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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

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.

ISPE GAMP® Good Practice Guide: a Risk-Based Approach to Operation of GxP Computerized Systems - Ispe 2011-08-09

Part 11 and Computer Validation Guidebook - Daniel Farb 2005
Gives an introduction to computer issues in the pharmaceutical industry, as well as to computer systems validation. This work helps you learn about regulations, the personnel responsible for computer validation, how to accomplish validation, examples of regulatory problems, and more. It is useful for research personnel in FDA-regulated industries.

Health Care Management and the Law - Hammaker 2017-03-02
Health Care Management and the Law-2nd Edition is a comprehensive practical health law text relevant to students seeking the basic management skills required to work in health care organizations, as well as students currently working in health care organizations. This text is also relevant to those general health care consumers who are simply attempting to navigate the complex American health care system. Every attempt is made within the text to support health law and management theory with practical applications to current issues.

GAMP Good Practice Guide - 2005

Supply Chain Management in the Drug Industry - Hedley Rees 2011-04-06
This book bridges the gap between practitioners of supply-chain management and pharmaceutical industry experts. It aims to help both these groups understand the different worlds they live in and how to jointly contribute to meaningful improvements in supply-chains within the globally important pharmaceutical sector. Scientific and technical staff must work closely with supply-chain practitioners and other relevant parties to help secure responsive, cost effective and risk mitigated supply chains to compete on a world stage. This should not wait until a drug has been registered, but should start as early as possible in the development process and before registration or clinical trials. The author suggests that CMC (chemistry manufacturing controls) drug development must reset the line of sight – from supply of drug to the clinic and gaining a registration, to the building of a patient value stream. Capable processes and suppliers, streamlined logistics, flexible plant and equipment, shorter cycle times, effective flow of information and reduced waste. All these factors can and should be addressed at the CMC development stage.

Implementing ISO/IEC 17025:2005 - Bhavan "Bob" Mehta 2013-04-16
The purpose of this book is to demystify the requirements delineated within ISO/IEC 17025:2005 while providing a road map for organizations that wish to receive/maintain accreditation for their laboratories. AS9100, ISO 9001, and ISO 13485 are standards that support the development and implementation of effective approaches to quality management and are recognized blueprints for the establishment of a quality management system (QMS) for diverse industries. Although similar to these recognized QMS standards, ISO/IEC 17025 serves a unique purpose: laboratory accreditation. It is not unusual for laboratories to retain dual certification to ISO 9001 and ISO/IEC 17025.

GAMP Good Practice Guide - International Society of Pharmaceutical Engineers 2011

GAMP Good Practice Guide - 2010

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.

Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook - Jordi Botet 2015-09-28
Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing, materials purchase (procurement), production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is

‘current good manufacturing practice (CGMP)’‘, which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements (such as risk management, quality hazards and management systems, documentation, clean environments, personnel training) and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.
A Risk-based Approach to GxP Compliant Laboratory Computerized Systems - Good Automated Manufacturing Practice Forum 2012

Good Informatics Practices (GIP) Module: Training and Training Practices - Heidi Bargerhuff

Digital Transformation with BPM - Nathaniel Palmer 2019-10-24
BPM is essential to a company's survival in today's hyper-speed business environment. The goal of Digital Transformation is to help empower enterprises to compete at the highest level in any marketplace. This book provides compelling award-wining case studies contributed by those who have been through the full BPM experience. The case studies describe the processes involved to generate successful ROIs and competitive advantages. Digital transformation describes the changes associated with the application of digital technology in all aspects of human society. Digital transformation may be thought of as the third stage of embracing digital technologies: from digital competence to digital usage to digital transformation, with usage and transformative ability informing digital literacy. The transformation stage means that digital usages inherently enable new types of innovation and creativity in a particular domain, rather than simply enhance and support the traditional methods. These industry thought-leaders together with the leading-edge case studies will help you understand the meaning and impact of Digital Transformation and how you can leverage that transformation; likely using BPM you already have. Learn how to extend that into core processes that run the business and thus engage more meaningfully with your customers. The authors discuss the impact of emerging technologies, the mandate for greater transparency and how the ongoing aftershocks of globalization have collectively impacted predictability within the business enterprise.
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
GAMP Good Practice Guide - 2011
This GAMP Good Practice Guide: A Risk-Based Approach to GxP Process Control Systems is a revision of the GAMP Good Practice Guide: Validation of Process Control Systems. It provides guidance and examples on the application of the principles and framework of GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems to a wide range of systems, from basic instruments to large, complex, distributed control systems.This Guide aims to achieve process control systems that are fit for intended use and compliant with applicable regulations; providing recommended good practice based on a life cycle approach for the development, maintenance, and management of process control systems. The Guide applies science-based Quality Risk Management, as described in ICH Q9 and GAMP 5. It describes the system life cycle from concept to retirement, providing a high level overview of the approach together with guidance on how activities might be scaled based on risk to product quality, system novelty, and complexity as well as other project specific factors.
ISPE GAMP® Good Practice Guide: a Risk-Based Approach to Compliant Electronic Records and Signatures - Ispe 2005-12-15

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.
ISPE GAMP® Good Practice Guide: a Risk-Based Approach to GxP Process Control Systems - Ispe 2013-01-31

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.
Supercritical Fluid Chromatography - Gregory K. Webster 2014-02-04
Analytical chemists in the pharmaceutical industry are always looking for more-efficient techniques to meet the analytical challenges of today’s pharmaceutical industry. One technique that has made steady advances in pharmaceutical analysis is supercritical fluid chromatography (SFC). SFC is meeting the chromatography needs of the industry by providing efficient and selective testing capabilities on the analytical and preparative scale. The supercritical fluid mobile phase, consisting mainly of CO2, facilitates cost reduction costs and helps the industry in meeting green chemistry standards. This book provides a comprehensive overview of the use of SFC in pharmaceutical analysis. Supercritical Fluid Chromatography reviews the use of SFC in drug-discovery applications and describes its application in drug development. When a drug is developed and brought to market, it is tested many times for impurities and degradants, enantiomeric purity, and analytical and preparative isolations—it is tested during discovery and development and for under-regulated and unregulated methodologies. The book describes the use of SFC for each of these applications and discusses more in-depth topics, such as the use of SFC in mass spectrometric and polarographic detection. The book also sheds light on the role of SFC in drug development from natural products and the advancement of SFC with new technologies and its use in pilot-scale operations as a chromatographic technique.
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
The Computer System Risk Management and Validation Life Cycle - R. Timothy Stein 2006

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.

Ensuring the Integrity of Electronic Health Records - Orlando Lopez 2020-12-22

Data integrity is a critical aspect to the design, implementation, and usage of any system which stores, processes, or retrieves data. The overall intent of any data integrity technique is the same: ensure data is recorded exactly as intended and, upon later retrieval, ensure the data is the same as it was when originally recorded. Any alternation to the data is then traced to the person who made the modification. The integrity of data in a patient's electronic health record is critical to ensuring the safety of the patient. This book is relevant to production systems and quality control systems associated with the manufacture of pharmaceuticals and medical device products and updates the practical information to enable better understanding of the controls applicable to e-records. The book highlights the e-records suitability implementation and associated risk-assessed controls, and e-records handling. The book also provides updated regulatory standards from global regulatory organizations such as MHRA, Medicines and Healthcare Products Regulatory Agency (UK); FDA, Food and Drug Administration (US); National Medical Products Association (China); TGA, Therapeutic Goods Administration (Australia); SIMGP, Russia State Institute of Medicines and Good Practices; and the World Health Organization, to name a few.

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.

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.

ISPE GAMP® Good Practice Guide: a Risk-Based Approach to Operation of GxP Computerized Systems - Ispe 2010-11-08

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.

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

GAMP Good Practice Guide - 2005

Biopharmaceutical Processing - Gunter Jagschies 2018-01-18

Biopharmaceutical Processing: Development, Design, and Implementation of Manufacturing Processes covers bioprocessing from cell line development to bulk drug substances. The methods and strategies described are essential learning for every scientist, engineer or manager in the biopharmaceutical and vaccines industry. The integrity of the bioprocess ultimately determines the quality of the product in the biotherapeutics arena, and this book covers every stage including all technologies related to downstream purification and upstream processing fields. Economic considerations are included throughout, with recommendations for lowering costs and improving efficiencies. Designed for quick reference and easy accessibility of facts, calculations and guidelines, this book is an essential tool for industrial scientists and managers in the biopharmaceutical industry. Offers a comprehensive, go-to reference for daily work decisions Covers both upstream and downstream processes Includes case studies that emphasize financial outcomes Presents summaries, decision grids, graphs and overviews for quick reference

Good Clinical Practice eRegs & Guides - For Your Reference Book 2 - eRegs & Guides 2013-11-22

Good Clinical Practice eRegs & Guides provides a reference to key US FDA Guides and regulations via your electronic reader. An excellent way to access the reference documents on your e-reader. No need to carry paper books and you can search for key terms. In this issue you will find: E6 Good Clinical Practice Guidance for Industry Part 11, Electronic Records; Electronic Signatures — Scope and Application CFR 21--General Part 11, Electronic Records; Electronic Signatures 21 CFR PART 50 Protection Of Human Subjects 21 CFR Part 54 Financial Disclosure By Clinical Investigators 21 CFR PART 56 Institutional Review Boards Title 21 PART 312 Investigational New Drug Application ICH E2A Clinical Safety Data Management: Definitions and Standards for Expedited Reporting ICH E8 General Considerations For Clinical Trials

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.

HPLC Method Development for Pharmaceuticals - Satinder Ahuja 2011-09-21

High pressure, or high performance, liquid chromatography (HPLC) is the method of choice for checking purity of new drug candidates, monitoring changes during scale up or revision of synthetic procedures, evaluating new formulations, and running control/assurance of the final drug product. HPLC Method Development for Pharmaceuticals provides an extensive overview of modern HPLC method development that addresses these unique concerns. Includes a review and update of the current state of the art and science of HPLC, including theory, modes of HPLC, column chemistry, retention mechanisms, chiral separations, modern instrumentation (including ultrahigh-pressure systems), and

sample preparation. Emphasis has been placed on implementation in a pharmaceutical setting and on providing a practical perspective. HPLC Method Development for Pharmaceuticals is intended to be particularly useful for both novice and experienced HPLC method development chemists in the pharmaceutical industry and for managers who are seeking to update their knowledge. Covers the requirements for HPLC in a pharmaceutical setting including strategies for software and hardware validation to allow for use in a regulated laboratory Provides an overview of the pharmaceutical development process (clinical phases, chemical and pharmaceutical development activities) Discusses how HPLC is used in each phase of pharmaceutical development and how methods are developed to support activities in each phase

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition - 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 final form on January 24, 2011. The book also provides guidelines and current practices, as well as industrial case studies illustrating the different approaches that can be taken for successful validation of biopharmaceutical processes. Case studies include Process validation for membrane chromatography Leveraging multivariate analysis tools to qualify scale-down models A matrix approach for process validation of a multivalent bacterial vaccine Purification validation for a therapeutic monoclonal antibody expressed and secreted by Chinese Hamster Ovary (CHO) cells Viral clearance validation studies for a product produced in a human cell line A much-needed resource, this book presents process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing, including chromatography, chemical modification reactions, ultrafiltration, and microfiltration. It also provides practical methods to test raw materials and in-process samples. Stressing the importance of taking a risk-based approach towards computerized system compliance, this book will help you and your team ascertain process validation is carried out and exceeds expectations.

A Risk-based Approach to Operation of GxP Computerized Systems - 2009

Good Informatics Practices (GIP) Module: Risk Management - Ford Winslow, Roger Fraumann, CISSP, Robert Sturm, MBA, DeEtte Trubey, PMP

A Risk-based Approach to Testing of GxP Systems - Good Automated Manufacturing Practice Forum 2012