Quality Manual Template For Pharmaceutical Company

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Rules and Guidance for Pharmaceutical Manufacturers and Distributors (Orange Guide) 2017 - Great Britain. Medicines and Healthcare products Regulatory Agency 2017-01-06
Familiarly known as the Orange Guide, this title is an essential reference work for all those involved in the manufacture and distribution of medicines in Europe. It is compiled by the UK drug regulatory body, MHRA, and brings together the European and UK guidance documents and information on legislation relating to the manufacture and distribution of medicines for human use. It contains EU guidance on good manufacturing and good distribution practice along with relevant information on EU and UK legislation. Changes in this new edition: Revised Annex 15. The revision of Annex 15 takes into account changes to other sections of the EudraLex, Volume 4, Part I, relationship to Part II, Annex 11, ICH Q8, Q9, Q10 and Q11, QWP guidance on process validation, and changes in manufacturing technology. Revised Annex 16. The GMP Guide Annex 16 has been revised to reflect the globalisation of the pharmaceutical supply chains and the introduction of new quality control strategies. The revision has been carried out in the light of Directive 2011/62/EU amending Directive 2001/83/EC as regards the prevention of the entry into the legal supply chain of falsified medicinal products. This version also implements ICH Q8, Q9 and Q10 documents, and interpretation documents, such as the manufacturing and importation authorisation (MIA) interpretation document, as applicable. Also, some areas, where the interpretation by Member States has not been consistent, have been clarified. This revised Annex came into operation 15 April 2016. The introduction of guidelines on setting health based exposure limits for use in risk identification in the manufacture of different medicinal products in shared facilities. The introduction of guidelines on the formalised risk assessment for ascertaining the appropriate GMP for excipients. The addition of the Guidelines on principles of Good Distribution Practice of active substances for medicinal products for human use (2015/C 95/01). These guidelines provide stand-alone guidance on Good Distribution Practice (GDP) for manufacturers, importers and distributors of active substances for medicinal products for human use. These guidelines should be followed as of 21 September 2015. The addition of the principles and guidelines of Good Manufacturing Practice (GMP) for active substances for medicinal products for human use, including active substances intended for export. Revisions to the UK Human Medicines Regulations 2012. MHRA GMP Data Integrity Definitions and Guidance for Industry is now included which sets out MHRA expectations for data integrity in good manufacturing practice (GMP). The Guidance complements existing EU GMP guidance and should be read in conjunction with national medicines legislation and the GMP standards published in Eudralex volume.
Measuring Productivity - OECD Manual Measurement of Aggregate and Industry-level Productivity Growth - OECD 2001-07-16
This manual presents the theoretical foundations to productivity measurement, and discusses implementation and measurement issues.
Achieving Customer Experience Excellence through a Quality Management System - Alka Jarvis 2016-07-08
We are in what many call The Age of the Customer. Customers are empowered more than ever before and demand a high level of customer attention and service. Their increasing expectations and demands worldwide have forced organizations to transform themselves and prepare for the customer experience (CX) battlefield. This landmark book addresses: What customer experience really means Why it matters Whether it has any substantial business impact What your organization can do to deliver and sustain your CX efforts, and How we got to this particular point in CX history This book is the result of exhaustive research conducted to incorporate various components that affect customer experience. Based on the research results, the authors make a case for seeing CX and associated transformations as the next natural evolution of the quality management system (QMS) already in place in most companies. Using an existing QMS as the foundation for CX not only creates a more sustainable platform, but it allows for a faster and more cost effective way to enable an organization to attain world-class CX.
International IT Regulations and Compliance - Siri H. Segalstad 2008-11-20
Standards, technologies, and requirements for computer validation have changed dramatically in recent years, and so have the interpretation of the standards and the understanding of the processes involved. International IT Regulations and Compliance brings together current thinking on the implementation of standards and regulations in relation to IT for a wide variety of industries. The book provides professionals in pharmaceutical and semiconductor industries with an updated overview of requirements for handling IT systems according to various Quality Standards and how to ?translate? these requirements in the regulations.
MEDINFO 2017: Precision Healthcare Through Informatics - A.V. Gundlapalli 2018-01-31
Medical informatics is a field which continues to evolve with developments and improvements in foundational methods, applications, and technology, constantly offering opportunities for supporting the customization of healthcare to individual patients. This book presents the proceedings of the 16th World Congress of Medical and Health Informatics (MedInfo2017), held in Hangzhou, China, in August 2017, which also marked the 50th anniversary of the International Medical Informatics Association (IMIA). The central theme of MedInfo2017 was "Precision Healthcare through Informatics", and the scientific program was divided into five tracks: connected and digital health; human data science; human, organizational, and social aspects; knowledge management and quality; and safety and patient outcomes. The 249 accepted papers and 168 posters included here span the breadth and depth of sub-disciplines in biomedical and health informatics, such as clinical informatics; nursing informatics; consumer health informatics; public health informatics; human factors in healthcare; bioinformatics; translational informatics; quality and safety; research at the intersection of biomedical and health informatics; and precision medicine. The book will be of interest to all those who wish to keep pace with advances in the science, education, and practice of biomedical and health informatics worldwide.
Chemical Genomics - Haian Fu 2012-02-13
Advances in chemistry, biology and genomics coupled with laboratory automation and computational technologies have led to the rapid emergence of the multidisciplinary field of chemical genomics. This edited text, with contributions from experts in the field, discusses the new techniques and applications that help further the study of chemical genomics. The beginning chapters provide an overview of the basic principles of chemical biology and chemical genomics. This is followed by a technical section that describes the sources of small-molecule chemicals; the basics of high-throughput screening technologies; and various bioassays

for biochemical-, cellular- and organism-based screens. The final chapters connect the chemical genomics field with personalized medicine and the druggable genome for future discovery of new therapeutics. This book will be valuable to researchers, professionals and graduate students in many fields, including biology, biomedicine and chemistry.

Implementing Quality in Laboratory Policies and Processes - Donnell R. Christian, Jr. 2009-11-24

In order to gain accreditation, every laboratory must have a superior quality assurance program. The keys to a successful program are the operational and technical manuals and associated documents which define the program and its various components. Written by experts with global experience in setting up laboratories, Implementing Quality in Laboratory Policies and Processes: Using Templates, Project Management, and Six Sigma provides templates for the various policies, procedures, and forms that should be contained in the quality assurance, operational, and technical manuals of a laboratory seeking accreditation. Templates for the entire project life cycle The book begins with a general introduction and overview of quality assurance and then moves on to cover implementation strategies. It contains best practices and templates for the project management of the design and implementation of the laboratory operational and technical manuals required to establish a quality assurance program. The templates span the entire project life cycle, from initiation, to planning, to execution, to monitoring, and finally, to closure. The book also examines how Six Sigma concepts can be used to optimize laboratories, and contains templates that cover administrative issues, quality assurance, sample control, and health and safety issues. In addition, there is a section of criteria files that relate the individual document templates to specific accreditation criterion. Addresses the standards of ISO 17025 The results of any laboratory examination have the potential to be presented in court and can ultimately affect the life and liberty of the parties involved. Therefore, a stringent quality assurance program, including well-documented policies and a procedure manual, is essential. Ensuring that laboratories meet the standards of ISO 17025, this volume is a critical component of any laboratory’s accreditation process.

Pharmaceutical Quality Systems - Oliver Schmidt 2000-04-30

When a pharmaceutical company decides to build a Quality System, it has to face the fact that there aren't any guideline that define exactly how such a system has to be built. With terms such as quality system, quality assurance, and quality management used interchangeably, even defining the system's objectives is a problem. This book provides a pr

Pharmaceutical Quality by Design - Sarwar Beg 2019-03-27

Pharmaceutical Quality by Design: Principles and Applications discusses the Quality by Design (QbD) concept implemented by regulatory agencies to ensure the development of a consistent and high-quality pharmaceutical product that safely provides the maximum therapeutic benefit to patients. The book walks readers through the QbD framework by covering the fundamental principles of QbD, the current regulatory requirements, and the applications of QbD at various stages of pharmaceutical product development, including drug substance and excipient development, analytical development, formulation development, dissolution testing, manufacturing, stability studies, bioequivalence testing, risk and assessment, and clinical trials. Contributions from global leaders in QbD provide specific insight in its application in a diversity of pharmaceutical products, including nanopharmaceuticals, biopharmaceuticals, and vaccines. The inclusion of illustrations, practical examples, and case studies makes this book a useful reference guide to pharmaceutical scientists and researchers who are engaged in the formulation of various delivery systems and the analysis of pharmaceutical product development and drug manufacturing process. Discusses vital QbD precepts and fundamental aspects of QbD implementation in the pharma, biopharma and biotechnology industries Provides helpful illustrations, practical examples and research case studies to explain QbD concepts to readers Includes contributions from global leaders and experts from academia, industry and regulatory agencies

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.

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

Bacteriological Analytical Manual - United States. Food and Drug Administration. Division of Microbiology 1969

Cobert's Manual of Drug Safety and Pharmacovigilance - Barton Cobert 2011-04

Completely revised and updated, the Manual of Drug Safety and Pharmacovigilance, Second Edition is a how-to manual for those working in the fields of drug safety, clinical research, pharmacology, regulatory affairs, government and legal professions. This comprehensive and practical guide discusses the theory and the practicalities of drug safety (also known as pharmacovigilance) and side effects, as well as providing essential information on drug safety and regulations, including: recognizing, monitoring, reporting and cataloging serious adverse drug reactions. The Manual of Drug Safety and Pharmacovigilance, Second Edition teaches the ins and outs of drug safety in the industry, hospitals, FDA, and other health agencies both in the US and around the world, and presents critical information about what is done when confronted with a drug safety problem.

Business Development for the Biotechnology and Pharmaceutical Industry - Martin Austin 2016-04-08

Business Development in the biotechnology and pharmaceutical industries accounts for over $5 billion in licensing deal value per year and much more than that in the value of mergers and acquisitions. Transactions range from licences to patented academic research, to product developments as licences, joint ventures and acquisition of intellectual property rights, and on to collaborations in development and marketing, locally or across the globe. Asset sales, mergers and corporate takeovers are also a part of the business development remit. The scope of the job can be immense, spanning the life-cycle of products from the earliest levels of research to the disposal of residual marketing rights, involving legal regulatory manufacturing, clinical development, sales and marketing and financial aspects. The knowledge and skills required of practitioners must be similarly broad, yet the availability of information for developing a career in business development is sparse. Martin Austin's highly practical guide spans the complete process and is based on his 30 years of experience in the industry and the well-established training programme that he has developed and delivers to pharmaceutical executives from across the world.

Story-Based Inquiry: A Manual for Investigative Journalists - Mark Lee Hunter 2011

"Investigative Journalism means the unveiling of matters that are concealed either deliberately by someone in a position of power, or accidentally, behind a chaotic mass of facts and circumstances - and the analysis and exposure of all relevant facts to the public. In this way investigative journalism crucially contributes to freedom of expression and freedom of information, which are at the heart of UNESCO's mandate. The role media can play as a watchdog is indispensable for democracy and it is for this reason that UNESCO fully supports initiatives to strengthen investigative journalism throughout the world. I believe this publication makes a significant contribution to promoting investigative journalism and I hope it will be a valuable resource for journalists and media professionals, as well as for journalism trainers and educators." -- Jānis Kārklinš, Assistant Director-General for Communication and

Information, UNESCO, Preface, page 1.

Validation Standard Operating Procedures - Syed Imtiaz Haider 2001-12-27

One of the most common reasons so many new drug, medical device, or equipment applications are rejected each year by the FDA is the failure to properly develop and document plans and procedures. This is required of both U.S. and foreign companies wishing to market their products in the United States. The lack of well defined validation standard operating procedures may result in adverse FDA findings, recalls, and heavy financial losses. Key FDA guidelines on good manufacturing practice (GMP), good laboratory practice (GLP), and validation do not describe exactly how to develop a master validation plan, how to achieve compliance, or the standard operating procedures and documentation required. This text provides the required validation standard operating procedures and documentation necessary for achieving compliance in the pharmaceutical industry. The text and CD are designed to minimize workload and optimize time, money, and resources. A comprehensive when-and-how-to-do-it guide, Validation Standard Operating Procedures provides the needed administrative solutions and guidance for achieving compliance with FDA requirements, and for obtaining authorization to market products in the United States. The CD-ROM contains 74 template validation standard operating procedures that can be tailored to meet the regulatory compliance requirements of any pharmaceutical, diagnostic, medical device, medical equipment, and biotech product. You can edit, print, and customize these procedures to fit your needs. The book and CD work together to minimize the number of documents used and to ensure their accuracy. All critical elements and requirements of validation are covered, so you can easily implement them and avoid the stress that usually accompanies an FDA audit. Features Provides all the information that managers need to establish functions, acceptance criteria, and validation procedures in compliance with FDA guidelines Includes step-by-step directions for translating GMP requirements into action, based on your company's Master Validation Plan and execution protocols Describes how to establish test functions and prevent defects in order to produce products that are fit for use Serves as an ideal companion to Haider's Pharmaceutical Master Validation Plan

Registries for Evaluating Patient Outcomes - Agency for Healthcare Research and Quality/AHRQ 2014-04-01

This User’s Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User’s Guide was created by researchers affiliated with AHRQ’s Effective Health Care Program, particularly those who participated in AHRQ’s DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

Quality Control Training Manual - Syed Imtiaz Haider 2016-04-19

Written to help companies comply with GMP, GLP, and validation requirements imposed by the FDA and regulatory bodies worldwide, Quality Control Training Manual: Comprehensive Training Guide for API, Finished Pharmaceutical and Biotechnologies Laboratories presents cost-effective training courses that cover how to apply advances in the life sciences

Improving Healthcare Quality in Europe Characteristics, Effectiveness and Implementation of Different Strategies - OECD 2019-10-17

This volume, developed by the Observatory together with OECD, provides an overall conceptual framework for understanding and applying strategies aimed at improving quality of care. Crucially, it summarizes available evidence on different quality strategies and provides recommendations for their implementation. This book is intended to help policy-makers to understand concepts of quality and to support them to evaluate single strategies and combinations of strategies.

Developing Solid Oral Dosage Forms - Yihong Qiu 2016-11-08

Developing Solid Oral Dosage Forms: Pharmaceutical Theory and Practice, Second Edition illustrates how to develop high-quality, safe, and effective pharmaceutical products by discussing the latest techniques, tools, and scientific advances in preformulation investigation, formulation, process design, characterization, scale-up, and production operations. This book covers the essential principles of physical pharmacy, biopharmaceutics, and industrial pharmacy, and their application to the research and development process of oral dosage forms. Chapters have been added, combined, deleted, and completely revised as necessary to produce a comprehensive, well-organized, valuable reference for industry professionals and academics engaged in all aspects of the development process. New and important topics include spray drying, amorphous solid dispersion using hot-melt extrusion, modeling and simulation, bioequivalence of complex modified-released dosage forms, biowaivers, and much more. Written and edited by an international team of leading experts with experience and knowledge across industry, academia, and regulatory settings Includes new chapters covering the pharmaceutical applications of surface phenomenon, predictive biopharmaceutics and pharmacokinetics, the development of formulations for drug discovery support, and much more Presents new case studies throughout, and a section completely devoted to regulatory aspects, including global product regulation and international perspectives

Establishing A CGMP Laboratory Audit System - David M. Bliesner 2006-04-28

The first systematic, hands-on auditing guide for today'spharmaceutical laboratories In today's litigious environment, pharmaceutical laboratories aresubject to ever stricter operational guidelines as mandated by theFDA, and must be able to establish and demonstrate sustainableoperational practices that ensure compliance with the current goodmanufacturing practice (CGMP) regulations. David Bliesner'sEstablishing a CGMP Laboratory Audit System: A Practical Guide isdesigned to provide laboratory supervisors and personnel with astep-by-step, hands-on audit system that they can rely on to ensuretheir facility remains compliant with all current and futurerequirements. Focusing on a "team approach," the author usesdetailed flowcharts, checklists, and descriptions of the auditingprocess to help readers develop a new audit system or upgrade theircurrent system in order to: * Improve current compliance * Demonstrate sustainable compliance * Produce data for federal inspections * Avoid regulatory action Enhanced with detailed checklists and a wealth of practical andflexible auditing tools on CD-ROM, this book provides an idealresource for new and future laboratory personnel, and an excellentmeans for keeping existing industry practitioners up to date on thenuances of operating a consistently compliant pharmaceuticallaboratory.

Quality Control with R - Emilio L. Cano 2015-11-20

Presenting a practitioner's guide to capabilities and best practices of quality control systems using the R programming language, this volume emphasizes accessibility and ease-of-use through detailed explanations of R code as well as standard statistical methodologies. In the interest of reaching the widest possible audience of quality-control professionals and statisticians, examples throughout are structured to simplify complex equations and data structures, and to demonstrate their applications to quality control processes, such as ISO standards. The volume balances its treatment of key aspects of quality

control, statistics, and programming in R, making the text accessible to beginners and expert quality control professionals alike. Several appendices serve as useful references for ISO standards and common tasks performed while applying quality control with R.

Quality Management and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy - Mahmoud Aljurf 2021-02-19

This open access book provides a concise yet comprehensive overview on how to build a quality management program for hematopoietic stem cell transplantation (HSCT) and cellular therapy. The text reviews all the essential steps and elements necessary for establishing a quality management program and achieving accreditation in HSCT and cellular therapy. Specific areas of focus include document development and implementation, audits and validation, performance measurement, writing a quality management plan, the accreditation process, data management, and maintaining a quality management program. Written by experts in the field, Quality Management and Accreditation in Hematopoietic Stem Cell Transplantation and Cellular Therapy: A Practical Guide is a valuable resource for physicians, healthcare professionals, and laboratory staff involved in the creation and maintenance of a state-of-the-art HSCT and cellular therapy program.

Handbook of Total Quality Management - Christian N. Madu 2012-12-06

Quality issues are occupying an increasingly prominent position in today's global business market, with firms seeking to compete on an international level on both price and quality. Consumers are demanding higher quality standards from manufacturers and service providers, while virtually all industrialized nations have instituted quality programs to help indigenous corporations. A proliferation in nation-wide and regional quality awards such as the Baldridge award and certification to ISO 9000 series are making corporations world-wide quality-conscious and eager to implement programs of continuous improvement. To achieve competitiveness, quality practice is a necessity and this book offers an exposition of how quality can be attained. The Handbook of Total Quality Management: Explores in separate chapters new topics such as re-engineering, concurrent engineering, ISO standards, QFD, the Internet, the environment, advanced manufacturing technology and benchmarking Discusses the views of leading quality practitioners such as Derning, Juran, Ishikawa, Crosby and Taguchi throughout the book Considers important strategies for quality improvement, including initiation and performance evaluation through auditing, re-engineering, and process and design innovations. With contributions from 47 authors in 13 different countries, the Handbook of Total Quality Management is invaluable as a reference guide for anyone involved with quality management and deployment, including consultants, practitioners and engineers in the professional sector, and students and lecturers of information systems, management and industrial engineering.

Guide for All-Hazard Emergency Operations Planning - Kay C. Goss 1998-05

Meant to aid State & local emergency managers in their efforts to develop & maintain a viable all-hazard emergency operations plan. This guide clarifies the preparedness, response, & short-term recovery planning elements that warrant inclusion in emergency operations plans. It offers the best judgment & recommendations on how to deal with the entire planning process -- from forming a planning team to writing the plan. Specific topics of discussion include: preliminary considerations, the planning process, emergency operations plan format, basic plan content, functional annex content, hazard-unique planning, & linking Federal & State operations.

Pharmaceutical Manufacturing Handbook - Shayne Cox Gad 2008-03-21

This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

Laboratory Quality Management System - World Health Organization 2011

Achieving, maintaining and improving accuracy, timeliness and reliability are major challenges for health laboratories. Countries worldwide committed themselves to build national capacities for the detection of, and response to, public health events of international concern when they decided to engage in the International Health Regulations implementation process. Only sound management of quality in health laboratories will enable countries to produce test results that the international community will trust in cases of international emergency. This handbook was developed through collaboration between the WHO Lyon Office for National Epidemic Preparedness and Response, the United States of America Centers for Disease Control and Prevention (CDC) Division of Laboratory Systems, and the Clinical and Laboratory Standards Institute (CLSI). It is based on training sessions and modules provided by the CDC and WHO in more than 25 countries, and on guidelines for implementation of ISO 15189 in diagnostic laboratories, developed by CLSI. This handbook is intended to provide a comprehensive reference on Laboratory Quality Management System for all stakeholders in health laboratory processes, from management, to administration, to bench-work laboratorians. This handbook covers topics that are essential for quality management of a public health or clinical laboratory. They are based on both ISO 15189 and CLSI GP26-A3 documents. Each topic is discussed in a separate chapter. The chapters follow the framework developed by CLSI and are organized as the "12 Quality System Essentials".

Quality Assurance of Aseptic Preparation Services - Alison M. Beaney 2016

Quality Assurance of Aseptic Preparation Services Standards Handbook (also known as the Yellow Guide) provides standards for unlicensed aseptic preparation in the UK, as well as practical information to aid implementation of the standards. The handbook delivers essential standards in a practical way and in a format that will be useful for pharmacy management, staff working in aseptic preparation units and those whose role it is to audit the services. The accompanying support resources help with understanding the complexities of relevant topics including microbiology, radiopharmaceuticals, advanced therapy medicinal products, technical (quality) agreements and capacity planning. All the standards have been revised and updated for this 5th edition. The text is produced on behalf of the Royal Pharmaceutical Society (RPS) and the NHS Pharmaceutical Quality Assurance Committee. New in this edition: Replaces the 4th edition standards and forms the basis for an ongoing audit program in the NHS Many new and revised standards Greater emphasis on Pharmaceutical Quality Systems; the responsibilities of pharmacy management, Chief Pharmacists (or equivalent), has been expanded in line with developments in Good Manufacturing Practice Reformatted into 2 parts: standards and support resources. This is a new collaboration between the RPS and NHS. Since the previous edition the RPS has become the professional body for pharmacists and pharmaceutical scientists. RPS launched these standards as part of a library of professional standards and a programme of work to create standards for all areas of pharmacy. The Handbook is essential for pharmacists, hospital pharmacy management and technical services teams, and auditors of unlicensed NHS hospital pharmacy aseptic preparation services in the UK, pharmacists and regulators. The text is used to inform standards used in several other countries.

ISO 17025-2017 Sample Quality Manual for Testing Lab - M. NAVEED 2018-12-17

This book is specially useful for the laboratories preparing Quality Manual as per ISO 17025-2017 Lab Quality Management System. It includes the index, release authorisation, amendment sheet, explanation of how lab complies with clause requirements, references to procedures and records for each clause as an evidence. The book is also useful to all the professionals associated with laboratory quality management as reference for preparing the lab for accreditation.

Pharmaceutical Microbiology Manual - United States Food and Drug Administration 2017-09-21

Manual and is a supplement to the United States Pharmacopeia (USP) for pharmaceutical microbiology testing, including antimicrobial effectiveness testing, microbial examination of non-sterile products, sterility testing, bacterial endotoxin testing, particulate matter, device bioburden and environmental monitoring testing. The goal of this manual is to provide an ORA/CDER harmonized framework on the knowledge, methods and tools needed, and to apply the appropriate scientific standards required to assess the safety and efficacy of medical products within FDA testing laboratories. The PMM has expanded to include some rapid screening techniques along with a new section that covers inspectional guidance for microbiologists that conduct team inspections. This manual was developed by members of the Pharmaceutical Microbiology Workgroup and includes individuals with specialized experience and training. The instructions in this document are guidelines for FDA analysts. When available, analysts should use procedures and worksheets that are standardized and harmonized across all ORA field labs, along with the PMM, when performing analyses related to product testing of pharmaceuticals and medical devices. When changes or deviations are necessary, documentation should be completed per the laboratory's Quality Management System. Generally, these changes should originate from situations such as new products, unusual products, or unique situations. This manual was written to reduce compendia method ambiguity and increase standardization between FDA field laboratories. By providing clearer instructions to FDA ORA labs, greater transparency can be provided to both industry and the public. However, it should be emphasized that this manual is a supplement, and does not replace any information in USP or applicable FDA official guidance references. The PMM does not relieve any person or laboratory from the responsibility of ensuring that the methods being employed from the manual are fit for use, and that all testing is validated and/or verified by the user. The PMM will continually be revised as newer products, platforms and technologies emerge or any significant scientific gaps are identified with product testing. Reference to any commercial materials, equipment, or process in the PMM does not in any way constitute approval, endorsement, or recommendation by the U.S. Food and Drug Administration.

Human Stem Cell Manual - Suzanne E. Peterson 2012-08-27

This reader-friendly manual provides a practical "hands on" guide to the culture of human embryonic and somatic stem cells. By presenting methods for embryonic and adult lines side-by-side, the authors lay out an elegant and unique path to understanding the science of stem cell practice. The authors begin with a broad-based introduction to the field, and also review legal and regulatory issues and patents. Each experimental strategy is presented with an historical introduction, detailed method, discussion of alternative methods, and common pitfalls. This lab guide for researchers also serves as a textbook for undergraduate and graduate students in laboratory courses. • Offers a comprehensive introduction to stem cell biology and culture for medical and biology researchers investigating diagnostics and treatments for various diseases • Presents a historical introduction, discussion of alternative methods, and common pitfalls for basic and advanced experimental strategies • Includes new chapters devoted to iPS cells and other alternative sources for generating human stem cells written by the scientists who made these breakthroughs

Guidance for the Validation of Analytical Methodology and Calibration of Equipment Used for Testing of Illicit Drugs in Seized Materials and Biological Specimens - United Nations 2009

The validation of analytical methods and the calibration of equipment are important aspects of quality assurance in the laboratory. This manual deals with both of these within the context of testing of illicit drugs in seized materials and biological specimens. It provides an introduction and practical guidance to national authorities and analysts in the implementation of method validation and verification, and also in the calibration/performance verification of laboratory instrumentation and equipment within their existing internal quality assurance programmes. The procedures described represent a synthesis of the experience of scientists from several reputable laboratories around the world.

WHO Expert Committee on Specifications for Pharmaceutical Preparations - World Health Organization 2013

WHO's international guidelines written and physical standards developed under the aegis of this Expert Committee for more than 60 years are designed to serve all Member States international organizations United Nations agencies regional and interregional harmonization efforts and underpin important initiatives including the prequalification of medicines the Roll Back Malaria Programme Stop TB essential medicines and medicines for children. The Forty-seventh WHO Expert Committee on Specifications for Pharmaceutical Preparations adopted 26 new monographs and general texts for inclusion in The In.

Executing Data Quality Projects - Danette McGilvray 2021-05-27

Executing Data Quality Projects, Second Edition presents a structured yet flexible approach for creating, improving, sustaining and managing the quality of data and information within any organization. Studies show that data quality problems are costing businesses billions of dollars each year, with poor data linked to waste and inefficiency, damaged credibility among customers and suppliers, and an organizational inability to make sound decisions. Help is here! This book describes a proven Ten Step approach that combines a conceptual framework for understanding information quality with techniques, tools, and instructions for practically putting the approach to work – with the end result of high-quality trusted data and information, so critical to today’s data-dependent organizations. The Ten Steps approach applies to all types of data and all types of organizations – for-profit in any industry, non-profit, government, education, healthcare, science, research, and medicine. This book includes numerous templates, detailed examples, and practical advice for executing every step. At the same time, readers are advised on how to select relevant steps and apply them in different ways to best address the many situations they will face. The layout allows for quick reference with an easy-to-use format highlighting key concepts and definitions, important checkpoints, communication activities, best practices, and warnings. The experience of actual clients and users of the Ten Steps provide real examples of outputs for the steps plus highlighted, sidebar case studies called Ten Steps in Action. This book uses projects as the vehicle for data quality work and the word broadly to include: 1) focused data quality improvement projects, such as improving data used in supply chain management, 2) data quality activities in other projects such as building new applications and migrating data from legacy systems, integrating data because of mergers and acquisitions, or untangling data due to organizational breakups, and 3) ad hoc use of data quality steps, techniques, or activities in the course of daily work. The Ten Steps approach can also be used to enrich an organization’s standard SDLC (whether sequential or Agile) and it complements general improvement methodologies such as six sigma or lean. No two data quality projects are the same but the flexible nature of the Ten Steps means the methodology can be applied to all. The new Second Edition highlights topics such as artificial intelligence and machine learning, Internet of Things, security and privacy, analytics, legal and regulatory requirements, data science, big data, data lakes, and cloud computing, among others, to show their dependence on data and information and why data quality is more relevant and critical now than ever before. Includes concrete instructions, numerous templates, and practical advice for executing every step of The Ten Steps approach Contains real examples from around the world, gleaned from the author’s consulting practice and from those who implemented based on her training courses and the earlier edition of the book Allows for quick reference with an easy-to-use format highlighting key concepts and definitions, important checkpoints, communication activities, and best practices A companion Web site includes links to numerous data quality resources, including many of the templates featured in the text, quick summaries of key ideas from the Ten Steps methodology, and other tools and information that are available online

Suggestions to Medical Authors and A.M.A. Style Book - American

Medical Association 1919

A Guide for Machine Vision in Quality Control - Sheila Anand 2019-12-23
Machine Vision systems combine image processing with industrial automation. One of the primary areas of application of Machine Vision in the Industry is in the area of Quality Control. Machine vision provides fast, economic and reliable inspection that improves quality as well as business productivity. Building machine vision applications is a challenging task as each application is unique, with its own requirements and desired outcome. A Guide to Machine Vision in Quality Control follows a practitioner’s approach to learning machine vision. The book provides guidance on how to build machine vision systems for quality inspections. Practical applications from the Industry have been discussed to provide a good understanding of usage of machine vision for quality control. Real-world case studies have been used to explain the process of building machine vision solutions. The book offers comprehensive coverage of the essential topics, that includes: Introduction to Machine Vision Fundamentals of Digital Images Discussion of various machine vision system components Digital image processing related to quality control Overview of automation The book can be used by students and academics, as well as by industry professionals, to understand the fundamentals of machine vision. Updates to the on-going technological innovations have been provided with a discussion on emerging trends in machine vision and smart factories of the future. Sheila Anand is a PhD graduate and Professor at Rajalakshmi Engineering College, Chennai, India. She has over three decades of experience in teaching, consultancy and research. She has worked in the software industry and has extensive experience in development of software applications and in systems audit of financial, manufacturing and trading organizations. She guides Ph.D. aspirants and many of her research scholars have since been awarded their doctoral degree. She has published many papers in national and international journals and is a reviewer for several journals of repute. L Priya is a PhD graduate working as Associate Professor and Head, Department of Information Technology at Rajalakshmi Engineering College, Chennai, India. She has nearly two decades of teaching experience and good exposure to consultancy and research. She has delivered many invited talks, presented papers and won several paper awards in International Conferences. She has published several papers in International journals and is a reviewer for SCI indexed journals. Her areas of interest include Machine Vision, Wireless Communication and Machine Learning.
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.
Medication Reconciliation - Kristine M. Gleason 2008
Tired of medication reconciliation headaches? Your remedy is here! Inadequate reconciliation is a significant source of preventable medication errors nationwide. Most hospitals have implemented medication reconciliation plans, but are still struggling with obstacles such as lack of communication, resistance to change, and evolving standards and regulations. Is medication reconciliation a headache for your organization? It's been several years since The Joint Commission made medication reconciliation a National Patient Safety Goal, but it's not getting any easier, as facilities adopt electronic forms and The NPSG continues to evolve. Furthermore, since that time, they have made significant changes to the scoring and the goal itself. Medication Reconciliation: Practical Strategies and Tools for Joint Commission Compliance, Second Edition, gives you best practices, step-by-step guidance, forms, and advice to: - Reduce medication errors - Streamline the process - Boost compliance - Fine tune policies and tools - Address problem areas - Comply with the latest Joint Commission and CAMH standards With the help of this book and bonus CD-ROM, you will: - Learn from the best practices of your peers - Obtain buy-in from physicians and directors - Train staff in all areas - Build an effective team approach - Improve documentation - Gather quality data Who will benefit from this helpful resource? Hospitals Healthcare systems Pharmacies Quality improvement Patient Safety Survey Committee Chief Nursing Officer Director/VP of Nursing Quality Manager/Director Pharmacy staff/director Risk Manager Survey Committee leader/team member
Pharmaceutical Quality by Design Using JMP - Rob Lievense 2018-10
Solve your pharmaceutical product development and manufacturing problems using JMP®. Pharmaceutical Quality by Design Using JMP®: Solving Product Development and Manufacturing Problems provides broad-based techniques available in JMP to visualize data and run statistical analyses for areas common in healthcare product manufacturing. As international regulatory agencies push the concept of Quality by Design (QbD), there is a growing emphasis to optimize the processing of products. This book uses practical examples from the pharmaceutical and medical device industries to illustrate easy-to-understand ways of incorporating QbD elements using JMP. Pharmaceutical Quality by Design Using JMP® opens by demonstrating the easy navigation of JMP to visualize data through the distribution function and the graph builder and then highlights the following: the powerful dynamic nature of data visualization that enables users to be able to quickly extract meaningful information tools and techniques designed for the use of structured, multivariate sets of experiments examples of complex analysis unique to healthcare products such as particle size distributions/drug dissolution, stability of drug products over time, and blend uniformity/content uniformity. Scientists, engineers, and technicians involved throughout the pharmaceutical and medical device product life cycles will find this book invaluable. This book is part of the SAS Press program.