

GAMP® Good Practice Guide

GxP Compliant Laboratory Computerized Systems (2nd edition)

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Gamp Good Practice Guide Validation Of Laboratory Computerized Systems

Guy Wingate



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GAMP Good Practice Guide, 2005-01-01 ISPE GAMP® Good Practice Guide: Validation of Laboratory Computerized Systems Ispe, 2007-04-05 Practical Approaches to Method Validation and Essential Instrument Qualification Chung Chow Chan, Herman Lam, Xue-Ming Zhang, 2011-03-01 Practical approaches to ensure that analytical methods and instruments meet GMP standards and requirements Complementing the authors first book Analytical Method Validation and Instrument Performance Verification this new volume provides coverage of more advanced topics focusing on additional and supplemental methods instruments and electronic systems that are used in pharmaceutical biopharmaceutical and clinical testing Readers will gain new and valuable insights that enable them to avoid common pitfalls in order to seamlessly conduct analytical method validation as well as instrument operation qualification and performance verification Part 1 Method Validation begins with an overview of the book s risk based approach to phase appropriate validation and instrument qualification it then focuses on the strategies and requirements for early phase drug development including validation of specific techniques and functions such as process analytical technology cleaning validation and validation of laboratory information management systems Part 2 Instrument Performance Verification explores the underlying principles and techniques for verifying instrument performance coverage includes analytical instruments that are increasingly important to the pharmaceutical industry such as NIR spectrometers and particle size analyzers and offers readers a variety of alternative approaches for the successful verification of instrument performance based on the needs of their labs At the end of each chapter the authors examine important practical problems and share their solutions All the methods covered in this book follow Good Analytical Practices GAP to ensure that reliable data are generated in compliance with current Good Manufacturing Practices cGMP Analysts scientists engineers technologists and technical managers should turn to this book to ensure that analytical methods and instruments are accurate and meet GMP standards and requirements **GAMP Good Practice Guide**, 2003 **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 *Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Volume 2. Good manufacturing practices and inspection* World Health Organization, 2024-01-31 The GMP Compendium for Medical Products is a valuable resource for manufacturers regulators and other stakeholders involved in producing and distributing medical products It

covers various topics from quality management systems to personnel hygiene equipment validation and complaint handling The guidance provided is based on the latest scientific and technical knowledge and considers the evolving regulatory landscape and the challenges faced by the industry Good Informatics Practices (GIP) Module: Validation & Verification

Frank Cicero, PMP, Jason Cooper, MS, Steven Fouskarinis, MBA, Kim Green, Barbara L Johnson, John Kim, Ben Larson, CSQE, Damian Gomez, CISSP, Linda Speake, Robert Sturm, MBA, Mark Vilivich, MS, CSM, Wen Wang, MS, CQA, CSQE, CQM/OE, Ford Winslow, 2011 **Validation of Pharmaceutical Processes** James P. Agalloco, Frederick J.

Carleton, 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 **Validating Pharmaceutical Systems** John Andrews, 2005-08-03 All too often the words computer validation

strike terror into the hearts of those new to the process and may even cause those familiar with it to tremble Validating Pharmaceutical Systems Good Computer Practice in Life Science Manufacturing delineates GCP GLP and GMP regulatory requirements and provides guidance from seasoned practitioners **WHO Expert Committee on Specifications for Pharmaceutical Preparations** WHO Expert Committee on Specifications for Pharmaceutical Preparations. Meeting, World Health Organization, 2016 The World Health Organization WHO Expert Committee on Specifications for Pharmaceutical Preparations advises the Director General of WHO in the area of medicines quality assurance It provides independent expert recommendations and guidance to ensure that medicines meet standards of quality safety and efficacy in all WHO Member States Its advice is developed through a broad consensus building process and covers all areas of quality assurance of medicines from their development to their distribution to patients In the area of quality control the Expert Committee reviewed new and revised specifications and general texts for inclusion in The International Pharmacopoeia and received the annual report of the European Directorate for the Quality of Medicines HealthCare EDQM the custodian centre for International Chemical Reference Substances ICRS The Committee adopted a number of monographs general texts and ICRS It noted the report on Phase 6 of the External Quality Assurance Assessment Scheme EQAAS and on new approaches to ensure sustainability of this scheme through user fees The Committee further acknowledged the progress of good pharmacopoeial practices GPhP and adopted the document on GPhP which was prepared by the consecutive international meetings of world pharmacopoeias In the various quality assurance related areas the Expert Committee was presented with a number of new and revised guidelines related to good manufacturing practices GMP distribution and trade of pharmaceuticals and regulatory practice It adopted 10 guidelines as listed below as well as 22 new specifications and general texts for inclusion in The International Pharmacopoeia The Committee took note of ongoing work to promote collaboration and information exchange through the good regulatory practice project and welcomed the development of a comprehensive

set of guidelines for all national regulatory authorities through this project Validation of Chromatography Data Systems
Robert D 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 *Practical Fermentation*

Technology Brian McNeil, Linda Harvey, 2008-04-15 A hands on book which begins by setting the context defining fermentation and the possible uses of fermenters and setting the scope for the book It then proceeds in a methodical manner to cover the equipment for research scale fermentation labs the different types of fermenters available their uses and modes of operation Once the lab is equipped the issues of fermentation media preservation strains and strain improvement strategies are documented along with the use of mathematical modelling as a method for prediction and control Broader questions such as scale up and scale down process monitoring and data logging and acquisition are discussed before separate chapters on animal cell culture systems and plant cell culture systems The final chapter documents the way forward for fermenters and how they can be used for non manufacturing purposes A glossary of terms at the back of the book along with a subject index will prove invaluable for quick reference Edited by academic consultants who have years of experience in fermentation technology each chapter is authored by experts from both industry and academia Industry authors come from GSK UK DSM Netherlands Eli Lilly USA and Broadley James UK USA **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 **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 *Method Validation in Pharmaceutical Analysis* Joachim Ermer, Phil W. Nethercote, 2014-08-27 This second edition of a global bestseller has been completely redesigned and extensively rewritten to take into account the new Quality by Design QbD and lifecycle concepts in pharmaceutical manufacturing As in the first edition the fundamental requirements for analytical method validation are covered but the second edition describes how these are applied systematically throughout the entire analytical lifecycle QbD principles require adoption of a systematic approach to development and validation that begin with predefined objectives For analytical methods these predefined objectives are established as an Analytical Target Profile ATP The book chapters are aligned with recently introduced standards and guidelines for manufacturing processes validation and follow the three stages of the analytical lifecycle Method Design Method Performance Qualification and Continued Method Performance Verification Case studies and examples from the pharmaceutical industry illustrate the concepts and guidelines presented and the standards and regulations from the US FDA European EMA and global ICH regulatory authorities are considered throughout The undisputed gold standard in the field **Process Validation in Manufacturing of Biopharmaceuticals, Third Edition** Anurag S. Rathore, Gail Sofer, 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 Application of Iso/Iec 17025 Technical Requirements in Industrial Laboratories M. L. Jane Weitzel, Wesley M. Johnson, 2013-03 The book introduces the new concepts of target measurement uncertainty and decision rules and explains how to use them to demonstrate a method is fit for purpose As well they can be used to set the acceptance criteria for a method validation clearly and quantitatively Examples are given that illustrate the concepts so that the reader can easily apply decision rules and target measurement uncertainty to their methods The book covers all aspects of method validation from stating the

purpose of the method using a Decision Rule calculating the target measurement uncertainty deciding the required parameters that need to be included in the method validation estimating the measurement uncertainty and setting the acceptance criteria With this approach the reader will fully understand the method what its critical control points are and what to control and monitor during routine use This approach fits in well with the lifecycle approach to analytical methods The book covers the basics and advanced aspects of method validation so that it is useful for people new to method validation and those with experience The book is applicable for laboratories in many industries from mining to pharmaceutical manufacturing to food analysis

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

Pharmaceutical Technology And Products Dr. Sadhu Venkateswara Rao, Dr. Kantamneni Padmalatha, 2022-09-02 This textbook takes an all encompassing approach to the topics of drug research and development manufacturing methodologies and technology pharmaceutical regulation and pharmaceutical marketing This book covers the essential chemistry to show how a drug was taken from the laboratory to the mass market Beginning with the discovery of the medicine's active medicinal components and continuing through its manufacture in a variety of dosage forms this book shows how a drug went from the lab to the market The study of medicines covers the whole process of creating pharmaceuticals from the initial discovery to the point when they are sold commercially Those who work in the pharmaceutical industry wear a variety of hats and some of those hats need them to use certain kinds of equipment carry out specific kinds of research and comply with specific kinds of legislation The most common dosage forms including tablets capsules parenteral solutions suspensions and emulsions have all been discussed here in detail Tablets and capsules are also included Products that have a regulated release methods of oral protein administration and other topics of a similar kind are also explored The book delves into topics such as the prospects for the pharmaceutical industry in the next years as well as issues such as quality control safety counterfeiting and improper medication usage

Analytical Method Validation and Instrument Performance Verification Chung Chow Chan, Y. C. Lee, Herman Lam, Xue-Ming Zhang, 2004-04-09 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

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