

## Process Analytical Technology Spectroscopic Tools And Implementation Strategies For The Chemical And Pharmaceutical Industries

This book provides a novel view of spectroscopic methods: it describes spectroscopy holistically in terms of integral physical aspects instead of the classical methodic order according to wavelengths. The book introduces the reader to UV/Vis, NIR, IR, ESR, and NMR spectroscopy. These methods and their common physical basis, namely the reversible absorption of energy from the respective region of the electromagnetic spectrum, are illustrated in a comprehensive manner with the help of a multitude of explicative colored graphics.

Offers a comprehensive overview of cell culture engineering, providing insight into cell engineering, systems biology approaches and processing technology In Cell Culture Engineering: Recombinant Protein Production, editors Gyun Min Lee and Helene Fastrup Kildegaard assemble top class authors to present expert coverage of topics such as: cell line development for therapeutic protein production; development of a transient gene expression upstream platform; and CHO synthetic biology. They provide readers with everything they need to know about enhancing product and bioprocess attributes using genome-scale models of CHO metabolism; omics data and mammalian systems biotechnology; perfusion culture; and much more. This all-new, up-to-date reference covers all of the important aspects of cell culture engineering, including cell engineering, system biology approaches, and processing technology. It describes the challenges in cell line development and cell engineering, e.g. via gene editing tools like CRISPR/Cas9 and with the aim to engineer glycosylation patterns. Furthermore, it gives an overview about synthetic biology approaches applied to cell culture engineering and elaborates the use of CHO cells as common cell line for protein production. In addition, the book discusses the most important aspects of production processes, including cell culture media, batch, fed-batch, and perfusion processes as well as process analytical technology, quality by design, and scale down models. -Covers key elements of cell culture engineering applied to the production of recombinant proteins for therapeutic use -Focuses on mammalian and animal cells to help highlight synthetic and systems biology approaches to cell culture engineering, exemplified by the widely used CHO cell line -Part of the renowned "Advanced Biotechnology" book series Cell Culture Engineering: Recombinant Protein Production will appeal to biotechnologists, bioengineers, life scientists, chemical engineers, and PhD students in the life sciences. This second edition of the successful ready reference is updated and revised with approximately 30% new content to reflect the numerous instrumental developments and improvements, as well as the significant expansion of this rapidly developing field. For example, the combination of IR imaging with AFM has enhanced the achievable lateral resolution by an order of magnitude down to a few hundred nanometers, thus launching a multiplicity of new applications in material science. Furthermore, Raman and IR spectroscopic imaging have become key technologies for the life sciences and today contribute tremendously to a better and more detailed understanding of numerous biological and medical research topics. The topical structure of this new edition is now subdivided into four parts. The first treats the fundamentals of the instrumentation for infrared and Raman imaging and mapping and an overview on the chemometric tools for image analysis. The second part describes a wide variety of applications ranging from biomedical via food, agriculture and plants to polymers and pharmaceuticals. This is followed by a description of imaging techniques operating beyond the diffraction limit, while the final part covers special methodical developments and their utility in specific fields. With its many valuable practical tips, this is a must-have overview for researchers in academic and industrial laboratories wishing to obtain reliable results with this method.

Over the past few decades, exciting developments have taken place in the field of near-infrared spectroscopy (NIRS). This has been enabled by the advent of robust Fourier transform interferometers and diode array solutions, coupled with complex chemometric methods that can easily be executed using modern microprocessors. The present edited volume intends to cover recent developments in NIRS and provide a broad perspective of some of the challenges that characterize the field. The volume comprises six chapters overall and covers several sectors. The target audience for this book includes engineers, practitioners, and researchers involved in NIRS system design and utilization in different applications. We believe that they will greatly benefit from the timely and accurate information provided in this work. Written by an international panel of professional and academic peers, the book provides the engineer and technologist working in research, development and operations in the food industry with critical and readily accessible information on the art and science of infrared spectroscopy technology. The book should also serve as an essential reference source to undergraduate and postgraduate students and researchers in universities and research institutions. Infrared (IR) Spectroscopy deals with the infrared part of the electromagnetic spectrum. It measure the absorption of different IR frequencies by a sample positioned in the path of an IR beam. Currently, infrared spectroscopy is one of the most common spectroscopic techniques used in the food industry. With the rapid development in infrared spectroscopic instrumentation software and hardware, the application of this technique has expanded into many areas of food research. It has become a powerful, fast, and non-destructive tool for food quality analysis and control. Infrared Spectroscopy for Food Quality Analysis and Control reflects this rapid technology development. The book is divided into two parts. Part I addresses principles and instruments, including theory, data treatment techniques, and infrared spectroscopy instruments. Part II covers the application of IRS in quality analysis and control for various foods including meat and meat products, fish and related products, and others. \*Explores this rapidly developing, powerful and fast non-destructive tool for food quality analysis and control \*Presented in two Parts -- Principles and Instruments, including theory, data treatment techniques, and instruments, and Application in Quality Analysis and Control for various foods making it valuable for understanding and application \*Fills a need for a comprehensive resource on this area that includes coverage of NIR and MVA

Multivariate Analysis in the Pharmaceutical Industry provides industry practitioners with guidance on multivariate data methods and their applications over the lifecycle of a pharmaceutical product, from process development, to routine manufacturing, focusing on the challenges specific to each step. It includes an overview of regulatory guidance specific to the use of these methods, along with perspectives on the applications of these methods that allow for testing, monitoring and controlling products and processes. The book seeks to put multivariate analysis into a pharmaceutical context for the benefit of pharmaceutical practitioners, potential practitioners, managers and regulators. Users will find a resources that addresses an unmet need on how pharmaceutical industry professionals can extract value from data that is routinely collected on products and processes, especially as these techniques become more widely used, and ultimately, expected by regulators. Targets pharmaceutical industry practitioners and regulatory staff by addressing industry specific challenges Includes case studies from different pharmaceutical companies and across product lifecycle of to introduce readers to the breadth of applications Contains information on the current regulatory framework which will shape how multivariate analysis (MVA) is used in years to come

Fossil fuels still need to meet the growing demand of global economic development, yet they are often considered as one of the main sources of the CO<sub>2</sub> release in the atmosphere. CO<sub>2</sub>, which is the primary greenhouse gas (GHG), is periodically exchanged among the land surface, ocean, and atmosphere where various creatures absorb and produce it daily. However, the balanced processes of producing and consuming the CO<sub>2</sub> by nature are unfortunately faced by the anthropogenic release of CO<sub>2</sub>. Decreasing the emissions of these greenhouse gases is becoming more urgent. Therefore, carbon sequestration and storage (CSS) of CO<sub>2</sub>, its utilization in oil recovery, as well as its conversion into fuels and chemicals emerge as active options and potential strategies to mitigate CO<sub>2</sub> emissions and climate change,

energy crises, and challenges in the storage of energy.

Since the completion of the first edition of this book, major developments have occurred in the pharmaceutical industry that have shaped the field of near-infrared (NIR) spectroscopy. A new initiative from the U.S. Food and Drug Administration (FDA) to modernize regulations of pharmaceutical manufacturing and drug quality has helped position NIR spectroscopy as an effective tool for pharmaceutical testing. *Pharmaceutical and Medical Applications of Near-Infrared Spectroscopy: Second Edition* reflects these developments and brings readers an up-to-date summary of how this technique is being applied to pharmaceutical manufacturing. Topics include: The origins and principles of NIR spectroscopy, including early instrumentation, spectroscopic theory, and light-particle interaction The physics of each instrument type, the strengths and weaknesses of each, and the manufacturers that produce them The possible advantages of using NIR methods for monitoring or controlling blending, as well as practical concerns for mixing processes NIR spectroscopy as applied to traditional granulation, drug layering, and film coating of beads or granules Pharmaceutical assays, including qualitative analysis, quantitative analysis, determination of actives in tablets and capsules, and considerations for intact dosage form analysis Steps involved in the validation and acceptance of an NIR spectroscopy method, including quality assurance, qualification and verification of instruments, and the International Conference on Harmonization (ICH) guidelines Medical applications, including those related to blood glucose measurements, tissue and major organ analysis, fetal analysis, and cancer research Providing comprehensive coverage of NIR spectroscopy, from theory, mathematics, application, and mechanics of NIR analysis, the book supplies ample references to facilitate further research into this burgeoning field.

Laser spectroscopy is a valuable tool for sensing and chemical analysis. Developments in lasers, detectors and mathematical analytical tools have led to improvements in the sensitivity and selectivity of spectroscopic techniques and extended their fields of application. *Laser Spectroscopy for Sensing* examines these advances and how laser spectroscopy can be used in a diverse range of industrial, medical, and environmental applications. Part one reviews basic concepts of atomic and molecular processes and presents the fundamentals of laser technology for controlling the spectral and temporal aspects of laser excitation. In addition, it explains the selectivity, sensitivity, and stability of the measurements, the construction of databases, and the automation of data analysis by machine learning. Part two explores laser spectroscopy techniques, including cavity-based absorption spectroscopy and the use of photo-acoustic spectroscopy to acquire absorption spectra of gases and condensed media. These chapters discuss imaging methods using laser-induced fluorescence and phosphorescence spectroscopies before focusing on light detection and ranging, photothermal spectroscopy and terahertz spectroscopy. Part three covers a variety of applications of these techniques, particularly the detection of chemical, biological, and explosive threats, as well as their use in medicine and forensic science. Finally, the book examines spectroscopic analysis of industrial materials and their applications in nuclear research and industry. The text provides readers with a broad overview of the techniques and applications of laser spectroscopy for sensing. It is of great interest to laser scientists and engineers, as well as professionals using lasers for medical applications, environmental applications, military applications, and material processing. Presents the fundamentals of laser technology for controlling the spectral and temporal aspects of laser excitation Explores laser spectroscopy techniques, including cavity-based absorption spectroscopy and the use of photo-acoustic spectroscopy to acquire absorption spectra of gases and condensed media Considers spectroscopic analysis of industrial materials and their applications in nuclear research and industry

*Developing Solid Oral Dosage Forms* is intended for pharmaceutical professionals engaged in research and development of oral dosage forms. It covers essential principles of physical pharmacy, biopharmaceutics and industrial pharmacy as well as various aspects of state-of-the-art techniques and approaches in pharmaceutical sciences and technologies along with examples and/or case studies in product development. The objective of this book is to offer updated (or current) knowledge and skills required for rational oral product design and development. The specific goals are to provide readers with: Basics of modern theories of physical pharmacy, biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation, formulation/process design, characterization and scale-up in pharmaceutical sciences and technologies New developments, challenges, trends, opportunities, intellectual property issues and regulations in solid product development The first book (ever) that provides comprehensive and in-depth coverage of what's required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market, including the most updated science and technologies, practice, applications, regulation, intellectual property protection and new development trends with case studies in every chapter A strong team of more than 50 well-established authors/co-authors of diverse background, knowledge, skills and experience from industry, academia and regulatory agencies

The third edition of the *Encyclopedia of Analytical Science* is a definitive collection of articles covering the latest technologies in application areas such as medicine, environmental science, food science and geology. Meticulously organized, clearly written and fully interdisciplinary, the *Encyclopedia of Analytical Science* provides foundational knowledge across the scope of modern analytical chemistry, linking fundamental topics with the latest methodologies. Articles will cover three broad areas: analytical techniques (e.g., mass spectrometry, liquid chromatography, atomic spectrometry); areas of application (e.g., forensic, environmental and clinical); and analytes (e.g., arsenic, nucleic acids and polycyclic aromatic hydrocarbons), providing a one-stop resource for analytical scientists. Offers readers a one-stop resource with access to information across the entire scope of modern analytical science Presents articles split into three broad areas: analytical techniques, areas of application and and analytes, creating an ideal resource for students, researchers and professionals Provides concise and accessible information that is ideal for non-specialists and readers from undergraduate levels and higher

The book presents developments and applications of these methods, such as NMR, mass, and others, including their applications in pharmaceutical and biomedical analyses. The book is divided into two sections. The first section covers spectroscopic methods, their applications, and their significance as characterization tools; the second section is dedicated to the applications of spectrophotometric methods in pharmaceutical and biomedical analyses. This book would be useful for students, scholars, and scientists engaged in synthesis, analyses, and applications of materials/polymers.

In processing food, hyperspectral imaging, combined with intelligent software, enables digital sorters (or optical sorters) to identify and remove defects and foreign material that are invisible to traditional camera and laser sorters. *Hyperspectral Imaging Analysis and Applications for Food Quality* explores the theoretical and practical issues associated with the development, analysis, and application of essential image processing algorithms in order to exploit hyperspectral imaging for food quality evaluations. It outlines strategies and essential image processing routines that are necessary for making the appropriate decision during detection, classification, identification, quantification, and/or prediction processes. Features Covers practical issues associated

with the development, analysis, and application of essential image processing for food quality applications Surveys the breadth of different image processing approaches adopted over the years in attempting to implement hyperspectral imaging for food quality monitoring Explains the working principles of hyperspectral systems as well as the basic concept and structure of hyperspectral data Describes the different approaches used during image acquisition, data collection, and visualization The book is divided into three sections. Section I discusses the fundamentals of Imaging Systems: How can hyperspectral image cube acquisition be optimized? Also, two chapters deal with image segmentation, data extraction, and treatment. Seven chapters comprise Section II, which deals with Chemometrics. One explains the fundamentals of multivariate analysis and techniques while in six other chapters the reader will find information on and applications of a number of chemometric techniques: principal component analysis, partial least squares analysis, linear discriminant model, support vector machines, decision trees, and artificial neural networks. In the last section, Applications, numerous examples are given of applications of hyperspectral imaging systems in fish, meat, fruits, vegetables, medicinal herbs, dairy products, beverages, and food additives.

Process Analytical Technology Spectroscopic Tools and Implementation Strategies for the Chemical and Pharmaceutical Industries John Wiley & Sons

Green Sustainable Process for Chemical and Environmental Engineering and Science: Solid State Synthetic Methods cover recent advances made in the field of solid-state materials synthesis and its various applications. The book provides a brief introduction to the topic and the fundamental principles governing the various methods. Sustainable techniques and green processes development in solid-state chemistry are also highlighted. This book also provides a comprehensive literature on the industrial application using solid-state materials and solid-state devices. Overall, this book is intended to explore green solid-state techniques, eco-friendly materials involved in organic synthesis and real-time applications. Provides a broad overview of solid-state chemistry Outlines an eco-friendly solid-state synthesis of modern nanomaterials, organometallic, coordination compounds and pure organic Gives a detailed account of solid-state chemistry, fundamentals, concepts, techniques and applications Deliberates cutting-edge recent advances in industrial technologies involved in energy, environmental, medicinal and organic chemistry fields

Infrared and Raman Spectroscopy, Principles and Spectral Interpretation, Second Edition provides a solid introduction to vibrational spectroscopy with an emphasis on developing critical interpretation skills. This book fully integrates the use of both IR and Raman spectroscopy as spectral interpretation tools, enabling the user to utilize the strength of both techniques while also recognizing their weaknesses. This second edition more than doubles the amount of interpreted IR and Raman spectra standards and spectral unknowns. The chapter on characteristic group frequencies is expanded to include increased discussions of sulphur and phosphorus organics, aromatic and heteroaromatics as well as inorganic compounds. New topics include a discussion of crystal lattice vibrations (low frequency/THz), confocal Raman microscopy, spatial resolution in IR and Raman microscopy, as well as criteria for selecting Raman excitation wavelengths. These additions accommodate the growing use of vibrational spectroscopy for process analytical monitoring, nanomaterial investigations, and structural and identity determinations to an increasing user base in both industry and academia. Integrates discussion of IR and Raman spectra Pairs generalized IR and Raman spectra of functional groups with tables and text Includes over 150 fully interpreted, high quality IR and Raman reference spectra Contains fifty-four unknown IR and Raman spectra, with a corresponding answer key

Rapid, inexpensive, and easy-to-deploy, near-infrared (NIR) spectroscopy can be used to analyze samples of virtually any composition, origin, and condition. The Handbook of Near Infrared Analysis, Fourth Edition, explores the factors necessary to perform accurate and time- and cost-effective analyses across a growing spectrum of disciplines. This updated and expanded edition incorporates the latest advances in instrumentation, computerization, chemometrics applied to NIR spectroscopy, and method development in NIR spectroscopy, and underscores current trends in sample preparation, calibration transfer, process control, data analysis, instrument performance testing, and commercial NIR instrumentation. This work offers readers an unparalleled combination of theoretical foundations, cutting-edge applications, and practical experience. Additional features include the following: Explains how to perform accurate as well as time- and cost-effective analyses. Reviews software-enabled chemometric methods and other trends in data analysis. Highlights novel applications in pharmaceuticals, polymers, plastics, petrochemicals, textiles, foods and beverages, baked products, agricultural products, biomedicine, nutraceuticals, and counterfeit detection. Underscores current trends in sample preparation, calibration transfer, process control, data analysis, and multiple aspects of commercial NIR instrumentation. Offering the most complete single-source guide of its kind, the Handbook of Near Infrared Analysis, Fourth Edition, continues to offer practicing chemists and spectroscopists an unparalleled combination of theoretical foundations, cutting-edge applications, and detailed practical experience provided firsthand by more than 50 experts in the field.

At the cross-roads of biology, microfluidics and photonics the field of optofluidics allows for quick and compact solutions for medical and biochemical sensing and manipulation. This book is concerned with the ingredients for a polymer-based platform which is able to culture and pattern life cells for a sufficient period of time, enables the integration of photonic devices, and provides means to integrate electronic readout. Thus – in its cross-discipline approach – it touches on aspects of photonics, nanofabrication, and biological methods alike.

This introduction into the multidisciplinary area of optofluidics offers the necessary foundations in photonics, polymer physics and process analytics to students, engineers and researchers to enter the field. All basic ingredients of a polymer-based platform as a foundation for quick and compact solutions for chemical, biological and medical sensing and manipulation are developed. Process Analytical Technology explores the concepts of PAT and its application in the chemical and pharmaceutical industry from the point of view of the analytical chemist. In this new edition all of the original chapters have been updated and revised, and new chapters covering the important topics of sampling, NMR, fluorescence, and acoustic chemometrics have been added.

Coverage includes: Implementation of Process Analytical Technologies UV-Visible Spectroscopy for On-line Analysis Infrared Spectroscopy for Process Analytical Applications Process Raman Spectroscopy Process NMR Spectroscopy: Technology and On-line Applications Fluorescent Sensing and Process Analytical Applications Chemometrics in Process Analytical Technology (PAT) On-Line PAT Applications of Spectroscopy in the Pharmaceutical Industry Future Trends for PAT for Increased Process Understanding and Growing Applications in Biomanufacturing NIR Chemical Imaging This volume is an important starting point for anyone wanting to implement PAT and is intended not only to assist a newcomer to the field but also to provide up-to-date information for those who practice process analytical chemistry and PAT. It is relevant for chemists, chemical and process engineers, and analytical chemists working on

process development, scale-up and production in the pharmaceutical, fine and specialty chemicals industries, as well as for academic chemistry, chemical engineering, chemometrics and pharmaceutical science research groups focussing on PAT. Review from the First Edition “The book provides an excellent first port of call for anyone seeking material and discussions to understand the area better. It deserves to be found in every library that serves those who are active in the field of Process Analytical Technology.”—Current Engineering Practice

Green chemistry and chemical engineering belong together and this twelfth volume in the successful Handbook of Green Chemistry series represents the perfect one-stop reference on the topic. Written by an international team of specialists with each section edited by international leading experts, this book provides first-hand insights into the field, covering chemical engineering process design, innovations in unit operations and manufacturing, biorefining and much more besides. An indispensable source for every chemical engineer in industry and academia.

Mathematical and Statistical Approaches in Food Science and Technology offers an accessible guide to applying statistical and mathematical technologies in the food science field whilst also addressing the theoretical foundations. Using clear examples and case-studies by way of practical illustration, the book is more than just a theoretical guide for non-statisticians, and may therefore be used by scientists, students and food industry professionals at different levels and with varying degrees of statistical skill.

Crystallization is an important technique for separation and purification of substances as well as for product design in chemical, pharmaceutical and biotechnological process industries. This ready reference and handbook draws on research work and industrial practice of a large group of experts in the various areas of industrial crystallization processes, capturing the essence of current trends, the markets, design tools and technologies in this key field. Along the way, it outlines trouble free production, provides laboratory controls, analyses case studies and discusses new challenges. First the instrumentation and techniques used to measure the crystal size distribution, the nucleation and solubility points, and the chemical composition of the solid and liquid phase are outlined. Then the main techniques adopted to control industrial crystallizers, starting from fundamental approaches to the most advanced ones, including the multivariable predictive control are described. An overview of the main crystallizer types is given with details of the main control schemes adopted in industry as well as the more suitable sensors and actuators.

The use of modeling and simulation tools is rapidly gaining prominence in the pharmaceutical industry covering a wide range of applications. This book focuses on modeling and simulation tools as they pertain to drug product manufacturing processes, although similar principles and tools may apply to many other areas. Modeling tools can improve fundamental process understanding and provide valuable insights into the manufacturing processes, which can result in significant process improvements and cost savings. With FDA mandating the use of Quality by Design (QbD) principles during manufacturing, reliable modeling techniques can help to alleviate the costs associated with such efforts, and be used to create in silico formulation and process design space. This book is geared toward detailing modeling techniques that are utilized for the various unit operations during drug product manufacturing. By way of examples that include case studies, various modeling principles are explained for the nonexpert end users. A discussion on the role of modeling in quality risk management for manufacturing and application of modeling for continuous manufacturing and biologics is also included. Explains the commonly used modeling and simulation tools Details the modeling of various unit operations commonly utilized in solid dosage drug product manufacturing Practical examples of the application of modeling tools through case studies Discussion of modeling techniques used for a risk-based approach to regulatory filings Explores the usage of modeling in upcoming areas such as continuous manufacturing and biologics manufacturing

**Bullet points**

Noble Metal-Metal Oxide Hybrid Nanoparticles: Fundamentals and Applications sets out concepts and emerging applications of hybrid nanoparticles in biomedicine, antibacterial, energy storage and electronics. The hybridization of noble metals (Gold, Silver, Palladium and Platinum) with metal-oxide nanoparticles exhibits superior features when compared to individual nanoparticles. In some cases, metal oxides act as semiconductors, such as nano zinc oxide or titanium oxide nanoparticles, where their hybridization with silver nanoparticles, enhanced significantly their photocatalytic efficiency. The book highlights how such nanomaterials are used for practical applications. Examines the properties of metal-metal oxide hybrid nanoparticles that make them so adaptable Explores the mechanisms by which nanoparticles interact with each other, showing how these can be exploited for practical applications Shows how metal oxide hybrid nanomaterials are used in a range of industry sectors, including energy, the environment and healthcare

The concepts, applications, and practical issues of Quality by Design Quality by Design (QbD) is a new framework currently being implemented by the FDA, as well as EU and Japanese regulatory agencies, to ensure better understanding of the process so as to yield a consistent and high-quality pharmaceutical product. QbD breaks from past approaches in assuming that drug quality cannot be tested into products; rather, it must be built into every step of the product creation process. Quality by Design: Perspectives and Case Studies presents the first systematic approach to QbD in the biotech industry. A comprehensive resource, it combines an in-depth explanation of basic concepts with real-life case studies that illustrate the practical aspects of QbD implementation. In this single source, leading authorities from the biotechnology industry and the FDA discuss such topics as: The understanding and development of the product's critical quality attributes (CQA) Development of the design space for a manufacturing process How to employ QbD to design a formulation process Raw material analysis and control strategy for QbD Process Analytical Technology (PAT) and how it relates to QbD Relevant PAT tools and applications for the pharmaceutical industry The uses of risk assessment and management in QbD Filing QbD information in regulatory documents The application of multivariate data analysis (MVDA) to QbD Filled with vivid case studies that illustrate QbD at work in companies today, Quality by Design is a core reference for scientists in the biopharmaceutical industry, regulatory agencies, and students.

A practical guide to Quality by Design for pharmaceutical product development Pharmaceutical Quality by Design: A Practical Approach outlines a new and proven approach to pharmaceutical product development which is now being rolled out across the pharmaceutical industry internationally. Written by experts in the field, the text explores the QbD approach to product development. This innovative approach is based on the application of product and process understanding underpinned by a systematic methodology which can enable pharmaceutical companies to ensure that quality is built into the product. Familiarity with Quality by Design is essential for scientists working in the pharmaceutical industry. The authors take a practical approach and put the focus on the industrial aspects of the new QbD approach to pharmaceutical product development and manufacturing. The text covers quality risk management tools and analysis, applications of QbD to analytical methods, regulatory aspects, quality systems and knowledge management. In addition, the book explores the development and manufacture of drug

substance and product, design of experiments, the role of excipients, multivariate analysis, and include several examples of applications of QbD in actual practice. This important resource: Covers the essential information about Quality by Design (QbD) that is at the heart of modern pharmaceutical development Puts the focus on the industrial aspects of the new QbD approach Includes several illustrative examples of applications of QbD in practice Offers advanced specialist topics that can be systematically applied to industry Pharmaceutical Quality by Design offers a guide to the principles and application of Quality by Design (QbD), the holistic approach to manufacturing that offers a complete understanding of the manufacturing processes involved, in order to yield consistent and high quality products.

Forensic Chemistry: Fundamentals and Applications presents a new approach to the study of applications of chemistry to forensic science. It is edited by one of the leading forensic scientists with each chapter written by international experts specializing in their respective fields, and presents the applications of chemistry, especially analytical chemistry, to various topics that make up the forensic scientists toolkit. This comprehensive, textbook includes in-depth coverage of the major topics in forensic chemistry including: illicit drugs, fibers, fire and explosive residues, soils, glass and paints, the chemistry of fingerprint recovery on porous surfaces, the chemistry of firearms analysis, as well as two chapters on the key tools of forensic science, microscopy and chemometrics. Each topic is explored at an advanced college level, with an emphasis, throughout the text, on the use of chemical tools in evidence analysis. Forensic Chemistry: Fundamentals and Applications is essential reading for advanced students of forensic science and analytical chemistry, as well as forensic science practitioners, researchers and faculty, and anyone who wants to learn about the fascinating subject of forensic chemistry in some depth. This book is published as part of the AAFS series 'Forensic Science in Focus'.

This second, thoroughly revised, updated and enlarged edition provides a straightforward introduction to spectroscopy, showing what it can do and how it does it, together with a clear, integrated and objective account of the wealth of information that may be derived from spectra. It also features new chapters on spectroscopy in nano-dimensions, nano-optics, and polymer analysis. Clearly structured into sixteen sections, it covers everything from spectroscopy in nanodimensions to medicinal applications, spanning a wide range of the electromagnetic spectrum and the physical processes involved, from nuclear phenomena to molecular rotation processes. In addition, data tables provide a comparison of different methods in a standardized form, allowing readers to save valuable time in the decision process by avoiding wrong turns, and also help in selecting the instrumentation and performing the experiments. These four volumes are a must-have companion for daily use in every lab.

Process Systems Engineering for Pharmaceutical Manufacturing: From Product Design to Enterprise-Wide Decisions, Volume 41, covers the following process systems engineering methods and tools for the modernization of the pharmaceutical industry: computer-aided pharmaceutical product design and pharmaceutical production processes design/synthesis; modeling and simulation of the pharmaceutical processing unit operation, integrated flowsheets and applications for design, analysis, risk assessment, sensitivity analysis, optimization, design space identification and control system design; optimal operation, control and monitoring of pharmaceutical production processes; enterprise-wide optimization and supply chain management for pharmaceutical manufacturing processes. Currently, pharmaceutical companies are going through a paradigm shift, from traditional manufacturing mode to modernized mode, built on cutting edge technology and computer-aided methods and tools. Such shifts can benefit tremendously from the application of methods and tools of process systems engineering. Introduces Process System Engineering (PSE) methods and tools for discovering, developing and deploying greener, safer, cost-effective and efficient pharmaceutical production processes Includes a wide spectrum of case studies where different PSE tools and methods are used to improve various pharmaceutical production processes with distinct final products Examines the future benefits and challenges for applying PSE methods and tools to pharmaceutical manufacturing

Specification of Drug Substances and Products: Development and Validation of Analytical Methods, Second Edition, presents a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products, with an emphasis on phase-appropriate development, validation of analytical methods, and their application in practice. This thoroughly revised second edition covers topics not covered or not substantially covered in the first edition, including method development and validation in the clinical phase, method transfer, process analytical technology, analytical life cycle management, special challenges with generic drugs, genotoxic impurities, topical products, nasal sprays and inhalation products, and biotechnology products. The book's authors have been carefully selected as former members of the ICH Expert Working Groups charged with developing the ICH guidelines, and/or subject-matter experts in the industry, academia and in government laboratories. Presents a critical assessment of the application of ICH guidelines on method validation and specification setting Written by subject-matter experts involved in the development and application of the guidelines Provides a comprehensive treatment of the analytical methodologies used in the analysis, control and specification of new drug substances and products Covers the latest statistical approaches (including analytical quality by design) in the development of specifications, method validation and shelf-life prediction

Automated Measurement and Monitoring of Bioprocesses: Key Elements of the M3C Strategy, by Bernhard Sonnleitner Automatic Control of Bioprocesses, by Marc Stanke, Bernd Hitzmann An Advanced Monitoring Platform for Rational Design of Recombinant Processes, by G. Striedner, K. Bayer Modelling Approaches for Bio-Manufacturing Operations, by Sunil Chhatre Extreme Scale-Down Approaches for Rapid Chromatography Column Design and Scale-Up During Bioprocess Development, by Sunil Chhatre Applying Mechanistic Models in Bioprocess Development, by Rita Lencastre Fernandes, Vijaya Krishna Bodla, Magnus Carlquist, Anna-Lena Heins, Anna Eliasson Lantz, Gürkan Sin and Krist V. Gernaey Multivariate Data Analysis for Advancing the Interpretation of Bioprocess Measurement and Monitoring Data, by Jarka Glassey Design of Pathway-Level Bioprocess Monitoring and Control Strategies Supported by Metabolic Networks, by Inês A. Isidro, Ana R. Ferreira, João J. Clemente, António E. Cunha, João M. L. Dias, Rui Oliveira Knowledge Management and Process Monitoring of Pharmaceutical Processes in the Quality by Design Paradigm, by Anurag S Rathore, Anshuman Bansal, Jaspinder Hans The Choice of Suitable Online Analytical Techniques and Data Processing for Monitoring of Bioprocesses, by Ian Marison, Siobhán Hennessy, Róisín Foley, Moira Schuler, Senthilkumar Sivaprakasam, Brian Freeland

The Process Analytical Technology (PAT) initiative aims to move from a paradigm of 'testing quality in' to 'building quality in by design'. It can be defined as the optimal application of process analytical technologies, feedback process control strategies, information management tools, and/or product-process optimization strategies. Recently, there have been significant advances in process sensors and in model-based monitoring and control methodologies, leading to enormous opportunities for improved performance of food manufacturing processes and for the quality of food products with the adoption of PAT. Improvements in process efficiency, reduced product variability, enhanced traceability, process understanding, and decreased risk of contamination are some of the benefits arising from the introduction of a PAT strategy in the food industry. Process Analytical Technology for the Food Industry reviews established and emerging PAT tools with potential application within the food processing industry. The book will also serve as a reference for industry, researchers, educators, and students by providing a comprehensive insight into the objectives, challenges, and benefits of adopting a Process Analytical Technology strategy in the food industry.

A rapidly growing field, vibrational spectroscopy has found applications in industries including pharmaceutical manufacture, food and drug safety, and process monitoring on production lines. In particular, interest in clinical spectroscopy is rising rapidly as researchers recognize the potential of the vibrational spectroscopic techniques—Infrared (IR) and Raman Spectroscopy—as noninvasive tissue diagnosis

tools. However, the details of the characteristic peak frequencies and their relationship to specific functional groups present in the biological tissues have not been fully understood. Vibrational Spectroscopy for Tissue Analysis introduces IR and Raman Spectroscopy to those scientists who are either using these spectroscopic techniques to address clinical problems or planning to use spectroscopy to analyze clinical tissues and understand their chemical composition. By compiling the interpretations and understandings of the spectral peaks of the biological molecules in one place, this book aids in the understanding of IR and Raman Spectroscopy, and what these techniques can offer both in early diagnosis of the disease and monitoring of the progression of the disease. Despite the tremendous advances in the field of spectroscopy, where new applications are emerging at the pace of development, there are still areas of research that are crying for further exploration. This book bridges the gap between the spectroscopic research and medical applications.

Research and development in the pharmaceutical industry is a time-consuming and expensive process, making it difficult for newly developed drugs to be formulated into commercially available products. Both formulation and process development can be optimized by means of statistically organized experiments, artificial intelligence and other computational methods. Simultaneous development and investigation of pharmaceutical products and processes enables application of quality by design concept that is being promoted by the regulatory authorities worldwide. Computer-aided applications in pharmaceutical technology covers the fundamentals of experimental design application and interpretation in pharmaceutical technology, chemometric methods with emphasis of their application in process control, neural computing (artificial neural networks, fuzzy logic and decision trees, evolutionary computing and genetic algorithms, self-organizing maps), computer-aided biopharmaceutical characterization as well as application of computational fluid dynamics in pharmaceutical technology. All of these techniques are essential tools for successful building of quality into pharmaceutical products and processes from the early stage of their development to selection of the optimal ones. In addition to theoretical aspects of various methods, the book provides numerous examples of their application in the field of pharmaceutical technology. A comprehensive review of the current state of the art on various computer aided applications in pharmaceutical technology Case studies are presented in order to facilitate understanding of various concepts in computer-aided applications

The present book is a definitive review in the field of Infrared (IR) and Near Infrared (NIR) Spectroscopies, which are powerful, non invasive imaging techniques. This book brings together multidisciplinary chapters written by leading authorities in the area. The book provides a thorough overview of progress in the field of applications of IR and NIR spectroscopy in Materials Science, Engineering and Technology. Through a presentation of diverse applications, this book aims at bridging various disciplines and provides a platform for collaborations among scientists.

This monograph provides foundations, methods, guidelines and examples for monitoring and improving resource efficiency during the operation of processing plants and for improving their design. The measures taken to improve their energy and resource efficiency are strongly influenced by regulations and standards which are covered in Part I of this book. Without changing the actual processing equipment, the way how the processes are operated can have a strong influence on the resource efficiency of the plants and this potential can be exploited with much smaller investments than needed for the introduction of new process technologies. This aspect is the focus of Part II. In Part III we discuss physical changes of the process technology such as heat integration, synthesis and realization of optimal processes, and industrial symbiosis. The last part deals with the people that are needed to make these changes possible and discusses the path towards a resource efficiency culture. Written with industrial solutions in mind, this text will benefit practitioners as well as the academic community.

The most comprehensive resource available on the many applications of portable spectrometers, including material not found in any other published work Portable Spectroscopy and Spectrometry: Volume Two is an authoritative and up-to-date compendium of the diverse applications for portable spectrometers across numerous disciplines. Whereas Volume One focuses on the specific technologies of the portable spectrometers themselves, Volume Two explores the use of portable instruments in wide range of fields, including pharmaceutical development, clinical research, food analysis, forensic science, geology, astrobiology, cultural heritage and archaeology. Volume Two features contributions by a multidisciplinary team of experts with hands-on experience using portable instruments in their respective areas of expertise. Organized both by instrumentation type and by scientific or technical discipline, 21 detailed chapters cover various applications of portable ion mobility spectrometry (IMS), infrared and near-infrared (NIR) spectroscopy, Raman and x-ray fluorescence (XRF) spectroscopy, smartphone spectroscopy, and many others. Filling a significant gap in literature on the subject, the second volume of Portable Spectroscopy and Spectrometry: Features a significant amount of content published for the first time, or not available in existing literature Brings together work by authors with assorted backgrounds and fields of study Discusses the central role of applications in portable instrument development Covers the algorithms, calibrations, and libraries that are of critical importance to successful applications of portable instruments Includes chapters on portable spectroscopy applications in areas such as the military, agriculture and feed, hazardous materials (HazMat), art conservation, and environmental science Portable Spectroscopy and Spectrometry: Volume Two is an indispensable resource for developers of portable instruments in universities, research institutes, instrument companies, civilian and government purchasers, trainers, operators of portable instruments, and educators and students in portable spectroscopy courses.

An increasing number of genetically modified organisms (GMOs) continues to be produced every day. In response to the concerns raised by the development of GMOs and their incorporation in foods and feed, guidelines and regulations to govern and control the use of GMOs and their products have been enacted. These regulations necessitated the design of methods to detect and analyse the presence of GMOs or their products in agriculture produce, food and feed production chains. Design of techniques and instruments that would detect, identify, and quantify GM ingredients in food and feed will help inspection authorities to relay reliable information to consumers who might be concerned about the presence of GM ingredients. Information generated by detection of GMOs in food and feed would be helpful for setting regulations that govern the use of GM components as well as for labeling purposes. Qualitative detection methods of GM-DNA sequences in foods and feeds have evolved fast during the past few years. There is continuous need for the development of more advanced multi-detection systems and for periodic updates of the databases related to these systems. Testing and Analysis of GMO-containing Foods

and Feed presents updates and comprehensive views on the various methods and techniques in use today for the detection, identification and quantification of GMOs in foods and feed. The eleven book chapters cover recent developments on sample preparation techniques, immunoassays methods and the PCR technique used in GMO analysis, the use of biosensors in relation to GMO analysis, the application of nucleic acid microarrays for the detection of GMOs, validation and standardization methods for GMO testing, in addition to the type of reference material and reference methods used in GMO testing and analysis. Some of the ISO standards designed for identifying and detecting the presence of GM material in foods are also presented in the book.

Modern Techniques for Food Authentication, Second Edition presents a comprehensive review of the novel techniques available to authenticate food products, including various spectroscopic technologies, methods based on isotopic analysis and chromatography, and other techniques based on DNA, enzymatic analysis and electrophoresis. This new edition pinpoints research and development trends for those working in research, development and operations in the food industry, giving them readily accessible information on modern food authentication techniques to ensure a safe and authentic food supply. It will also serve as an essential reference source to undergraduate and postgraduate students, and for researchers in universities and research institutions. Presents emerging imaging techniques that have proven to be powerful, non-destructive tools for food authentication Includes applications of hyperspectral imaging to reflect the current trend of developments in food imaging technology for each topic area Provides pixel level visualization techniques needed for fast and effective food sample testing Contains two new chapters on Imaging Spectroscopic Techniques

The intent of this book a collection of manuscripts - is to provide general descriptions of analytical techniques which we believe to be useful to the biological scientist, and to provide examples of the utility of each technique. The contributing authors were asked to focus on examples in which their particular technique has proven particularly useful in studies of biological systems. Many commonly used analytical techniques such as NMR and ESR are not included in this work, it is preferred to focus on techniques which perhaps have not received as much coverage as in the recent literature. All of the analytical tools covered in this volume have great utility, and the scientific community can expect to see increasing usage of most if not all of these techniques.

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