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Single-Use Technology in Biopharmaceutical Manufacture Regine Eibl,Dieter Eibl,2019-07-18 Authoritative guide to the principles characteristics engineering aspects economics and applications of disposables in the manufacture of biopharmaceuticals The revised and updated second edition of Single Use Technology in Biopharmaceutical Manufacture offers a comprehensive examination of the most commonly used disposables in the manufacture of biopharmaceuticals The authors noted experts on the topic provide the essential information on the principles characteristics engineering aspects economics and applications This authoritative guide contains the basic knowledge and information about disposable equipment The author also discusses biopharmaceuticals applications through the lens of case studies that clearly illustrate the role of manufacturing quality assurance and environmental influences This updated second edition revises existing information with recent developments that have taken place since the first edition was published The book also presents the latest advances in the field of single use technology and explores topics including applying single use devices for microorganisms human mesenchymal stem cells and T cells This important book Contains an updated and end to end view of the development and manufacturing of single use biologics Helps in the identification of appropriate disposables and relevant vendors Offers illustrative case studies that examine manufacturing quality assurance and environmental influences Includes updated coverage on cross functional transversal dependencies significant improvements made by suppliers and the successful application of the single use technologies Written for biopharmaceutical manufacturers process developers and biological and chemical engineers Single Use Technology in Biopharmaceutical Manufacture 2nd Edition provides the information needed for professionals to come to an easier decision for or against disposable alternatives and to choose the appropriate system

Specification of Drug Substances and Products Christopher M. Riley,K. Lien Nguyen,2024-09-22 Specification of Drug Substances and Drug Products is a fully comprehensive reference on Specification Setting for Pharmaceuticals There have been several recent developments in the ICH Guidelines which were not captured in previous editions notably the new guideline on Development of Analytical Procedure and the revisions to the validation guidelines and the specification guidelines This edition contains chapters discussing the unique requirements for the universal critical quality attributes as well as the specific tests required to characterize and control different types of products ranging in complexity from small molecules in immediate release oral dosage forms to complex products such as drug antibody conjugates and mRNA based products This substantially expanded revision of the 2nd edition will serve as practical comprehensive reference for scientists managers educators and consultants involved in the development and regulation of pharmaceutical products Presents critical assessment potential impact and application of the recent revisions to ICH guidelines on method validation Q2 as well as the latest guideline on Analytical Method Development Q14 and the special regional requirements in non ICH regions Addresses comprehensive treatment of the development and validation of

analytical methodologies used in the analysis control and specification of a variety of different types of dosage forms ranging from traditional oral solid dosage forms to proteins nRNA based drugs vaccines and gene therapy This book will also address drug device combinationproducts such as digital drug delivery systems transdermal systems and inhalation products Presents detailed treatment of latest statistical approaches including new approaches to the treatment of validation data method specification setting and shelf life prediction based on stability data **Advances in Genomics of Crossbred Farm Animals** Xiao-Lin Wu, Shu-Hong Zhao, 2021-09-24 Oral Formulation Roadmap from Early Drug Discovery to Development Elizabeth Kwong, 2017-01-03 Detailing formulation approaches by stage of discovery to early development this book gives a playbook of practical and efficient strategies to formulate drug candidates with the least chance of failing in clinical development Comes from contributing authors with experience developing formulations on the frontlines of the pharmaceutical industry Focuses on pre or non clinical and early stage development the phases where most compounds are used in drug research Features case studies to illustrate practical challenges and solutions in formulation selection Covers regulatory filing drug metabolism and physical and chemical properties toxicology formulation biopharmaceutics classification system BCS screening approaches early stage clinical formulation development and outsourcing

Evidence-Based Validation of Herbal Medicine Pulok K. Mukherjee, 2015-02-17 Evidence Based Validation of Herbal Medicines brings together current thinking and practice in the areas of characterization and validation of natural products This book reviews all aspects of evaluation and development of medicines from plant sources including their cultivation collection phytochemical and phyto pharmacological evaluation and therapeutic potential Emphasis is placed on describing the full range of evidence based analytical and bio analytical techniques used to characterize natural products including omic technologies phyto chemical analysis hyphenated techniques and many more Includes state of the art methods for detecting isolating and performing structure elucidation by degradation and spectroscopic techniques Covers biosynthesis synthesis and biological activity related to natural products Consolidates information to save time and money in research Increases confidence levels in quality and validity of natural products **Tortillas: Wheat Flour and Corn Products** LW

Rooney, Sergio O. Serna-Saldivar, 2015-01-01 Corn and wheat are among the most important cereals worldwide representing many of the calories and proteins consumed Tortillas and tortilla related products are among the fastest growing segments of the food industry and represent a sizeable portion of those calories Tortillas Wheat Flour and Corn Products answers the food industry s need to meet the growing demand for high quality tortillas and tortilla based foods This book will guide food scientists product developers and nutritionists through the fascinating science and technology behind the production of corn and wheat flour tortillas This title is the most comprehensive English language book of its kind It fully describes the technology nutritional value and quality control measures of corn and wheat flour tortillas tortilla chips and related products It accomplishes this through 300 pages of quality text complemented by easy to understand facts figures tables and

summaries that seamlessly guide users to an understanding of the fundamental underlying principles that optimize tortilla production and guide product development Tortillas Wheat Flour and Corn Products is ideal for academics and industry professionals including food science and nutrition students people working in the tortilla and snack food industries industry staff interested in the quality control assurance aspects of tortillas and professionals interested in cereal processing and product development Edited by the renowned food science educators in tortilla production this book provides high quality training at both the academic and corporate levels A history of corn and wheat flour tortillas Ideal physicochemical properties of corn kernels and wheat flours to optimize processing Quality attributes of processed products and quality control troubleshooting Food safety and quality control from the raw materials to intermediate and finished products Various industrial setups and pilot plant techniques currently used to manufacture wheat flour tortillas Ideal physical chemical and rheological properties of tortilla flours Roles of leavening agents in tortilla quality Functions of dough emulsifiers and reducing agents in textural shelf life and process ability Effects and roles of preservatives and supplemented enzymes on shelf life Common quality and consistency issues encountered by the flour tortilla industry along with solutions and recommendations Optimum properties of corn kernels for tortillas and nixtamalized snacks such as parched fried corn corn chips and tortilla chips Milling processes and quality control testing used to obtain lime cooked dough the backbone for the fabrication of table tortillas and corn and tortilla chips

Emerging Non-Clinical Biostatistics in Biopharmaceutical Development and Manufacturing Harry Yang, 2016-11-30 The premise of Quality by Design QbD is that the quality of the pharmaceutical product should be based upon a thorough understanding of both the product and the manufacturing process This state of the art book provides a single source of information on emerging statistical approaches to QbD and risk based pharmaceutical development A comprehensive resource it combines in depth explanations of advanced statistical methods with real life case studies that illustrate practical applications of these methods in QbD implementation *GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, (Volume 1 - With Checklists and Software Package)*

Leonard Steinborn, 2019-04-23 Volume 1 of this two part package provides a complete set of checklists for internal and contract device and drug manufacturers and developers contract software developers and suppliers of chemical printed material electronic component and general supplies It also includes a simulated QSIT audit and a new product market launch All of these **The GMP Handbook** Brendan Cooper, 2017-07-17 CGMP Current Good Manufacturing Practices has legal and practical implications for manufacturers of medicinal products and medical devices The requirements to meet CGMP is legal requirement but it also ensures the patient receives products that are safe effective and of consistent quality The FDA WHO ICH PIC s AND Eudralex provide extensive guidance and regulations on many topics related to the manufacture of medicinal and drug products A large body of reference materials is available to manufacturers and engineering professionals This book brings together the key requirements of GMP and briefly examines the common themes and requirements

published by the various authorities bodies and international organisations The book includes the following chapters Chapter 1 Overview of Good Manufacturing Practices Chapter 2 Quality Management Chapter 3 Personnel Chapter 4 Buildings and Facilities Chapter 5 Process Equipment Chapter 6 Documentation and Records Chapter 7 Materials Management Chapter 8 Rejection and re use of materials Chapter 9 Validation Chapter 10 Change Control Chapter 11 Complaints and recalls Page count 160 Paperback book Large 8 x 10 format

GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, (Volume 2 - Regulations, Standards, and Guidelines) Leonard Steinborn, 2004-12-30 This well known QA manual has been updated to provide the guidance readers need to assess their compliance with standard regulations This Volume 2 of a three part package contains the full text on FDA regulations EC and IPEC guidelines ISO BSI standards referenced in the checklists furnished in volume 1 Easy to read and organized to provide fa

Developing Procedures to Meet GMP Requirements MJ. Malooley, 1996 A comprehensive set of documented quality procedures is required by the Food and Drug Administration s Good Manufacturing Practices In order to successfully develop a comprehensive set of procedures the motivation must be to maintain quality and reduce variability Quality system procedures should follow a logical structure One such structure consists of tiered Quality Policies Administrative Support Procedures and Technical Procedures Each procedure should be traceable to a requirement established in the Quality Policy Manual Once an effective set of procedures is in place it must be actively managed Procedure management includes mechanisms for keeping the documents current ensuring accessibility to the procedure users and training on the use of the procedures

GMP/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers Leonard Steinborn, 2003 Volume 1 of this two part package provides a complete set of checklists for internal and contract device and drug manufacturers and developers contract software developers and suppliers of chemical printed material electronic component and general supplies It also includes a simulated QSIT audit and a new product market launch All of these

Quality Systems and GMP Regulations for Device Manufacturers Steven Kuwahara, 1998-03-31 This book provides a single roadmap for compliance with the US QSR the European Medical Device Directives and ISO Standards for device and diagnostic products Written in case study format it begins with information on how to establish a QSR documentation system Dr Kuwahara explains implementation methods for each section of the QSRs 21 CFR 820 Documentation requirements and guidelines for what documentation you need for your quality system why you need it and how to prepare it are detailed as well as practical information on efficiently and effectively organizing your records procedures work instructions and Quality Manual The book shows you how to evaluate your existing documentation s fit with the worldwide quality systems and the GMPs QSRs A grid comparing ISO 9001 and US 21 CFR 820 requirements is included

Gmp/ISO Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, (Volume 2 - Regulations, Standards, and Guidelines) Leonard Steinborn, 2019-08-30 This well known QA manual has been updated to provide the guidance readers need to assess their compliance with standard regulations This Volume 2 of a three

part package contains the full text on FDA regulations EC and IPEC guidelines ISO BSI standards referenced in the checklists furnished in volume 1 Easy to read and organized to provide fast access to guidelines and regulations this is an essential reference for those working in the field

Medical Device Quality Systems Manual - For GMP and ISO 9001-9002 Compliance Gunther Gump, 1998-10-01

Dietary Supplement Good Manufacturing Practices William J. Mead, 2024-10-14 Dietary Supplement GMP is a one stop how to road map to the final dietary supplement GMP regulations recently issued by the FDA covering the manufacture packaging and holding of dietary supplement products The recent regulations outlining broad goals intentionally avoid specifics to allow for future technological advances leaving implementation to the discretion of each firm Given this latitude and flexibility this new resource is an essential source of workable and practical suggestions on ways the industry can best meet the goals Based on broad experience with GMP compliance techniques worked out over the years in the food drug and medical device industries it is a must have guide for all DS companies especially the many smaller firms for whom this is new territory Dietary Supplement GMP provides a practical guide in easy to understand language to help navigate through the requirements for systems covering process and quality control suggestions and practical recommendations on how to achieve full compliance explanation of the FDA's role regarding inspection enforcement recall seizure of products and prosecution Dietary Supplement Good Manufacturing Practices GMP covers Personnel Plants and Grounds Equipment and Utensils Sanitation of Buildings and Equipment Quality Assurance and Laboratory Operations The Quality Control Unit Production and Process Controls

Gmp and Gxp Guide for Engineers Priscilla Browne, 2017-08-09 The GMP and GXP Guide for Engineers brings together regulatory guidance and industry norms into a paperback resource for Engineers and professionals working in Life Sciences Medical devices Pharmaceutical and Biotechnology It is a powerful resource for those looking to refresh knowledge or those who wish to have a practical resource at their fingertips The title is divided into five comprehensive chapters Chapter 1 Good Manufacturing Practices GMP This chapter reviews the body of guidance and regulations on GMP published by the FDA PICs EU GMP and WHO It will provide the reader with a broad understanding of what is required to meet GMP in a manufacturing setting Chapter 2 Data Integrity reviews the increasingly critical area of Data and ensuring data reliability and integrity in a CGMP setting Chapter 3 Test Method Validation takes the reader through the fundamentals of TMV Chapter 4 Cleaning and GMP provides an overview of a process approach to cleaning along with an explanation of key concepts In conclusion Chapter 5 Audit and Inspection Guide examines auditor approaches and key focus areas on what is expected for onsite inspection Large Paperback 8 X 10 310 pages

Quality Rules John Sharp, 2001-06-30 This updated edition introduces Good Manufacturing Practices GMPs for workers recently hired into the pharmaceutical chemical biotechnology and bulk pharmaceutical industries It covers all aspects of GMP explaining the rationale of GMP and the key role played by the worker in the production of safe pure and quality products All critical GMP concepts required by the US FDA the British MCA and the

European GMPs are covered This is the perfect GMP introductory training text that in many companies is required material for new employees Many corporation also use it as the central tool for training retraining and reinforcement programs

GMP/ISO/EN Quality Audit Manual for Healthcare Manufacturers and Their Suppliers, Fifth Edition, (Volume I - Checklists) Leonard Steinborn,1999-06-30 The world s most widely recognized QA manual GMP ISO EN Quality Audit Manual for Healthcare Manufacturers and Their Suppliers has been updated to provide the audit system you need to assess compliance with current standards and regulations The Fifth Edition continues a nearly two decade long tradition of widely recognized and utilized guidance for performing effective audits against regulations and guidelines Complying with FDA Good Manufacturing Practice Requirements William Cotliar,1996-01-01

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