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Susan Neadle



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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

Pharmaceutical Microbiological Quality Assurance and Control David Roesti,Marcel Goverde,2019-12-02 Relying on practical examples from the authors experience this book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non sterile pharmaceuticals Offers a comprehensive guidance for non sterile pharmaceuticals microbiological QA QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors experience in globalized pharmaceutical companies and expert networks

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 Handbook of Formulating Dermal Applications Nava Dayan,2016-12-15 The conceptualization and formulation of skin care products intended for topical use is a multifaceted and evolving area of science Formulators must account for myriad skin types emerging opportunities for product development as well as a very temperamental retail market Originally published as Apply Topically in 2013 now out of print this reissued detailed and comprehensive handbook offers a practical approach to the formulation chemist s day to day endeavors by Addressing the innumerable challenges facing the chemist both in design and at the bench such as formulating with for specific properties formulation processing and production techniques sensory and elegance stability and preservation color cosmetics sunscreens Offering valuable guidance to troubleshooting issues regarding ingredient selection and interaction regulatory concerns that must be addressed early in development and the extrapolation of preservative systems fragrances stability and texture aids Exploring the advantages and limitations of raw materials Addressing scale up and pilot production process and concerns Testing and Measurements Methods The 22 chapters written by industry experts such as Roger L McMullen Paul Thau Hemi Nae Ada Polla Howard Epstein Joseph Albanese Mark Chandler Steve Herman Gary Kelm Patricia Aikens and Sam Shefer along with many others give the reader and user the ultimate handbook on topical product development *Handbook of Pharmaceutical Analysis* Lena Ohannesian,Anthony Streeter,2001-11-09 Exploring the analysis of pharmaceuticals including polymorphic forms this book discusses regulatory requirements in pharmaceutical product development and pharmaceutical testing It covers methods of drug separation and procedures such as capillary electrophoresis for chromatographic separation of molecules Additional topics include drug formulation analysis using vibrational and magnetic resonance spectroscopy and identification of drug metabolites and decomposition products using such techniques as mass spectrometry The book provides more than 300 tables equations drawings and photographs and convenient easy to use indices facilitating quick access to each topic The Combination Products Handbook Susan

Needle,2023-05-16 Combination products are therapeutic and diagnostic products that combine drugs devices and or biological products According to the US Food and Drug Administration FDA a combination product is one composed of any combination of a drug and a device a biological product and a device a drug and a biological product or a drug device and a biological product Examples include prefilled syringes pen injectors autoinjectors inhalers transdermal delivery systems drug eluting stents and kits containing drug administration devices co packaged with drugs and or biological products This handbook provides the most up to date information on the development of combination products from the technology involved to successful delivery to market The authors present important and up to the minute pre and post market reviews of international combination product regulations guidance considerations and best practices This handbook Brings clarity of understanding for global combination products guidance and regulations Reviews the current state of the art considerations and best practices spanning the combination product lifecycle pre market through post market Reviews medical product classification and assignment issues faced by global regulatory authorities and industry The editor is a recognized international Combination Products and Medical Device expert with over 35 years of industry experience and has an outstanding team of contributors Endorsed by AAMI Association for the Advancement of Medical Instrumentation Supply Chain Planning for Clinical Trials Ryan Mills,2024-08-13 Ensure your clinical trial supply chain is running smoothly with this practical guide Clinical trials are a critical part of the pharmaceutical development process These trials cannot proceed without timely and regular receipt of the drugs being tested which can prove a challenge for drug manufacturers who have not yet established the structures required to produce quality controlled specimens of the drug at scale Managing supply chains of pre production drugs for clinical trials is therefore an essential component of drug development Supply Chain Planning for Clinical Trials offers a practical introduction to this process for researchers and industry professionals Beginning with the basics of clinical trial supply chain management it proceeds step by step through all aspects of demand and supply planning for clinical trials The result is a thorough overview that also offers practical examples of how to plan supply for clinical trials Supply Chain Planning for Clinical Trials readers will also find Tools for minimizing risk and expense by optimizing the relationship between supply and demand Detailed discussion of topics including quality and regulatory considerations and the business processes that support clinical trial supply chain management Spreadsheet based models to illustrate key concepts adaptable to the readers specific scenarios Supply Chain Planning for Clinical Trails is ideal for pharmaceutical industry professionals involved in clinical trial supply planning as well as academics and researchers interested in the pharmaceutical industry and its logistics **The Regulation of Dietary Supplements** United States. Congress. House. Committee on Government Reform,2006 **Advances in Genomics of Crossbred Farm Animals** Xiao-Lin Wu,Shu-Hong Zhao,2021-09-24 *Research Methods in Sport Studies and Sport Management* A.J. Veal,Simon Darcy,2014-03-26 Research can be a challenging but rewarding activity All degree level students studying sport and all

effective professionals working in the sport sector need to have a sound understanding of research methods and how to critically interpret research findings This broad ranging in depth and practical textbook introduces research methods for students on sport related degree courses outlining the knowledge and practical skills needed to undertake meaningful research and to become a knowledgeable consumer of the research of others The book explores every element of the research process from the fundamental what why and who questions through research plans literature review qualitative and quantitative methods of data collection and data analysis to the communication of research results It offers a critical appraisal of alternative methods including mixed methods as well as clear guidance on how to use each particular method Every chapter contains test questions and practical exercises detailed case studies a clear chapter summary and extensive guides to further sport related study resources to enable students to check their understanding and develop extend and apply their practical skills Step by step introductions to the use of the key statistical packages Excel SPSS and NVivo in sport research are included On line support materials include some 400 PowerPoint slides and copies of data sets used in the book With deeper and broader coverage than any other sport related research methods textbook and a clear focus on how to do it Research Methods for Sport Studies and Sport Management is an essential companion for any sport related degree course

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