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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.

This first comprehensive treatment of the intertwined roles of micro-instrumentation, high throughput experimentation and process intensification as valuable tools for process analytical technology covers both industrial as well as academic aspects. First class editors and authors from top companies and universities provide interdisciplinary coverage ranging from chemistry

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and analytics to process design and engineering, supported throughout by case studies and ample analytical data.

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.

For almost a decade, quantitative NMR spectroscopy (qNMR) has been established as valuable tool in drug analysis. In all disciplines, i. e. drug identification, impurity profiling and assay, qNMR can be utilized. Separation techniques such as high performance liquid

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chromatography, gas chromatography, super fluid chromatography and capillary electrophoresis techniques, govern the purity evaluation of drugs. However, these techniques are not always able to solve the analytical problems often resulting in insufficient methods. Nevertheless such methods find their way into international pharmacopoeias. Thus, the aim of the book is to describe the possibilities of qNMR in pharmaceutical analysis. Beside the introduction to the physical fundamentals and techniques the principles of the application in drug analysis are described: quality evaluation of drugs, polymer characterization, natural products and corresponding reference compounds, metabolism, and solid phase NMR spectroscopy for the characterization drug substances, e.g. the water content, polymorphism, and drug formulations, e.g. tablets, powders. This part is accompanied by more special chapters dealing with representative examples. They give more detailed information by means of concrete examples. Combines theory, techniques, and concrete applications—all of which closely resemble the laboratory experience Considers international pharmacopoeias, addressing the concern for licensing Features the work of academics and researchers, appealing to a broad readership

This second edition of the successful reference work has been 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

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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.

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

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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

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

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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.

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.

A guide to the development and manufacturing of pharmaceutical products written for professionals in the industry, revised second edition The revised and updated second edition of Chemical Engineering in the Pharmaceutical Industry is a practical book that highlights chemistry and chemical engineering. The book's regulatory quality strategies target the development and manufacturing of pharmaceutically active ingredients of pharmaceutical products. The expanded second edition contains revised content with many new case studies and additional example calculations that are of interest to chemical engineers. The 2nd Edition is divided into two separate books: 1) Active Pharmaceutical Ingredients (API's) and 2) Drug Product Design, Development and Modeling. The active pharmaceutical ingredients book puts the focus on the chemistry, chemical engineering, and unit operations specific to development and manufacturing of the active ingredients of the pharmaceutical product. The drug substance operations section includes information on chemical reactions, mixing, distillations, extractions,

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crystallizations, filtration, drying, and wet and dry milling. In addition, the book includes many applications of process modeling and modern software tools that are geared toward batch-scale and continuous drug substance pharmaceutical operations. This updated second edition:

- Contains 30 new chapters or revised chapters specific to API, covering topics including: manufacturing quality by design, computational approaches, continuous manufacturing, crystallization and final form, process safety
- Expanded topics of scale-up, continuous processing, applications of thermodynamics and thermodynamic modeling, filtration and drying
- Presents updated and expanded example calculations
- Includes contributions from noted experts in the field

Written for pharmaceutical engineers, chemical engineers, undergraduate and graduate students, and professionals in the field of pharmaceutical sciences and manufacturing, the second edition of *Chemical Engineering in the Pharmaceutical Industry* focuses on the development and chemical engineering as well as operations specific to the design, formulation, and manufacture of drug substance and products.

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

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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.

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

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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 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.

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

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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.

This book provides practical information on the use of infrared (IR) spectroscopy for the analysis of materials found in cultural objects. Designed for scientists and students in the fields of archaeology, art conservation, microscopy, forensics, chemistry, and optics, the book discusses techniques for examining the microscopic amounts of complex, aged components in objects such as paintings, sculptures, and archaeological fragments. Chapters include the history of infrared spectroscopy, the basic parameters of infrared absorption theory, IR instrumentation, analysis methods, sample collection and preparation, and spectra interpretation. The authors cite several case studies, such as examinations of Chumash Indian paints and the Dead Sea Scrolls. The Institute's Tools for Conservation series provides practical scientific procedures and methodologies for the practice of conservation. The series is specifically directed to conservation scientists, conservators, and technical experts in related fields.

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

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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.

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),

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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. Pharmaceutical companies are progressively adopting and introducing the Process Analytical Technology (PAT) concept to control and ensure in real-time product quality in development and manufacturing. PAT is a key component of the Quality-by-Design (QbD) framework promoted by the regulatory authorities, aiming the building of product quality based on both a strong scientific background and a quality risk management approach. An analytical method based on near infrared (NIR) spectroscopy was developed as a PAT tool to control on-line an API (active pharmaceutical ingredient) crystallization. During this process the API and residual solvent contents need to be precisely determined to reach a predefined seeding point. An original methodology based on the QbD principles was applied to conduct the development

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and validation of the NIR method and to ensure that it is fitted for its intended use. Partial least squares (PLS) models were developed and optimized through chemometrics tools in order to quantify the 2 analytes of interest. The method was fully validated according to the official requirements using the accuracy profile approach. Besides, a real-time process monitoring was added to the validation phase to prove and document that the method is fitted for purpose. Implementation of this method as an in-process control at industrial plant from the launch of this new pharmaceutical process will enable automatic control of the crystallization step in order to ensure a predefined quality level of the API. Other valuable benefits are expected such as reduction of the process time, and suppression of a difficult sampling and tedious off-line analyzes.

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.

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

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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

This book provides knowledge of the basic theory, spectral analysis methods, chemometrics, instrumentation, and applications of near-infrared (NIR) spectroscopy—not as a handbook but rather as a sourcebook of NIR spectroscopy. Thus, some emphasis is placed on the description of basic knowledge that is important in learning and using NIR spectroscopy. The book also deals with applications for a variety of research fields that are very useful for a wide range of readers from graduate students to scientists and engineers in both academia and industry. For readers who are novices in NIR spectroscopy, this book provides a good introduction, and for those who already are familiar with the field it affords an excellent means

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of strengthening their knowledge about NIR spectroscopy and keeping abreast of recent developments.

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

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comprehensive resource on this area that includes coverage of NIR and MVA 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 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

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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.

Over the last few years, near-infrared (NIR) spectroscopy has rapidly developed into an important and extremely useful method of analysis. In fact, for certain research areas and applications, ranging from material science via chemistry to life sciences, it has become an indispensable tool because this fast and cost-effective type of spectroscopy provides qualitative and quantitative information not available from any other technique. This book offers a balanced overview of the fundamental theory and instrumentation of NIR spectroscopy, introducing the material in a readily comprehensible manner. A considerable part of the text is dedicated to practical applications, including sample preparation and investigations of polymers, textiles, drugs, food and animal feed. However, special topics, such as two-dimensional correlation analysis, are also covered in separate chapters. Written by eight experts in different fields, this book presents an introduction to the current state of developments and is valuable to spectroscopists and to practitioners applying NIR spectroscopy as a daily

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analytical tool.

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.

Forensic Chemistry is a comprehensive overview of the subject aimed at those students who have a basic understanding of the underlying principles and are looking for a more detailed reference text. This book is aimed at advanced students who are studying forensic science or analytical chemistry, faculty and researchers, and practitioners such as crime laboratory bench scientists. The authors will assume that the reader will have an introductory knowledge of forensic science and forensic chemistry and will have had analytical, organic and instrumental chemistry. None of the major analytical chemical techniques will have separate treatments in the book, with the exception of forensic microscopy, which will have a chapter because many students in chemistry and forensic science do not get dedicated classes in this area. The book will have separate

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chapters on all of the major areas of forensic chemistry and, in addition, will have a chapter devoted to chemometrics, which is the statistical treatment of large amounts of data to discover groupings, similarities and differences among the data. Each chapter will be written by an acknowledged international expert in that area. Each author will be given detailed instructions as to the intended audience, as well as expected breadth and depth of coverage of the material in the hopes that this will minimize the problem of uneven coverage of topics and chapters that often occurs in edited books. Although each of the types of evidence covered in the book use methods of analysis that lie outside chemistry, these will be mentioned only for completeness in passing. The emphasis will be on the use of chemical tools in evidence analysis. This book is designed to be either a text book for an advanced forensic chemistry course, or a treatise in forensic chemistry for the scientist who wants to learn the subject in some depth. It is not designed to be a survey of the current literature in the field or a reference manual.

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

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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

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active in the field of Process Analytical Technology.”—Current Engineering Practice

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

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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. 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

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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

Fluorescence is the most popular technique in chemical and biological sensing and this book provides systematic knowledge of basic principles in the design of fluorescence sensing and imaging techniques together with critical analysis of recent developments. Its ultimate sensitivity, high temporal and spatial resolution and versatility enables high resolution imaging within living cells. It develops rapidly in the directions of constructing new molecular recognition units, new fluorescence reporters and in improving sensitivity of response, up to the detection of single molecules. Its application areas range from the control of industrial processes to environmental monitoring and clinical diagnostics. Being a guide for students and young researchers, it also addresses professionals involved in basic and applied research. Making a strong link between education, research and product development, this book discusses prospects for future progress.

Crystallization; Process Analytical Technology Tools; Raman Spectroscopy; ATR-MIR Spectroscopy; NIR Spectroscopy; UV-VIS Spectroscopy; Ultrasound;8. Turbidity; Transferability of Calibration Models; Laboratory and Pilot Plant Scales

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,

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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 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.

This book provides a novel view of spectroscopic methods: it describes spectroscopy

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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.

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

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