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GREGORY EWING

GB/T-2005, GB-2005 -- Chinese National Standard PDF-English, Catalog (year 2005) John Wiley & Sons
This is the first book to show how to apply the principles of quality assurance to the identification of analytes (qualitative chemical analysis). After presenting the principles of identification and metrological basics, the author focuses on the reliability and the errors of chemical identification. This is then applied to practical examples such as EPA methods, EU, FDA, or WADA regulations. Two whole chapters are devoted to the analysis of unknowns and identification of samples such as foodstuffs or oil pollutions. Essential reading for researchers and professionals dealing with the identification of chemical compounds and the reliability of chemical analysis.
Topics in Model Validation and Uncertainty Quantification, Volume 5 https://www.chinesestandard.net
This document provides the comprehensive list of Chinese National Standards - Category: GB, GB/T Series of year 2016.
ITIL Intermediate Certification Companion Study Guide CRC Press
Provides a concise and authoritative reference on the use of vaccines against diseases of livestock Compiled by Senior Animal Health Officers at The Food and Agriculture Organization of the United Nations, and with contributions from international leading experts, Veterinary Vaccines: Principles and Applications is a concise and authoritative reference featuring easily readable reviews of the latest research in vaccinology and vaccine immune response to pathogens of major economic impact to livestock. It covers advice and recommendations for vaccine production, quality control, and effective vaccination schemes including vaccine selection, specifications, vaccination programs, vaccine handling in the field, application, failures, and assessment of herd

protection. In addition, the book presents discussions on the current status and potential future developments of vaccines and vaccination against selected transboundary animal diseases. Provides a clear and comprehensive guide on using veterinary vaccines to protect livestock from diseases Teaches the principles of vaccinology and vaccine immune response Highlights the vaccine production schemes and standards for quality control testing Offers easy-to-read reviews of the most current research on the subject Gives readers advice and recommendations on which vaccination schemes are most effective Discusses the today's state of vaccines and vaccination against selected transboundary animal diseases as well as possible future developments in the field Veterinary Vaccines: Principles and Applications is an important resource for veterinary practitioners, animal health department officials, vaccine scientists, and veterinary students. It will also be of interest to professional associations and NGO active in livestock industry.

Statistical Applications for Chemistry, Manufacturing and Controls (CMC) in the Pharmaceutical Industry

John Wiley & Sons

"The greater our knowledge increases, the more our ignorance unfolds. " U. S. President John F. Kennedy, speech, Rice University, September 12, 1962 My primary purpose for writing this book was much more than to provide another information source on Chemistry, Manufacturing & Controls (CMC) that would rapidly become out of date. My primary purpose was to provide insight and practical suggestions into a common sense business approach to manage the CMC regulatory compliance requirements for biopharmaceuticals. Such a common sense business approach would need (1) to be applicable for all types of biopharmaceutical products both present and future, (2) to address the needs of a biopharmaceutical manufacturer from the beginning to the end of the clinical development stages and including post market approval, and (3) to be adaptable to the constantly changing CMC regulatory compliance requirements and guidance. Trying to accomplish this task was a humbling experience for this author! In Chapter 1, the CMC regulatory process is explained, the breadth of products included under the umbrella ofbiopharmaceuticals are identified, and the track record for the pharmaceutical and biopharmaceutical industry in meeting CMC regulatory compliance is discussed. In Chapter 2, while there are many CMC commonalities between biopharmaceuticals and chemically-synthesized pharmaceuticals, the significant differences in the way the regulatory agencies handle them are examined and the reasons for why such differences are necessary is discussed. Also, the importance of CMC FDA is stressed.

Handbook of Pharmaceutical Manufacturing Formulations, Third Edition

https://www.chinesestandard.net

The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume Three, Liquid Products is an

authoritative and practical guide to the art and science of formulating drugs for commercial manufacturing. With thoroughly revised and expanded content, this third volume of a six-volume set, compiles data from FDA and EMA new drug applications, patents and patent applications, and other sources of generic and proprietary formulations including author's own experience, to cover the broad spectrum of cGMP formulations and issues in using these formulations in a commercial setting. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent. Features: Largest source of authoritative and practical formulations, cGMP compliance guidance and self-audit suggestions Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing Tackles common difficulties in formulating drugs and presents details on stability testing, bioequivalence testing, and full compliance with drug product safety elements Written by a well-recognized authority on drug and dosage form development including biological drugs and alternative medicines

Multiresidue Methods for the Analysis of Pesticide Residues in Food John Wiley & Sons

Food Safety Management: A Practical Guide for the Food Industry with an Honorable Mention for Single Volume Reference/Science in the 2015 PROSE Awards from the Association of American Publishers is the first book to present an integrated, practical approach to the management of food safety throughout the production chain. While many books address specific aspects of food safety, no other book guides you through the various risks associated with each sector of the production process or alerts you to the measures needed to mitigate those risks. Using practical examples of incidents and their root causes, this book highlights pitfalls in food safety management and provides key insight into the means of avoiding them. Each section addresses its subject in terms of relevance and application to food safety and, where applicable, spoilage. It covers all types of risks (e.g., microbial, chemical, physical) associated with each step of the food chain. The book is a reference for food safety managers in different sectors, from primary producers to processing, transport, retail and distribution, as well as the food services sector. Honorable Mention for Single Volume Reference/Science in the 2015 PROSE Awards from the Association of American Publishers Addresses risks and controls (specific technologies) at various stages of the food supply chain based on food type, including an example of a generic HACCP study Provides practical guidance on the implementation of elements of the food safety assurance system Explains the role of different stakeholders of the food supply

DBMS MCQs Academic Press

This work is an examination of all aspects

of the science in developing effective dosage form for drug delivery Pharmaceutics refers to the subfield of pharmaceutical sciences that develops drug delivery products or devices to optimize the drug's performance once administered. This multidisciplinary field draws on physical chemistry, organic chemistry, and biophysics to generate and refine these crucial elements of medical care. Moreover, incorporating such disparate dimensions of drug product design as material properties and legal regulation bridges the gap between effective chemicals and viable medical treatments. Integrated Pharmaceutics provides a comprehensive introduction to the creation and manufacture of effective dosage forms for drug delivery. It presents its subject following the principles of physical pharmacy, product design, and drug regulations. This tripartite structure allows readers to move from theory to practice, beginning from a firm foundation of physical pharmacy principles, including drug solubility and stability estimation, rheology, and interfacial properties. From there, it proceeds to discussions of drug product design and of harmonizing pharmaceutical design with the regulatory regimens and technological standards of the United States, European Union, and Japan. Readers of the second edition of Integrated Pharmaceutics will also find: A glossary defining key terms, extensive informative appendices, and a list of references leading to the primary literature in the field for each chapter Earlier chapters are expanded, with additional new chapters including one entitled “Biotechnology Products” Supplementary instructor guide with questions and solutions available online for registered professors Updated regulatory guidelines including quality by design, design space analysis, process analytical technology, polymorphism characterization, blend sample uniformity, and stability protocols Integrated Pharmaceutics is a useful textbook for graduate students in pharmaceutical sciences, drug formulation and design, and biomedical engineering. In addition, professionals in the pharmaceutical industry, including regulatory bodies, will find it a helpful reference guide.

Sterile Product Development Springer Provides a single-source reference for readers interested in the development of analytical methods for analyzing non-antimicrobial veterinary drug residues in food Provides a comprehensive set of information in the area of consumer food safety and international trade Covers general issues related to analytical quality control and quality assurance, measurement uncertainty, screening and confirmatory methods Details many techniques including nanotechnology and aptamer based assays covering current and potential applications for non-antimicrobial veterinary drugs Provides guidance for analysis of banned drugs including natural and synthetic steroids, Resorcylic acid lactones, and Beta-agonists

MSDN Magazine John Wiley & Sons The expert-led, full-coverage supporting guide for all four ITIL exams ITIL Intermediate Certification Companion Study Guide is your ultimate support system

for the Intermediate ITIL Service Capability exams. Written by Service Management and ITIL framework experts, this book gives you everything you need to pass, including full coverage of all objectives for all four exams. Clear, concise explanations walk you through the process areas, concepts, and terms you need to know, and real-life examples show you how they are applied by professionals in the field every day. Although this guide is designed for exam preparation, it doesn't stop there — you also get expert insight on major topics in the field. The discussion includes operational support and analysis; planning, protection and optimization; release, control and validation; and service offerings and agreements that you'll need to know for the job. ITIL is the most widely-adopted IT Service Management qualification in the world, providing a practical, no-nonsense framework for identifying, planning, delivering, and supporting IT services to businesses. This book is your ideal companion for exam preparation, with comprehensive coverage and detailed information. Learn service strategy principles, organization, and implementation Master the central technologies used in IT Service Management Be aware of inherent challenges, risks, and critical success factors Internalize the material covered on all four ITIL exams The ITIL qualification is recognized around the globe, and is seen as the de facto certification for those seeking IT Service Management positions. Passing these exams requires thorough preparation and rigorous self-study, but the reward is a qualification that can follow you anywhere. ITIL Intermediate Certification Companion Study Guide for the ITIL Service Capability Exams leads you from Foundation to Master, giving you everything you need for exam success.

Veterinary Vaccines John Wiley & Sons

This document provides the comprehensive list of Chinese National Standards - Category: GB Series.

Hazard Analysis and Risk-Based Preventive Controls

https://www.chinesestandard.net

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.

Bayesian Analysis with R for Drug Development John Wiley & Sons

Finite Element Analysis Applications: A Systematic and Practical Approach strikes a solid balance between more traditional FEA textbooks that focus primarily on theory, and the software specific guidebooks that help teach students and professionals how to use particular FEA software packages without

providing the theoretical foundation. In this new textbook, Professor Bi condenses the introduction of theories and focuses mainly on essentials that students need to understand FEA models. The book is organized to be application-oriented, covering FEA modeling theory and skills directly associated with activities involved in design processes. Discussion of classic FEA elements (such as truss, beam and frame) is limited. Via the use of several case studies, the book provides easy-to-follow guidance on modeling of different design problems. It uses SolidWorks simulation as the platform so that students do not need to waste time creating geometries for FEA modelling. Provides a systematic approach to dealing with the complexity of various engineering designs Includes sections on the design of machine elements to illustrate FEA applications Contains practical case studies presented as tutorials to facilitate learning of FEA methods Includes ancillary materials, such as a solutions manual for instructors, PPT lecture slides and downloadable CAD models for examples in SolidWorks

GB/T-2016, GB-2016 -- Chinese National Standard PDF-English, Catalog (year 2016) John Wiley & Sons

Topics in Model Validation and Uncertainty Quantification, Volume : Proceedings of the 31st IMAC, A Conference and Exposition on Structural Dynamics, 2013, the fifth volume of seven from the Conference, brings together contributions to this important area of research and engineering. The collection presents early findings and case studies on fundamental and applied aspects of Structural Dynamics, including papers on: Uncertainty Quantification & Propagation in Structural Dynamics Robustness to Lack of Knowledge in Design Model Validation

MSEB MAHAGENCO Assistant Programmer Exam PDF eBook World Health Organization

This document provides the comprehensive list of Chinese National Standards - Category: GB, GB/T Series of year 2015.

WHO Expert Committee on Specifications for Pharmaceutical Preparations World Health Organization

This comprehensive book encompasses various facets of sterile product development. Key concepts relevant to the successful development of sterile products are illustrated through case studies and are covered under three sections in this book: • Formulation approaches that discuss a variety of dosage forms including protein therapeutics, lipid-based controlled delivery systems, PEGylated biotherapeutics, nasal dosage form, and vaccines • Process, container closure and delivery considerations including freeze-thaw process challenges, best practices for technology transfer to enable commercial product development, innovations and advancement in aseptic fill-finish operations, approaches to manufacturing lyophilized parenteral products, pen / auto-injector delivery devices, and associated container closure integrity testing hurdles for sterile product closures • Regulatory and quality aspects in the areas of particulate matter and appearance evaluation, sterile filtration, admixture compatibility considerations, sterilization process considerations, microbial contamination

investigations and validation of rapid microbiological methods, and dry and moist heat sterilizers This book is a useful resource to scientists and researchers in both industry and academia, and it gives process and product development engineers insight into current industry practices and evolving regulatory expectations for sterile product development.

GB/T-2017, GB-2017 -- Chinese National Standard PDF-English, Catalog (year 2017)

Academic Conferences and publishing limited This book examines statistical techniques that are critically important to Chemistry, Manufacturing, and Control (CMC) activities. Statistical methods are presented with a focus on applications unique to the CMC in the pharmaceutical industry. The target audience consists of statisticians and other scientists who are responsible for performing statistical analyses within a CMC environment. Basic statistical concepts are addressed in Chapter 2 followed by applications to specific topics related to development and manufacturing. The mathematical level assumes an elementary understanding of statistical methods. The ability to use Excel or statistical packages such as Minitab, JMP, SAS, or R will provide more value to the reader. The motivation for this book came from an American Association of Pharmaceutical Scientists (AAPS) short course on statistical methods applied to CMC applications presented by four of the authors. One of the course participants asked us for a good reference book, and the only book recommended was written over 20 years ago by Chow and Liu (1995). We agreed that a more recent book would serve a need in our industry. Since we began this project, an edited book has been published on the same topic by Zhang (2016). The chapters in Zhang discuss statistical methods for CMC as well as drug discovery and nonclinical development. We believe our book complements Zhang by providing more detailed statistical analyses and examples.

Leading Issues in Cyber Warfare and Security

https://www.chinesestandard.net

An insightful exploration of the key aspects concerning the chemical analysis of antibiotic residues in food The presence of excess residues from frequent antibiotic use in animals is not only illegal, but can pose serious health risks by contaminating products for human consumption such as meat and milk. Chemical Analysis of Antibiotic Residues in Food is a single-source reference for readers interested in the development of analytical methods for analyzing antibiotic residues in food. It covers themes that include quality assurance and quality control, antibiotic chemical properties, pharmacokinetics, metabolism, distribution, food safety regulations, and chemical analysis. In addition, the material presented includes background information valuable for understanding the choice of marker residue and target animal tissue to use for regulatory analysis. This comprehensive reference: Includes topics on general issues related to screening and confirmatory methods Presents updated information on food safety regulation based on

routine screening and confirmatory methods, especially LC-MS Provides general guidance for method development, validation, and estimation of measurement uncertainty Chemical Analysis of Antibiotic Residues in Food is written and organized with a balance between practical use and theory to provide laboratories with a solid and reliable reference on antibiotic residue analysis. Thorough coverage elicits the latest scientific findings to assist the ongoing efforts toward refining analytical methods for producing safe foods of animal origin.

GB/T-2015, GB-2015 -- Chinese National Standard PDF-English, Catalog (year 2015) Charles C Thomas Publisher

Discover the latest ICH news from international experts in the pharmaceutical industry, academia, and regulatory bodies. The recent International Conference on Harmonisation (ICH) revisions of regulatory requirements for quality, nonclinical, and clinical pharmaceutical product registration are the focus of this timely update. This cutting-edge resource includes the major headings in the modular structure of the Common Technical Document (CTD), which is now the agreed format for product information submission. The format, specification, and technical requirements of the e-CTD, the electronic version of CTD, are also thoroughly discussed. The book is organized into six highly practical segments: Part I: CTD, eCTD, Module 1, and Environmental Risk Assessment Part II: CTD Summaries Part III: Quality Topics Part IV: Nonclinical Topics Part V: Clinical Topics Part VI: Other Topics (including drug-device combination products) This text is a must-have for those in the pharmaceutical industry determining regulatory requirements for the major world markets in Europe, the US, Canada, and Japan.

Food Safety Management John Wiley & Sons

More than 20 billion dollars worth of biopharmaceuticals are scheduled to go off-patent by 2006. Given the strong political impetus and the development of technological tools that can answer the questions regulatory authorities may raise, it is inevitable that the FDA and EMEA will allow biogeneric or biosimilar products. Even with all the regulato

Advanced Power Applications for System Reliability Monitoring Springer Nature

Focusing on the application of physical pharmacy, drug design, and drug regulations as they relate to produce effective dosage forms for drug delivery, Integrated Pharmaceutics provides a comprehensive picture of pharmaceutical product design, describing the science and art behind the concepts of dosage form development. Combining physical pharmacy, product design, and regulatory affairs issues in a single book, the authors address topics governing drug regulations of United States, European, and Japanese agencies and detail new regulatory guidelines, including quality by design, design space analysis, and blend sample uniformity.