Qbd Approach To Analytical Rp Hplc Method Development And

Biopharmaceuticals (i.e., biological medicines sourced from genetically-engineered living systems) for treatment of human diseases have become a significant percentage of the pharmaceutical industry. And not just the recombinant DNA-derived proteins and monoclonal antibodies (both from the innovators and biosimilars); but now, an increasing awareness of the importance of gene therapy and genetically engineered cellular medicinal products. These biopharmaceuticals are being developed by many companies whose Chemistry, Manufacturing & Control (CMC) teams have varying degrees of familiarity or experience with the CMC strategy and regulatory compliance requirements for these challenging products. Companies clearly plan out the strategy for their clinical study plans, but frequently, the development of a strategy for CMC is an afterthought. Coupled with the complexity of the biopharmaceutical manufacturing processes and products, and this can be a recipe for disaster. The third edition of this book provides insights and practical guidance for the CMC teams to develop an acceptable cost-effective, risk-based CMC regulatory compliance strategy for all biopharmaceuticals (recombinant proteins, monoclonal antibodies, genetically engineered viruses and genetically engineered human cells) from early clinical stage development through market approval. The third edition of this book provides added coverage for the biosimilars, antibody drug conjugates (ADCs), bispecific antibodies, genetically engineered viruses, and genetically engineered cells. This third edition of the book also addresses the heightened pressure on CMC regulatory compliance timelines due to the introduction of expedited clinical pathways moving the clinical development closer to a seamless phase process (e.g., FDA Breakthrough Therapy designation, CBER Regenerative Medicine Advanced Therapy (RMAT) designation, EMA Priority Medicines (PRIME) designation). The Challenge of CMC Regulatory Compliance for Biopharmaceuticals is essential, practical information for all pharmaceutical development scientists, Manufacturing and Quality Unit staff, Regulatory Affairs personnel, and senior management involved in the manufacture of biopharmaceuticals.

In the field of Analytical Chemistry and, in particular, whenever a quali-quantitative analysis is required, until a few years ago, reference was made exclusively to instrumental methods (more or less hyphenated) which, once validated, were able to provide the answers to the questions present, even if only in a limited way to analytical targets. Nowadays, the landscape has become considerably complicated (natural adulterants, assessment of geographical origin, sophistication, need for non-destructive analysis, search for often unknown compounds), and new procedures for processing data have greatly increased the potential of analyses that are conducted (even routinely) in the laboratory. In this scenario, chemometrics is master, able to manage and process a huge amount of information based both on data relating only to the analytes of interest, but also by applying "general" procedures to process raw untargeted analysis data. It is within this strand of analysis that many of the works reported in this Special Issue fall. In the succession of works in this printed version, the criterion that guided us was to highlight how—starting exclusively from chromatographic techniques (HPLC and GC) with conventional detectors and moving to exclusively spectroscopic techniques (MS, FT-IR and Raman)—it is possible arrive at extremely powerful coupled techniques and procedures (HPLC and FT-IR) able to meet research needs. Finally, at the end of the printed volume, there are two reviews that surveying the state of the art regarding the assessment of authenticity through qualitative analyses and the application of chemometrics in the pharmaceutical field in the study of forced drug degradation products. From the succession of works (and, above all, from the various application fields) it can immediately be seen how the application of chemometrics and its procedures to both raw and processed data is a powerful means of obtaining robust, reproducible, and predictive information. In this manner, it is possible to create models able to explain and respond to the original problem in a much more detailed way. , and Honghe through Fourier transform mid infrared (FT-MIR) spectra combined with partial least squares discriminant analysis (PLS-DA), random forest (RF), and hierarchical cluster analysis (HCA) methods. Melucci and collaborators apply chemometric approaches to non-destructive analysis of ATR-FT-IR for the determination of biosilica content. This value was directly evaluated in sediment samples, without any chemical alteration, using attenuated total reflection Fourier transform infrared (ATR-FTIR) spectroscopy, and the quantification was performed by combining the multivariate standard addition method (MSAM) with the net analyte signal (NAS) procedure to solve the strong matrix effect of sediment samples. Still in the food and food supplements field, Anguebes-Franseschi and collaborators report an article where 10 chemometric models based on Raman spectroscopy were applied to predict the physicochemical properties of honey produced in the state of Campeche, Mexico.

A practical guide for chemists in the pharmaceutical industry to making automated analyses of drugs that will meet the standards of regulatory agencies. Reviews the standard techniques of high-performance liquid chromatography, specialized detection methods, automation in pharmaceutical analysis, an

This 6th edition of the established textbook covers every aspect of drug properties from the design of dosage forms to their delivery by all routes to sites of action in the body.

HPLC Method Development for Pharmaceuticals

A Sampling of Current Approaches

Process Understanding

HPLC in the Pharmaceutical Industry

Advances in Chemical Analysis Procedures (Part II)

CRC Handbook of Basic Tables for Chemical Analysis

Technology Transfer

Learn to maximize the performance of your HPLC or UHPLC system with this resource from leading experts in the field Optimization in HPLC: Concepts and Strategies delivers tried-and-tested strategies for optimizing the performance of HPLC and UHPLC systems for a wide variety of analytical tasks. The book explains how to optimize the different HPLC operation modes for a range of analyses, including small molecules, chiral substances, and biomolecules. It also shows readers when and how computational tools may be used to optimize performance. The practice-oriented text describes common challenges faced by users and developers of HPLC and UHPLC systems, as well as how those challenges can be overcome. Written for first-time and experienced users of HPLC technology and keeping pace with recent developments in HPLC instrumentation and operation modes, this comprehensive guide leaves few questions unanswered. Readers will also benefit from the inclusion of: A thorough introduction to optimization strategies for different modes and uses of HPLC, including working under regulatory constraints An exploration of computer aided HPLC optimization, including ChromSwordAuto and Fusion QbD A treatment of current challenges for HPLC users in industry as well as large and small analytical service providers Discussions of current challenges for HPLC equipment suppliers Tailor-made for analytical chemists, chromatographers, pharmacologists, toxicologists, and lab technicians, Optimization in HPLC: Concepts and Strategies will also earn a place on the shelves of analytical laboratories in academia and industry who seek a one-stop reference for optimizing the performance of HPLC systems.

High pressure, or high performance, liquid chromatography (HPLC) is the method of choice for checking purity of new drug candidates, monitoring changes during scale up or revision of synthetic procedures, evaluating new formulations, and running control/assurance of the final drug product. HPLC Method Development for Pharmaceuticals provides an extensive overview of modern HPLC method development that addresses these unique concerns. Includes a review and update of the current state of the art and science of HPLC, including theory, modes of HPLC, column chemistry, retention mechanisms, chiral separations, modern instrumentation (including ultrahigh-pressure systems), and sample preparation. Emphasis has been placed on implementation in a pharmaceutical setting and on providing a practical perspective. HPLC Method Development for Pharmaceuticals is intended to be particularly useful for both novice and experienced HPLC method development chemists in the pharmaceutical industry and for managers who are seeking to update their knowledge. Covers the requirements for HPLC in a pharmaceutical setting including strategies for software and hardware validation to allow for use in a regulated laboratory Provides an overview of the pharmaceutical development process (clinical phases, chemical and pharmaceutical development activities) Discusses how HPLC is used in each phase of pharmaceutical development and how methods are developed to support activities in each phase

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

This revision brings the reader completely up to date on the evolving methods associated with increasingly more complex sample types analyzed using high-performance liquid chromatography, or HPLC. The book also incorporates updated discussions of many of the fundamental components of HPLC systems and practical issues associated with the use of this analytical method. This edition includes new or expanded treatments of sample preparation, computer assisted method development, as well as biochemical samples, and chiral separations.

Concepts and Strategies

Pharmaceutical Manufacturing Handbook

Handbook of Modern Pharmaceutical Analysis

Software-assisted Method Development In High Performance Liquid Chromatography

Dosage Form Design Considerations

Melt Extrusion

Past, Present and Perspectives

This volume provides readers with the basic principles and fundamentals of extrusion technology and a detailed description of the practical applications of a variety of extrusion processes, including various pharma grade extruders. In addition, the downstream production of films, pellets and tablets, for example, for oral and other delivery routes, are presented and discussed utilizing melt extrusion. This book is the first of its kind that discusses extensively the well-developed science of extrusion technology as applied to pharmaceutical drug product development and manufacturing. By covering a wide range of relevant topics, the text brings together all technical information necessary to develop and market pharmaceutical dosage forms that meet current quality and regulatory requirements. As extrusion technology continues to be refined further, usage of extruder systems and the array of applications will continue to expand, but the core technologies will remain the same.

Updated and revised throughout. Second Edition explores the chromatographic methods used for the measurement of drugs, impurities, and excipients in pharmaceutical preparations--such as tablets, ointments, and injectables. Contains a 148-page table listing the chromatographic data of over 1300 drugs and related substances--including sample matrix analyzed, sample handling procedures, column packings, mobile phase, mode of detection, and more.

This volume explores the application of Quality by Design (QbD) to biopharmaceutical drug product development. Twenty-eight comprehensive chapters cover dosage forms, liquid and lyophilized drug products. The introductory chapters of this book define key elements of QbD and examine how these elements are integrated into drug product development. These chapters also discuss lessons learned from the FDA Office of Biotechnology Products pilot program. Following chapters demonstrate how QbD is used for formulation development ranging from screening of formulations to developability assessment to development of lyophilized and liquid formats. The next few chapters study the use of small-scale and surrogate models as well as QbD application to drug product processes such as drug substance freezing and thawing, mixing, sterile filtration, filling, lyophilization, inspection and shipping and handling. Later chapters describe more specialized applications of QbD in the drug product realm. This includes the use of QbD in primary containers, devices and combination product development. The volume also explores QbD applied to vaccine development, automation, mathematical modeling and monitoring, and controlling processes and defining control strategies. It concludes with a discussion on the application of QbD to drug product technology transfer as well as overall regulatory considerations and lifecycle management. Quality by Design for Biopharmaceutical Drug Product Development is an authoritative resource for scientists and researchers interested in expanding their knowledge on QbD principles and uses in creating better drugs.

This book seeks to introduce the reader to current methodologies in analytical calibration and validation. This collection of contributed research articles and reviews addresses current developments in the calibration of analytical methods and techniques and their subsequent validation. Section 1, "Introduction," contains the Introductory Chapter, a broad overview of analytical calibration and validation, and a brief synopsis of the following chapters. Section 2 "Calibration Approaches" presents five chapters covering calibration schemes for some modern analytical methods and techniques. The last chapter in this section provides a segue into Section 3, "Validation Approaches," which contains two chapters on validation procedures and parameters. This book is a valuable source of scientific information for anyone interested in analytical calibration and validation.

Nanotechnology-Based Approaches for Targeting and Delivery of Drugs and Genes

Quality by Design for Biopharmaceutical Drug Product Development

Computer-aided applications in pharmaceutical technology

Regulatory, Clinical, and Biopharmaceutical Development

Chromatographic Analysis of Pharmaceuticals

Development and Validation of Analytical Methods

Multi- and Megavariate Data Analysis Basic Principles and Applications

Describes analytical methods development, optimization and validation, and provides examples of successful methods development and validation in high-performance liquid chromatography (HPLC) areas. The text presents an overview of Food and Drug Administration (FDA)/International Conference on Harmonization (ICH) regulatory guidelines, compliance with validation requirements for regulatory agencies, and methods validation criteria stipulated by the US Pharmacopia, FDA and ICH.

This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

The need to validate an analytical or bioanalytical method is encountered by analysts in the pharmaceutical industry on an almost daily basis, because adequately validated methods are a necessity for approvable regulatory filings. What constitutes a validated method, however, is subject to analyst interpretation because there is no universally accepted industry practice for assay validation. This book is intended to serve as a guide to the analyst in terms of the issues and parameters that must be considered in the development and validation of analytical methods. In addition to the critical issues surrounding method validation, this book also deals with other related factors such as method development, data acquisition, automation, cleaning validation and regulatory considerations. The book is divided into three parts. Part One, comprising two chapters, looks at some of the basic concepts of method validation. Chapter 1 discusses the general concept of validation and its role in the process of transferring methods from laboratory to laboratory. Chapter 2 looks at some of the critical parameters included in a validation program and the various statistical treatments given to these parameters. Part Two (Chapters 3, 4 and 5) of the book focuses on the regulatory perspective of analytical validation. Chapter 3 discusses in some detail how validation is treated by various regulatory agencies around the world, including the United States, Canada, the European Community, Australia and Japan. This chapter also discusses the International Conference on Harmonization (ICH) treatment of assay validation. Chapters 4 and 5 cover the issues and various perspectives of the recent United States vs. Barr Laboratories Inc. case involving the retesting of samples. Part Three (Chapters 6 - 12) covers the development and validation of various analytical components of the pharmaceutical product development process. This part of the book contains specific chapters dedicated to bulk drug substances and finished products, dissolution studies, robotics and automated workstations, biotechnology products, biological samples, analytical methods for cleaning procedures and computer systems and computer-aided validation. Each chapter goes into some detail describing the critical development and related validation considerations for each topic. This book is not intended to be a practical description of the analytical validation process, but more of a guide to the critical parameters and considerations that must be attended to in a pharmaceutical development program. Despite the existence of numerous guidelines including the recent attempts by the ICH to be implemented in 1998, the practical part of assay validation will always remain, to a certain extent, a matter of the personal preference of the analyst or company. Nevertheless, this book brings together the perspectives of several experts having extensive experience in different capacities in the pharmaceutical industry in an attempt to bring some consistency to analytical method development and validation.

In this era of increased pharmaceutical industry competition, success for generic drug companies is dependent on their ability to manufacture therapeutic-equivalent drug products in an economical and timely manner, while also being cognizant of patent infringement and other legal and regulatory concerns.Generic Drug Product Development: Solid Oral Regulations, Methodologies, and Best Practices

Green Analytical Chemistry

Production and Processes

Supercritical Fluid Chromatography

Nonclinical Statistics for Pharmaceutical and Biotechnology Industries

Materials, Technology and Drug Product Design

This first chapter introduces the concept of quality-by-design (QbD) and its role in pharmaceutical product development. QbD assures the quality of a pharmaceutical product through scientific development and risk management tools, and will eventually enable real-time release, regardless of the formulation type. Several guidelines on pharmaceutical development, quality risk management, and pharmaceutical quality systems are presented that are applicable throughout the product lifecycle. Design space appointment and control strategies for risk management are introduced. The meaning of the QbD concept is presented from both regulatory and manufacturers' points of view. Several illustrative examples are provided to facilitate the understanding of the QbD concept and ease of its application.

Praise for the Third Edition: "This new third edition has been substantially rewritten and updated with new topics and material, new examples and exercises, and to more fully illustrate modern applications of RSM." - Zentralblatt Math Featuring a substantial revision, the Fourth Edition of Response Surface Methodology: Process and Product Optimization Using Designed Experiments presents updated coverage on the underlying theory and applications of response surface methodology (RSM). Providing the assumptions and conditions necessary to successfully apply RSM in modern applications, the new edition covers classical and modern response surface designs in order to present a clear connection between the designs and analyses in RSM. With multiple revised sections with new topics and expanded coverage, Response Surface Methodology: Process and Product Optimization Using Designed Experiments, Fourth Edition includes: Many updates on topics such as optimal designs, optimization techniques, robust parameter design, methods for design evaluation, computer-generated designs, multiple response optimization, and non-normal responses Additional coverage on topics such as experiments with computer models, definitive screening designs, and data measured with error Expanded integration of examples and experiments, which present up-to-date software applications, such as JMP®, SAS, and Design-Expert®, throughout An extensive references section to help readers stay up-to-date with leading research in the field of RSM An ideal textbook for upper-undergraduate and graduate-level courses in statistics, engineering, and chemical/physical sciences, Response Surface Methodology: Process and Product Optimization Using Designed Experiments, Fourth Edition is also a useful reference for applied statisticians and engineers in disciplines such as quality, process, and chemistry.

Handbook of Modern Pharmaceutical Analysis, Second Edition, synthesizes the complex research and recent changes in the field, while covering the techniques and technology required for today's laboratories. The work integrates strategy, case studies, methodologies, and implications of new regulatory structures, providing complete coverage of quality assurance from the point of discovery to the point of use. Treats pharmaceutical analysis (PA) as an integral partner to the drug development process rather than as a service to it Covers method development, validation, selection, testing, modeling, and simulation studies combined with advanced exploration of assays, impurity testing, biomolecules, and chiral separations Features detailed coverage of QA, ethics, and regulatory guidance (quality by design, good manufacturing practice), as well as high-tech methodologies and technologies from "lab-on-a-chip" to LC-MS, LC-NMR, and LC-NMR-MS

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.

Solid Oral Dosage Forms, Second Edition

Optimization in HPLC

Response Surface Methodology

Practical HPLC Method Development

Principles and Case Studies

Analytical Method Development and Validation

Process and Product Optimization Using Designed Experiments

A great deal of confusion and uncertainty over genotoxic impurity (GTI) identification, assessment, and control exists in the pharmaceutical industry today. Pharmaceutical Industry Practices on Genotoxic Impurities strives to facilitate scientific and systematic consensus on GTI management by presenting rationales, strategies, methods, interpretations, practices, and case studies from the pharmaceutical industry. Featuring the contributions of industry leaders from nine major pharmaceutical companies, this authoritative text: Explores t safety, quality, and regulatory aspects of GTIs Provides an overview of the latest FDA and EMEA guidelines Explains the how and why of various GTI control tactics and practices Describes genotoxicity evaluation, acceptable exposure calculation, and analytical methods for testing Includes real-life examples of GTI control in drug substance and drug product development processes Containing case studies from large and small pharmaceutical firms in multiple geographical regions, Pharmaceutical Industry Practices on Genotoxic Impu supplies an overview of—and a current framework for—GTI control in the pharmaceutical industry, demonstrating how proper management of GTIs can occur with the appropriate guidance, a firm grasp of the practical implications, and effective information sharing between disciplines.

The main goal of this book is to establish what constitutes a best practices QbD approach to LC method development. The book contains many case studies and examples of both risky and QbD-aligned work borrowed from pharmaceutical companies working with large and small molecule separations. It allows the reader to understand why and how QbD applies to LC method development and by direct extension the development of all analytical instrument methods. The book teaches the reader why it is necessary to advance from the univariate (one-factor-at-a-time) approach to method development to a modern multivariate approach in which the work is done according to QbD principles utilizing a statistical experimental design framework.

The book explains the principles and fundamentals of Green Analytical Chemistry (GAC) and highlights the current developments and future potential of the analytical green chemistry-oriented applications of various solutions. The book consists of sixteen chapters, including the history and milestones of GAC; issues related to teaching of green analytical chemistry and greening the university laboratories; evaluation of impact of analytical activities on the environmental and human health, direct techniques of detection, identification and determination of trace constituents; new achievements in the field of extraction of trace analytes from samples characterized by complex composition of the matrix; "green" nature of the derivatization process in analytical chemistry; passive techniques of sampling of analytes; green sorption materials used in analytical procedures; new types of solvents in the field of analytical chemistry. In addition green chromatography and related techniques, fast tests for assessment of the wide spectrum of pollutants in the different types of the medi remote monitoring of environmental pollutants, qualitative and comparative evaluation, quantitative assessment, and future trends and perspectives are discussed. This book appeals to a wide readership of the academic and industrial researchers. In addition, it can be used in the classroom for undergraduate and graduate Ph.D. students focusing on elaboration of new analytical procedures for organic and inorganic compounds determination in different kinds of samples characterized by complex matrices composition.Jacek Namie?nik Professor at the Department of Analytical Chemistry, Gda?sk University of Technology, Poland. Justyna P?otka-Wasylka is a teacher and researcher at the same department.

The concepts, applications, and practical issues of Quality byDesign Quality by Design (QbD) is a new framework currently beingimplemented by the FDA, as well as EU and Japanese regulatoryagencies, to ensure better understanding of the process so as toyield a consistent and high-quality pharmaceutical product. QbDbreaks from past approaches in assuming that drug quality cannot betested into products; rather, it must be built into every step ofthe product creation process. Quality by Design: Perspectives and Case Studies pres systematic approach to QbD in the biotech industry. Acomprehensive resource, it combines an in-depth explanation ofbasic concepts with real-life case studies that illustrate thepractical aspects of QbD implementation. In this single source, leading authorities from thebiotechnology industry and the FDA discuss such topics as: The understanding and development of the product's criticalquality attributes (CQA) Development of the design space for a manufacturingprocess How to employ QbD to design a formulation process Raw materi analysis and control strategy for QbD Process Analytical Technology (PAT) and how it relates toQbD Relevant PAT tools and applications for the pharmaceuticalindustry The uses of risk assessment and management in QbD Filing QbD information in regulatory documents The application of multivariate data analysis (MVDA) toQbD Filled with vivid case studies that illustrate QbD at work incompanies today, Quality by Design is a core reference forscientists in the biopharmaceutical industry, regulatory agencies,and students.

Calibration and Validation of Analytical Methods

Physicochemical Principles of Pharmacy

For Scale-Up and Manufacture of Active Ingredients

Quality-by-Design Methodology for Rapid LC Method Development

In Manufacture, Formulation and Clinical Use

Handbook of Analytical Validation

Handbook of Stability Testing in Pharmaceutical Development

'The book is a useful contribution in the field of HPLC, and may represent a valuable tool for chromatography practitioners in different fields, as well as teachers and instructors. The 12 chapters provide comprehensive insights of current day retention and resolution modelling in HPLC, and its applications for small and large molecule analysis. It may be a useful reference for specialists in pharmaceuticals but not limited to … It may be a valuable resource to assist scientists involved in method development, aiming to achieve the best results with reduced costs, time, and efforts.'Analytical and Bioanalytical ChemistryThis handbook gives a general overview of the possibilities in recent developments in chromatographic retention modeling. As a result of the latest developments in modeling software, several new features are now accessible, opening a new level in HPLC method development.Many of these current possibilities in software assisted liquid chromatographic method modeling for analytical purposes are presented. Several modes of chromatography, including Reversed-Phase Liquid Chromatography (RPLC), Ion Exchange Chromatography (IEX), Hydrophobic Interaction Chromatography (HIC), and Hydrophilic Interaction Liquid Chromatography (HILIC) are explained in detail. For all these chromatographic modes, the most important variables for tuning retention and selectivity are exposed.Beside the industrial and practical benefits of retention modeling, the possibilities in teaching and education are also illustrated. Finally, numerous representative industrial examples are shown, to highlight the benefits, time and cost savings offered by state-of-the-art software assisted HPLC method development.

Nanotechnology-Based Approaches for Targeting and Delivery of Drugs and Genes provides an overview of the important aspects of nanomedicine in order to illustrate how to design and develop novel and effective drug delivery systems using nanotechnology. The book is organized into three sections, beginning with an introduction to nanomedicine and its associated issues. Section two discusses the latest technologies in nanomedicine, while the third section covers future developments and challenges in the field. By focusing on the design, synthesis, and application of a variety of nanocarriers in drug and gene delivery, this book provides pharmaceutical and materials science students, professors, clinical researchers, and industry scientists with a valuable resource aimed at tackling the challenges of delivering drugs and genes in a more targeted manner. Explores a wide range of promising approaches for the diagnosis and treatment of diseases using the latest advances in cutting-edge nanomedical technologies Contains contributions from world-renowned experts and researchers working in the area of nanomedicine and drug delivery Covers the associated challenges and potential solutions to working with nanotechnology in drug delivery Highlights crucial topics, such as biopharmaceutical and toxicity issues, quality by design, drug targeting, and more

This book provides a comprehensive overview of the biosimilar regulatory framework, the development process and clinical aspects for development of biosimilars. The development path of a biosimilar is just as unique as a development path of a new drug, tailored by the mechanism of action, the quality of the molecule, published information on the reference product, the current competitive environment, the target market and regulatory guidance, and most importantly, the emerging totality of evidence for the proposed biosimilar during development. For the ease of readers, the book comprises of six sections as follows: Section I: Business, Health Economics and Intellectual Property Landscape for Biosimilars Section II: Regulatory Aspects of Development and Approval for Biosimilars Section III: Biopharmaceutical Development and Manufacturing of Biosimilars Section IV: Analytical Similarity Considerations for Biosimilars Section V: Clinical aspects of Biosimilar Development Section VI: Biosimilars- Global Development and Clinical Experience Chapters have been written by one or more experts from academia, industry or regulatory agencies who have been involved with one or more aspects of biosimilar product development. The authors and editors have an expertise in commercialization and pricing of biosimilars, intellectual property considerations for biosimilars, chemistry manufacturing controls (CMC) and analytical development for biosimilars, regulatory and clinical aspects of biosimilar development. Besides the industry practitioners, the book includes several contributions from regulators across the globe.

Profiles of Drug Substances, Excipients, and Related Methodology, Volume 46 contains comprehensive profiles of five drug compounds: Darunavir, Bisoprolol, Betaxolol, Rabeprazole and Irbesartan. In addition, the work contains a chapter reviewing Bioassay Methods and Their Applications in Herbal Drug Research. The comprehensive reviews in the book cover all aspects of drug development and the formulation of drugs, helping readers understand how the drug development community remains essential to all phases of pharmaceutical development. In addition, this work answers why such profiles are of immeasurable importance to workers in the field. The scope of the Profiles series encompasses review articles and database compilations that fall within one or more of the following five broad categories: Physical Profiles of Drug Substances and Excipients, Analytical Profiles of Drug Substances and Excipients, ADME Profiles of Drug Substances and Excipients, Methodology Related to the Characterization of Drug Substances and Excipients, and Methods of Chemical Synthesis. Contains contributions from leading authorities Presents an excellent overview on the physical, chemical and biomedical properties of some regularly prescribed drugs Includes a cumulative index in each volume

Long Acting Animal Health Drug Products

Pharmaceutical Industry Practices on Genotoxic Impurities

Quality by Design for Biopharmaceuticals

ISPE Good Practice Guide

1. Quality-by-design in pharmaceutical development

Fundamentals and Applications

Advances and Challenges in Pharmaceutical Technology

Handbook of Analytical Quality by DesignAcademic Press

Offers practical advice on planning, setting, and achieving quality goals, looks at three case studies, and explains why quality is essential for business success

Long acting veterinary formulations play a significant role in animal health, production and reproduction within the animal health industry. Such technologies offer beneficial advantages to the veterinarian, farmer and pet owner. These advantages have resulted in them growing in popularity in recent years. The pharmaceutical scientist is faced with many challenges when innovating new products in this demanding field of controlled release. This book provides the reader with a comprehensive guide on the theories, applications, and challenges associated with the design and development of long acting veterinary formulations. The authoritative chapters of the book are written by some of the leading experts in the field. The book covers a wide scope of areas including the market influences, preformulation, biopharmaceutics, in vitro drug release testing and specification setting to name but a few. It also provides a detailed overview of the major technological advances made in this area. As a result this book covers everything a formulation scientist in industry or academia, or a student needs to know about this unique drug delivery field to advance health, production and reproduction treatment options and benefits for animals worldwide.

Handbook of Analytical Quality by Design addresses the steps involved in analytical method development and validation in an effort to avoid quality crises in later stages. The AQbD approach significantly enhances method performance and robustness which are crucial during inter-laboratory studies and also affect the analytical lifecycle of the developed method. Sections cover sample preparation problems and the usefulness of the QbD concept involving Quality Risk Management (QRM), Design of Experiments (DoE) and Multivariate (MVT) Statistical Approaches to solve by optimizing the developed method, along with validation for different techniques like HPLC, UPLC, UFLC, LC-MS and electrophoresis. This will be an ideal resource for graduate students and professionals working in the pharmaceutical industry, analytical chemistry, regulatory agencies, and those in related academic fields. Concise language for easy understanding of the novel and holistic concept Covers key aspects of analytical development and validation Provides a robust, flexible, operable range for an analytical method with greater excellence and regulatory compliance

Statistical and Chemometric Approaches

The New Steps for Planning Quality Into Goods and Services
The Challenge of CMC Regulatory Compliance for Biopharmaceuticals
Materials, Process Development and Drug Delivery Strategies
Juran on Quality by Design
Data-Driven Methods and Interpretation
Handbook of Analytical Quality by Design

This book serves as a reference text for regulatory, industry and academic statisticians and also a handy manual for entry level Statisticians. Additionally it aims to stimulate academic interest in the field of Nonclinical Statistics and promote this as an important discipline in its own right. This text brings together for the first time in a single volume a comprehensive survey of methods important to the nonclinical science areas within the pharmaceutical and biotechnology industries. Specifically the Discovery and Translational sciences, the Safety/Toxiology sciences, and the Chemistry, Manufacturing and Controls sciences. Drug discovery and development is a long and costly process. Most decisions in the drug development process are made with incomplete information. The data is rife with uncertainties and hence risky by nature. This is therefore the purview of Statistics. As such, this book aims to introduce readers to important statistical thinking and its application in these nonclinical areas. The chapters provide as appropriate, a scientific background to the topic, relevant regulatory guidance, current statistical practice, and further research directions.

To understand the world around us, as well as ourselves, we need to measure many things, many variables, many properties of the systems and processes we investigate. Hence, data collected in science, technology, and almost everywhere else are multivariate, a data table with multiple variables measured on multiple observations (cases, samples, items, process time points, experiments). This book describes a remarkably simple minimalistic and practical approach to the analysis of data tables (multivariate data). The approach is based on projection methods, which are PCA (principal components analysis), and PLS (projection to latent structures) and the book shows how this works in science and technology for a wide variety of applications. In particular, it is shown how the great information content in well collected multivariate data can be expressed in terms of simple but illuminating plots, facilitating the understanding and interpretation of the data. The projection approach applies to a variety of data-analytical objectives, i.e., (i) summarizing and visualizing a data set, (ii) multivariate classification and discriminant analysis, and (iii) finding quantitative relationships among the variables. This works with any shape of data table, with many or few variables (columns), many or few observations (rows), and complete or incomplete data tables (missing data). In particular, projections handle data matrices with more variables than observations very well, and the data can be noisy and highly collinear. Authors: The five authors are all connected to the Umetrics company (www.umetrics.com) which has developed and sold software for multivariate analysis since 1987, as well as supports customers with training and consultations. Umetrics' customers include most large and medium sized companies in the pharmaceutical, biopharm, chemical, and semiconductor sectors.

Advances and Challenges in Pharmaceutical Technology: Materials, Process Development and Drug Delivery Strategies examines recent advancements in pharmaceutical technology. The book discusses common formulation strategies, including the use of tools for statistical formulation optimization, Quality by design (QbD), process analytical technology, and the uses of various pharmaceutical biomaterials, including natural polymers, synthetic polymers, modified natural polymers, bioceramics, and other bioinorganics. In addition, the book covers rapid advancements in the field by providing a thorough understanding of pharmaceutical processes, formulation developments, explorations, and exploitation of various pharmaceutical biomaterials to formulate pharmaceutical dosage forms. Provides extensive information and analysis on recent advancements in the field of pharmaceutical technology Includes contributions from global leaders and experts in academia, industry and regulatory agencies Uses high quality illustrations, flow charts and tables to explain concepts and text to readers, along with practical examples and research case studies

Dosage Form Design Parameters, Volume I, examines the history and current state of the field within the pharmaceutical sciences, presenting key developments. Content includes drug development issues, the scale up of formulations, regulatory issues, intellectual property, solid state properties and polymorphism. Written by experts in the field, this volume in the Advances in Pharmaceutical Product Development and Research series deepens our understanding of dosage form design parameters. Chapters delve into a particular aspect of this fundamental field, covering principles, methodologies and the technologies employed by pharmaceutical scientists. In addition, the book contains a comprehensive examination suitable for researchers and advanced students working in pharmaceuticals, cosmetics, biotechnology and related industries. Examines the history and recent developments in drug dosage forms for pharmaceutical sciences Focuses on physicochemical aspects, prefomulation solid state properties and polymorphism Contains extensive references for further discovery and learning that are appropriate for advanced undergraduates, graduate students and those interested in drug dosage design

Generic Drug Product Development

Biosimilars

Pharmaceutical Quality by Design

Principles and Applications

Prof. of Drug Substances, Excipients and Related Methodology

Supercritical fluid chromatography (SFC) is a rapidly developing laboratory technique for the separation and identification of compounds in mixtures. Significant improvements in instrumentation have rekindled interest in SFC in recent years and enhanced its standing in the scientific community. Many scientists are familiar with column liquid chromatography and its strengths and weaknesses, but the possibilities brought to the table by SFC are less well-known and are underappreciated. Supercritical Fluid Chromatography is a thorough and encompassing reference that defines the concept of contemporary practice in SFC and how it should be implemented in laboratory science. Given the changes that have taken place in SFC, this book presents contemporary aspects and applications of the technique and introduces SFC as a natural solution in the larger field of separation science. The focus on state-of-the-art instrumental SFC distinguishes this work as the go-to reference work for those interested in implementing the technique at an advanced level. Edited and authored by world-leading chromatography experts Provides comprehensive coverage of SFC in a single source Extensive referencing facilitates identification of key research developments More than 200 figures and tables aid in the retention of key concepts

Process Understanding is the underpinning knowledge that allows the manufacture of chemical entities to be carried out routinely, robustly and to the required standard of quality. This area has gained in importance over the last few years, particularly due to the recent impetus from the USA`s Food and Drug Administration. This book covers the multidisciplinary aspects required for successful process design, safety, modeling, scale-up, PAT, pilot plant implementation, plant design as well the rapidly expanding area of outsourcing. In discussing what process understanding means to different disciplines and sectors throughout a product`s life cycle, this handbook and ready reference reveals the factors important to the development and manufacture of chemicals. The book focuses on the fundamental scientific understanding necessary. for a smoother technical transfer between the disciplines, leading to more effective and effi cient process development and manufacturing. A range of case studies are used to exemplify and illustrate the main issues raised. As a result, readers will appreciate that process understanding can deliver a real competitive advantage within the pharmaceuticals and fine chemicals industry. This book serves as an aid to meeting the stringent regulations required by the relevant authorities through demonstrable understanding of the underlying science.

Written for practitioners in both the drug and biotechnology industries, the Handbook of Analytical Validation carefully compiles current regulatory requirements on the validation of new or modified analytical methods. Shedding light on method validation from a practical standpoint, the handbook:Contains practical, up-to-date guidelines for analyti

Researchers in chemistry, chemical engineering, pharmaceutical science, forensics, and environmental science make routine use of chemical analysis, but the information these researchers need is often scattered in different sources and difficult to access. The CRC Handbook of Basic Tables for Chemical Analysis: Data-Driven Methods and Interpretation, Fourth Edition is a one-stop reference that presents updated data in a handy format specifically designed for use when reaching a decision point in designing an analysis or interpreting results. This new edition offers expanded coverage of calibration and uncertainty, and continues to include the critical information scientists rely on to perform accurate analysis. Enhancements to the Fourth Edition: Compiles a huge array of useful and important data into a single, convenient source Explanatory text provides context for data and guidelines on applications Coalesces information from several different fields Provides information on the most useful "wet" chemistry methods as well as instrumental techniques, with an expanded discussion of laboratory safety Contains information of historical importance necessary to interpret the literature and understand current methodology. Unmatched in its coverage of the range of information scientists need in the lab, this resource will be referred to again and again by practitioners who need quick, easy access to the data that forms the basis for experimentation and analysis.