

GAMP

- GAMP, which stands for "Good Automated Manufacturing Practice," is a set of guidelines and best practices for the validation of computerized systems in the pharmaceutical and healthcare industries. It was developed by the International Society for Pharmaceutical Engineering (ISPE).
- GAMP provides a framework for ensuring that computerized systems used in pharmaceutical manufacturing, laboratory analysis, and other regulated processes are fit for their intended use, comply with regulatory requirements, and operate in a consistent and reliable manner.

Gamp Automated Manufacturing Practices International

Robert D McDowall



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Industrial Process Automation Systems B.R. Mehta,Y. Jaganmohan Reddy,2014-11-26 Industrial Process Automation Systems Design and Implementation is a clear guide to the practicalities of modern industrial automation systems Bridging the gap between theory and technician level coverage it offers a pragmatic approach to the subject based on industrial experience taking in the latest technologies and professional practices Its comprehensive coverage of concepts and applications provides engineers with the knowledge they need before referring to vendor documentation while clear guidelines for implementing process control options and worked examples of deployments translate theory into practice with ease This book is an ideal introduction to the subject for junior level professionals as well as being an essential reference for more experienced practitioners Provides knowledge of the different systems available and their applications enabling engineers to design automation solutions to solve real industry problems Includes case studies and practical information on key items that need to be considered when procuring automation systems Written by an experienced practitioner from a leading technology company

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

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

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** World Health

Organization, 2024-04-26 The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines and provision of global regulatory tools The Expert Committee develops standards through worldwide consultation and an international consensus building process The following new guidance texts were adopted and recommended for use WHO good manufacturing practices for excipients used in pharmaceutical products revision IAEA WHO good manufacturing practices for in house cold kits for radiopharmaceutical preparations new WHO good practices for pharmaceutical quality control laboratories revision WHO UNFPA female condom generic specification new WHO Biowaiver List proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate release updated solid oral dosage forms WHO guideline on Biopharmaceutics Classification System based biowaivers revision and Multisource generic pharmaceutical products guidelines on registration requirements to establish interchangeability republished All of the above are included in this report and recommended for implementation *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 Pharmaceutical

Anti-Counterfeiting Mark Davison, 2011-07-26 This book overviews and integrates the business and technical issues that pharmaceutical companies need to know in order to combat the major global problem of counterfeit medicines In addition to discussion of the problems the author Davison addresses analytical techniques scientists use to detect counterfeits and presents some possible solutions to the threat of counterfeit medical products Coverage moves from basic overview of the problem costs risks to consumers toxic products mistrust of drug companies and business revenue loss public trust government oversight and regulation authentication strategies packaging analytical techniques product tracking and supply

chain and case studies from around the globe **The GAMP Guide for Validation of Automated Systems** [Anonymus AC05703882],2001 *Data Integrity and Data Governance* Robert 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 **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 efficient 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

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

Practical Guide to Single-use Technology Adriana G Lopes,2016-08-31 Single use technology SUT is now available for all processing operations within the biopharmaceutical industry It has the potential to reduce capital costs improve plant throughput and reduce the risk of cross contamination However there are no clear guidelines to aid the end user on implementation of these technologies into a validated good manufacturing practice GMP environment This book is the first comprehensive publication of practical considerations for each stage of the implementation process of SUT and covers the selection specification design and qualification of systems to meet end user requirements Serving as an introduction and practical reference to this growing area of application within the biopharmaceutical industry this handbook presents An approach for SUT implementation within an end users facility with examples for bioreactors tangential flow filtration and fill finish systems SUT within the context of regulatory guidance such as ICH Q8 Q9 Q10 and GMP Strategy for standardisation of single use bag systems and assessment of extractables and leachables Specifications of user requirements and design of specific SUT alongside process descriptions and flow diagrams Strategies and tools to evaluate risk with examples of risk assessments applicable to design processing and product quality and Qualification approach for different SUT types With the information presented in this book engineers researchers and professionals involved in biopharmaceuticals will be better prepared to plan and make effective decisions to design and implement SUT

Quality Assurance and Management Mehmet Savsar,2012-03-23 The purpose of this book is to present new concepts state of the art techniques and advances in quality related research Novel ideas and current developments in the field of quality assurance and related topics are presented in different chapters which are organized according to application areas Initial chapters present basic ideas and historical

perspectives on quality while subsequent chapters present quality assurance applications in education healthcare medicine software development service industry and other technical areas This book is a valuable contribution to the literature in the field of quality assurance and quality management The primary target audience for the book includes students researchers quality engineers production and process managers and professionals who are interested in quality assurance and related areas

Bioreaction Engineering K. Schügerl, K.-H. Bellgardt, 2012-12-06 The book is intended to present various examples for reactor and process modeling and control as well as for metabolic flux analysis and metabolic design at an advanced level In Part A General principles and techniques with regard to reactor and process models process control and metabolic flux analysis are presented In addition the accuracy precision and reliability of the measured data are discussed which are extremely important for process modeling and control A virtual bioreactor system is presented as well which can be used for the training of students and operators of industrial plants and for the development of advanced automation tools In Part B the General principles are applied for particular bioreactor models It covers the application of the computational fluiddynamic CFD technique to stirred tank and bubble column bioreactors Different solution methods are presented the Reynolds averaging of the turbulent Navier Stokes equations and modeling of the Reynolds stresses with an appropriate turbulence k- ϵ model and the Euler two fluid model as well as the Euler-Lagrange approaches

Single-Use Technology Adriana G. Lopes, Andrew Brown, 2019-06-17 Single Use Technology SUT is the first comprehensive publication of practical considerations for each stage of the implementation process of SUT and covers the selection specification design and qualification of systems to meet end user requirements Having become readily available for all processing operations within the biopharmaceutical industry SUT has the potential to reduce capital costs improve plant throughput and reduce the risk of cross contamination However there are no clear guidelines to aid the end user on implementation of these technologies into a validated good manufacturing practice GMP environment This book presents approaches for the implementation within various end user facilities and systems SUT within regulatory frameworks ICH Q8 Q9 Q10 and GMP standardisation and assessment strategies specification of user requirements and SUT design risk assessment and evaluation as well as qualification for different SUT types

Good Informatics Practices (GIP) Module: Training and Training Practices Heidi Bargerhuff, Brenda Beckett, Cindy Breed, Ursula Centers, Stacy Craft, Jane Derman, Cathy Francis, Bryanna Gallaway, Karen Gividen RN, Robert Gividen, Summer Harrieff PhD, Jennifer R. Hawkins MS, Gina Ketcherside PHR CPT M. Ed, Maureen Martin, Susan Meineke, Brenda Money LPN CSS CBAP, Bryan Ricke, Juanita Schoen, Margaret Schulte, Linda Speake, Dianna Woodall,

The Pharmaceutical Regulatory Process Ira R. Berry, Robert P. Martin, 2008-12-02 This Second Edition examines the mechanisms and means to establish regulatory compliance for pharmaceutical products and company practices It focuses on major legislative revisions that impact requirements for drug safety reviews product regulatory approvals and marketing practices Written by top industry professionals practicing attorneys and

Text Book of Industrial Pharmacy Professor (Dr.)

D.Christopher Vimalson,Dr. Arjun Goje, Satyabrata Jena,Mrs. Swati Vikas Gondikar,2022-12-06 This book describes how products may help individuals have better health by treating pharmaceutical disorders Before these medicines are released to the market extensive research is often conducted Before all these medicines are used on actual people they are subjected to rigorous clinical testing To ensure their safety and effectiveness they are initially tested on animals Quickly afterwards individuals have health to these drugs because of doctors prescriptions In several chapters we learn that the Food and Drug Administration FDA is the agency responsible for determining whether or not a certain medication is safe for human consumption The Food and Drug Administration FDA constantly monitors the pharmaceutical industry The FDA will be notified of any claims made after or in connection with the use of the drugs and it has the power to withdraw the drugs sale approval Before issuing a sales sale they go through the whole testing and presenting method Some pharmaceutical companies base a significant portion of their operations on animal healthcare Research disorders and their outer signs are remembered as animals produce new medicines These drugs are prescribed by veterinarians for pets and other animals kept as pets Prior to being tested into the general iv public the drugs might undergo rigorous medical testing to ensure their safety Pharmaceuticals enormous impact on boosting general public health has led to their rapid expansion within the health care sector Because of their efforts people are treating longer with treatable diseases that were once fatal *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 *ePro* Brian Tiplady,2016-05-13 Patient self reported data has become increasingly important in today s clinical trials Trials in some disease indications rely upon patient recorded diary data as the primary endpoint to demonstrate drug efficacy including for example indications such as insomnia migraine and pain In addition improvements in quality of life measured using patient questionnaires can now be included as claims on drug labelling Traditionally these data have been collected using paper questionnaires and diaries issued to subjects Regulators and the industry have become increasingly aware of the limitations of recording patient reported outcomes data on paper including data quality and integrity issues As a result there is a growing interest in collection of patient reported outcomes data using electronic means ePRO Solutions include handheld PDAs Interactive Voice Response IVR systems and other site based hardware such as touchscreen PCs Recently there has been much open debate with the regulators around the use of ePRO in clinical drug submissions US and European agencies have approved new drugs that have included ePRO data in the submission dossier but there are many questions around the adoption of the technology that concern the community These include How should instruments developed on paper be adapted for electronic use and what degree of validation should be done between paper and electronic forms How can

researchers ensure they are complying with regulatory requirements including the PRO guidance published by FDA in 2009 when using ePRO solutions Can fewer patients be exposed in a clinical trial as a result of improved data quality obtained using electronic diaries What type of solution should be used for certain patient populations and protocols and how can ePRO solutions be designed optimally to increase patient acceptability and compliance Bill Byrom and Brian Tiplady's ePro addresses all these issues reviews the new FDA guidance and provides a very contemporary view on this important subject

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