how to ensure that your DMB system is in compliance with federal regulations, build a strategic data management and database plan, track and record CRFs, deal with problem data, adverse event data, and legacy data, manage and store lab data, identify and manage discrepancies, ensure

quality control over reports Choose a CDM system that is right for your company Create and implement a system validation plan and process Set up and enforce data collection standards Develop test plans and change control systems This book is your guide to finding the most successful and practical options for effective clinical data management

Validating Corporate Computer Systems

Guy Wingate,2000-05-31 One of the biggest computer validation challenges facing pharmaceutical manufacturers is the large corporate system This book provides practical information and advice on good IT practice and validation principles Written by experts it includes case studies on EDMSs EAM systems LIMSS and MRP II systems

21 Cfr Part 11 Orlando Lopez,2019-08-30 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 regulatory compliance within the context of quality assurance He demonstrates the importance of integrating validation activities into the system lifecycle using a structured top down approach He covers practical applications of quality assurance and engineering techniques as they relate to the development of systems fit to meet user and regulatory requirements

Data Integrity in Pharmaceutical and Medical Devices Regulation Operations Orlando Lopez,2016-11-03 Data integrity is fundamental in a pharmaceutical and medical devices quality system This book provides practical information to enable compliance with data integrity while highlighting and efficiently integrating worldwide regulation into the subject The ideas presented in this book are based on many years experience in regulated industries in various computer systems development maintenance and quality functions In addition to case studies a practical approach will be presented to increase efficiency and to ensure that the design and testing of the data integrity controls are correctly achieved

Compliance Handbook for Pharmaceuticals, Medical Devices, and Biologics Carmen Medina,2003-12-09 This text lists the necessary steps for meeting compliance requirements during the drug development process It presents comprehensive approaches for validating analytical methods for pharmaceutical applications

Annual Book of ASTM Standards ASTM International,American Society for Testing and Materials,2003

South African Computer Science and Information Systems Research Trends Aurona Gerber,2024-07-07 This book contains a selection of the best papers of the 45th Annual Conference SAICSIT 2024 held in Gqeberha South Africa in July 2024 The 26 full papers included in this book were carefully reviewed and selected from 81 submissions They focus on the transforming relationship between humans and machines This year's theme is Human Machine Digital Convergence

Annual Book of ASTM Standards American Society for Testing and Materials,1986 A compilation of all ASTM standards issued each year

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Simulators IX Ariel Sharon,1992

Quality Assurance for Analytical Laboratories Michael Parkany,1993 At the present time when public opinion is demanding accountability of laboratories carrying out analyses related to socially sensitive issues such as drug testing blood alcohol monitoring HIV testing water and air purity acid rain etc the importance

of harmonizing protocols for quality assurance schemes cannot be over emphasized The first step in obtaining the status of Certified in Accordance with is for a laboratory to make a full and detailed internal evaluation and this invaluable new book will assist you in that step Quality Assurance for Analytical Laboratories shows how to introduce internal quality assurance schemes that can form the basis for third party assessment certification and accreditation It gives real life examples from a wide range of laboratories illustrates the statistical tools needed and details the correct terms and their definitions It also contains a list of all relevant International Standards For those laboratories wishing to establish a self audit for checking conformity with the ISO 9000 series this book is a must **Simulators** ,1992 Good Laboratory Practices Willa Y. Garner,American Chemical Society. Division of Agrochemicals,American Chemical Society. Meeting,1988 Annotation Papers from a symposium during the ACS meeting in New Orleans Sept 1987 they analyze how GLP programs have affected government industrial and academic labs and cover compliance quality assurance standard operating procedures and financial considerations Has case histories Annotation c 2003 Book News Inc Portland OR booknews com Transactions of the American Nuclear Society ,1991 *Harvard Business School Career Guide* ,1995 **The Cumulative Book Index** ,1996 A world list of books in the English language

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