

Validation Of Chromatography Data Systems Ensuring Data Integrity Meeting Business And Regulatory Requirements Rsc Chromatography Monographs

All the information and tools needed to set up a successful method validation system Validating Chromatographic Methods brings order and Current Good Manufacturing Practices to the often chaotic process of chromatographic method validation. It provides readers with both the practical information and the tools necessary to successfully set up a new validation system or upgrade a current system to fully comply with government safety and quality regulations. The net results are validated and transferable analytical methods that will serve for extended periods of time with minimal or no complications. This guide focuses on high-performance liquid chromatographic methods validation; however, the concepts are generally applicable to the validation of other analytical techniques as well. Following an overview of analytical method validation and a discussion of its various components, the author dedicates a complete chapter to each step of validation: Method evaluation and further method development Final method development and trial method validation Formal method validation and report generation Formal data review and report issuance Templates and examples for Methods Validation Standard Operating Procedures, Standard Test Methods, Methods Validation Protocols, and Methods Validation Reports are all provided. Moreover, the guide features detailed flowcharts and checklists that lead readers through every stage of

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method validation to ensure success. All of the templates are also included on a CD-ROM, enabling readers to easily work with and customize them. For scientists and technicians new to method validation, this guide provides all the information and tools needed to develop a top-quality system. For those experienced with method validation, the guide helps to upgrade and improve existing systems. Note: CD-ROM/DVD and other supplementary materials are not included as part of eBook file.

Selection of the HPLC Method in Chemical Analysis serves as a practical guide to users of high-performance liquid chromatography and provides criteria for method selection, development, and validation. High-performance liquid chromatography (HPLC) is the most common analytical technique currently practiced in chemistry. However, the process of finding the appropriate information for a particular analytical project requires significant effort and pre-existent knowledge in the field. Further, sorting through the wealth of published data and literature takes both time and effort away from the critical aspects of HPLC method selection. For the first time, a systematic approach for sorting through the available information and reviewing critically the up-to-date progress in HPLC for selecting a specific analysis is available in a single book. Selection of the HPLC Method in Chemical Analysis is an inclusive go-to reference for HPLC method selection, development, and validation. Addresses the various aspects of practice and instrumentation needed to obtain reliable HPLC analysis results Leads researchers to the best choice of an HPLC method from the overabundance of information existent in the field Provides criteria for HPLC method selection, development, and validation Authored by world-renowned HPLC experts who have more than 60 years of combined experience in the field

Thoroughly revised and expanded, the third edition of the

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Encyclopedia of Chromatography is an authoritative source of information for researchers in chemistry, biology, physics, engineering, and materials science. This quick reference and guide to specific chromatographic techniques and theory provides a basic introduction to the science and techn
Thoroughly revised to include the latest industry developments, the Second Edition presents a comprehensive overview of computer validation and verification principles and how to put them into practice. To provide the current best practice and guidance on identifying and implementing improvements for computer systems, the text extensively reviews r

For decades gas chromatography has been and will remain an irreplaceable analytical technique in many research areas for both quantitative analysis and qualitative characterization/identification, which is still supplementary with HPLC. This book highlights a few areas where significant advances have been reported recently and/or a revisit of basic concepts is deserved. It provides an overview of instrumental developments, frontline and modern research as well as practical industrial applications. The topics include GC-based metabolomics in biomedical, plant and microbial research, natural products as well as characterization of aging of synthetic materials and industrial monitoring, which are contributions of several experts from different disciplines. It also contains best hand-on practices of sample preparation (derivatization) and data processing in daily research. This book is recommended to both basic and experienced researchers in gas chromatography.

This book comprises a large selection of papers presented at the second European Scientific Computing and Automation meeting (SCA 90 (Europe)) which was held in June 1990 in Maastricht, The Netherlands. The increasing use of computers for making measurements, interpreting data, and

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filling results brings a new unity to science. SCA concentrates on common computer-based tools which are useful in several disciplines. Practical problems in laboratory automation, robotics and information management with LIMS are covered in depth. The process of designing and acquiring a LIMS is described and standards for data transfer between instruments, between LIMS and instruments and between different LIMS are discussed. The applications of statistics and expert systems are covered in several chapters. Strategies for drug design are discussed with various practical examples. Finally the display of scientific results as images and computer-based animations is demonstrated by several examples with their color illustrations. The book should be of interest to those managing R&D projects, doing research in laboratories, acquiring or planning LIMS, designing instruments and laboratory automation systems and those involved in data analysis of scientific results. Written by the author of "HPLC: A Practical Guide" (RSC, 1999), this book presents the possibilities for characterising biological applications by combining analytical and computational chemistries.

This three-volume handbook is the standard reference in the field, unparalleled in its comprehensiveness. It covers every conceivable topic related to the expanding and increasingly important field of ion chromatography. The fourth edition is completely updated and revised to include the latest developments in the instrumentation, now stretching to three volumes to reflect the current state of applications. Ion chromatography is one of the most widely used separation techniques of analytical chemistry with applications in fields such as medicinal chemistry, water chemistry and materials science. Consequently, the number of users of this method is continuously growing, underlining the need for an up-to-date reference. A true pioneer of this method, Joachim Weiss

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studied chemistry at the Technical University of Berlin (Germany), where he also received his PhD degree in Analytical Chemistry. In 2002, he did his habilitation in Analytical Chemistry at the Leopold-Franzens University in Innsbruck (Austria), where he is also teaching liquid chromatography. Since 1982, Dr. Weiss has worked at Dionex (now being part of Thermo Fisher Scientific), where he currently holds the position of Technical Director for Dionex Products within the Chromatography and Mass Spectrometry Division (CMD) of Thermo Fisher Scientific, located in Dreieich (Germany).

You cannot afford to be in the dark when it comes to validating your analytical systems and lab software. Written by international laboratory and compliance expert Dr. Ludwig Huber, *Validation of Computerized Analytical and Networked Systems* is an invaluable validation tool. Covering the initial writing of the validation plan through implementation, testing, and installation qualification, through ongoing calibration, performance qualification, and change control, the book provides guidance throughout the entire validation process. Huber pays special attention to 21CFR Part 11 electronic records and signatures compliance, including recommendations for implementation and the scope of Part 11 for chromatographic systems. He discusses vendor assessment, covers the criteria and procedures for vendor audits, and includes vendor assessment checklists. He also explores the validation of complex networked systems and "office software" such as Macros, spreadsheets, and databases, and the operational compliance of legacy systems. The book contains everything you need to perform computer systems validation cost-effectively and in a manner acceptable to national and international regulatory agencies. Chemometrics uses advanced mathematical and statistical algorithms to provide maximum chemical information by

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analyzing chemical data, and obtain knowledge of chemical systems. Chemometrics significantly extends the possibilities of chromatography and with the technological advances of the personal computer and continuous development of open-source software, many laboratories are interested in incorporating chemometrics into their chromatographic methods. This book is an up-to-date reference that presents the most important information about each area of chemometrics used in chromatography, demonstrating its effective use when applied to a chromatographic separation. This volume is one in a series designed for the individual chromatographer, providing guidance and advice on a wide range of chromatographic techniques with emphasis on important practical aspects of the subject.

This book provides a comprehensive guide on validating analytical methods. Key features: Full review of the available regulatory guidelines on validation and in particular, ICH. Sections of the guideline, Q2(R1), have been reproduced in this book with the kind permission of the ICH Secretariat; Thorough discussion of each of the validation characteristics (Specificity; Linearity; Range; Accuracy; Precision; Detection Limit; Quantitation Limit; Robustness; System Suitability) plus practical tips on how they may be studied; What to include in a validation protocol with advice on the experimental procedure to follow and selection of appropriate acceptance criteria; How to interpret and calculate the results of a validation study including the use of suitable statistical calculations; A fully explained case study demonstrating how to plan a validation study, what to include in the protocol, experiments to perform, setting acceptance criteria, interpretation of the results and reporting the study.

A concise yet comprehensive reference guide on HPLC/UHPLC that focuses on its fundamentals, latest developments, and best practices in the pharmaceutical and

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biotechnology industries Written for practitioners by an expert practitioner, this new edition of HPLC and UHPLC for Practicing Scientists adds numerous updates to its coverage of high-performance liquid chromatography, including comprehensive information on UHPLC (ultra-high-pressure liquid chromatography) and the continuing migration of HPLC to UHPLC, the modern standard platform. In addition to introducing readers to HPLC's fundamentals, applications, and developments, the book describes basic theory and terminology for the novice, and reviews relevant concepts, best practices, and modern trends for the experienced practitioner. HPLC and UHPLC for Practicing Scientists, Second Edition offers three new chapters. One is a standalone chapter on UHPLC, covering concepts, benefits, practices, and potential issues. Another examines liquid chromatography/mass spectrometry (LC/MS). The third reviews the analysis of recombinant biologics, particularly monoclonal antibodies (mAbs), used as therapeutics. While all chapters are revised in the new edition, five chapters are essentially rewritten (HPLC columns, instrumentation, pharmaceutical analysis, method development, and regulatory aspects). The book also includes problem and answer sections at the end of each chapter. Overviews fundamentals of HPLC to UHPLC, including theories, columns, and instruments with an abundance of tables, figures, and key references Features brand new chapters on UHPLC, LC/MS, and analysis of recombinant biologics Presents updated information on the best practices in method development, validation, operation, troubleshooting, and maintaining regulatory compliance for both HPLC and UHPLC Contains major revisions to all chapters of the first edition and substantial rewrites of chapters on HPLC columns, instrumentation, pharmaceutical analysis, method development, and regulatory aspects Includes end-of-chapter

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quizzes as assessment and learning aids Offers a reference guide to graduate students and practicing scientists in pharmaceutical, biotechnology, and other industries Filled with intuitive explanations, case studies, and clear figures, HPLC and UHPLC for Practicing Scientists, Second Edition is an essential resource for practitioners of all levels who need to understand and utilize this versatile analytical technology. It will be a great benefit to every busy laboratory analyst and researcher.

Mass spectrometry is becoming increasingly popular in the field of therapeutic drug monitoring. The aim of this publication is to provide practical guidance for laboratories on the implementation of mass spectrometry into a clinical service where there might be limited expertise in the technique. This guidance is the author's personal recommendation based on over ten years' experience of clinical mass spectrometry. Throughout the text, examples are given to illustrate issues that a clinical laboratory might encounter. While some examples relate to the field of immunosuppressive drug monitoring, the issues are common and relevant to any clinical application. The guidance provided is also applicable to instrumentation made by any manufacturer. This practical guide covers instrument selection through business planning to installation, risk management and validation, and includes suggestions for future prospects for this developing field.

The field of aromatic interactions, the fundamental nature of substituent effects and the identification of contacts between anions and aromatic systems have generated stimulating arguments in recent years. New theoretical frameworks have been developed and tested and aromatic interactions have emerged as potential solutions for varied problems in biology and materials science. This book provides a wide ranging survey of the latest findings and advances surrounding

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aromatic interactions, stretching from the fundamentals to modern applications in synthesis, biology and materials chemistry. It also discusses computational, experimental and analytical approaches to understanding these interactions, including pi-pi, anion-pi, and cation-pi interactions. *Aromatic Interactions: Frontiers in Knowledge and Application* is a useful text for advanced students and researchers, and appeals to those working within the fields of supramolecular chemistry, computational chemistry and thermodynamics.

Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of process validation. It includes discussion on the final version of the FDA 2011 Guidance for Industry on Process Validation Principles and Practices, commonly referred to as the Process Validation Guidance or PVG, issued in final form on January 24, 2011. The book also provides guidelines and current practices, as well as industrial case studies illustrating the different approaches that can be taken for successful validation of biopharmaceutical processes. Case studies include Process validation for membrane chromatography Leveraging multivariate analysis tools to qualify scale-down models A matrix approach for process validation of a multivalent bacterial vaccine Purification validation for a therapeutic monoclonal antibody expressed and secreted by Chinese Hamster Ovary (CHO) cells Viral clearance validation studies for a product produced in a human cell line A much-needed resource, this book presents process characterization techniques for scaling down unit operations in biopharmaceutical manufacturing, including chromatography, chemical modification reactions, ultrafiltration, and microfiltration. It also provides practical methods to test raw materials and in-process samples. Stressing the importance of taking a risk-based approach towards computerized system compliance, this book will help

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you and your team ascertain process validation is carried out and exceeds expectations.

This book provides insight into the world of pharmaceutical quality systems and the key elements that must be in place to change the business and organizational dynamics from task-oriented procedure-based cultures to truly integrated quality business systems that are self-detecting and correcting. Chapter flow has been changed to adopt a quality systems organization approach, and supporting chapters have been updated based on current hot topics including the impact of the worldwide supply chain complexity and current regulatory trends.

Data integrity is fundamental in a pharmaceutical and medical devices quality system. This book provides practical information to enable compliance with data integrity, while highlighting and efficiently integrating worldwide regulation into the subject. The ideas presented in this book are based on many years' experience in regulated industries in various computer systems development, maintenance, and quality functions. In addition to case studies, a practical approach will be presented to increase efficiency and to ensure that the design and testing of the data integrity controls are correctly achieved.

Advances in Chromatography is a venerable series that has reported on the latest state-of-the-art developments in the field for the past four decades. The newest installment, Volume 49, continues the tradition of compiling the work of expert contributors who present timely and cutting edge reviews of current and emerging methods and applications in this dynamic field. Highlights in this edition include: The hyphenation of liquid chromatography with mass spectrometry in order to determine oligonucleotide adducts as markers for cancer Glycoproteomics and the glycosylation of proteins, addressing biomarkers in different types of diseases

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Chiral separation, an important area particularly in the pharmaceutical industry, where the technique has been applied with varying results Ion-pairing chromatography and analyte retention Conveying the most recent significant scientific developments in separation science, the book and its series are known for the authors' clear presentation of topics and vivid illustrations. Accessible and engaging, this volume forms a solid foundation for the work of biochemists and analytical, organic, polymer, and pharmaceutical chemists at all levels of technical skill. Meticulously referenced, it will help fuel further research across a range of fields.

Standards, technologies, and requirements for computer validation have changed dramatically in recent years, and so have the interpretation of the standards and the understanding of the processes involved. International IT Regulations and Compliance brings together current thinking on the implementation of standards and regulations in relation to IT for a wide variety of industries. The book provides professionals in pharmaceutical and semiconductor industries with an updated overview of requirements for handling IT systems according to various Quality Standards and how to ?translate? these requirements in the regulations.

Mechanochromic fluorescent (or mechanofluorochromic) materials change their emission colours (spectra) when an appropriate external mechanical force stimulus is applied. This is an important group of materials with a huge range of applications, including use in sensors, memory chips, security inks, and light devices. Mechanochromic Fluorescent Materials introduces the reader to the concept of mechanofluorochromism and the variety of applications of this group of materials. Prominent international figures in mechanofluorochromism consider the innovative research in this field over the last ten years. Chapters provide in depth

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coverage of most reported mechanofluorochromic systems, including organic and organic-inorganic complexes; polymer and polymer composites; and aggregation-induced emission. This book is aimed to inform all students and researchers with an interest in mechanofluorochromism, and to help researchers identify and synthesize more of these materials, and develop the study and application of mechanofluorochromic materials.

Closing a gap in the current literature by addressing the evaluation and quality assessment of raw data, this practice-oriented guide is clearly divided into three parts. The first describes basic considerations of chromatographic data quality, common errors and potential pitfalls in reading out and quantifying the data. Part two systematically covers the most important chromatographic methods as well as the specific requirements for obtaining good chromatographic data. The final part looks at data quality from the perspective of those regulatory authorities demanding certain standards in data quality, describing in detail best practices. Written with the practitioner in mind, the text not only teaches the mathematical basics but also provides invaluable advice.

High pressure liquid chromatography—frequently called high performance liquid chromatography (HPLC or, LC) is the premier analytical technique in pharmaceutical analysis and is predominantly used in the pharmaceutical industry. Written by selected experts in their respective fields, the Handbook of Pharmaceutical Analysis by HPLC Volume 6, provides a complete yet concise reference guide for utilizing the versatility of HPLC in drug development and quality control. Highlighting novel approaches in HPLC and the latest developments in hyphenated techniques, the book captures the essence of major pharmaceutical applications (assays, stability testing, impurity testing, dissolution testing, cleaning validation, high-throughput screening). A complete reference

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guide to HPLC Describes best practices in HPLC and offers 'tricks of the trade' in HPLC operation and method development Reviews key HPLC pharmaceutical applications and highlights current trends in HPLC ancillary techniques, sample preparations, and data handling

The validation of analytical methods is based on the characterisation of a measurement procedure (selectivity, sensitivity, repeatability, reproducibility). This volume collects 31 outstanding papers on the topic, mostly published in the period 2000-2003 in the journal "Accreditation and Quality Assurance." They provide the latest understanding, and possibly the rationale why it is important to integrate the concept of validation into the standard procedures of every analytical laboratory. In addition, this anthology considers the benefits to both: the analytical laboratory and the user of the measurement results.

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Chemistry

How to hone your analytical skills and obtain high-quality data in the era of GMP requirements With increased regulatory pressures on the pharmaceutical industry, there is a growing need for capable analysts who can ensure appropriate scientific practices in laboratories and manufacturing sites worldwide. Based on Johnson & Johnson's acclaimed in-house training program, this practical guide provides guidance for laboratory analysts who must juggle the Food and Drug Administration's good manufacturing practices (GMP) rules with rapidly changing analytical technologies. Highly qualified industry experts walk readers step-by-step through the concepts, techniques, and tools necessary to perform analyses in an FDA-regulated environment, including clear instructions on all major analytical chemical methods- from spectroscopy to chromatography to dissolution. An ideal

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manual for formal training as well as an excellent self-study guide, Analytical Chemistry in a GMP Environment features: *

- * The drug development process in the pharmaceutical industry
- * Uniform and consistent interpretation of GMP compliance issues
- * A review of the role of statistics and basic topics in analytical chemistry
- * An emphasis on high-performance liquid chromatographic (HPLC) methods
- * Chapters on detectors and quantitative analysis as well as data systems
- * Methods for ensuring that instruments meet standard operating procedures (SOP) requirements
- * Extensive appendixes for unifying terms, symbols, and procedural information

Guiding chromatographers working in regulated industries and helping them to validate their chromatography data systems to meet data integrity, business and regulatory needs. This book is a detailed look at the life cycle and documented evidence required to ensure a system is fit for purpose throughout the lifecycle. Initially providing the regulatory, data integrity and system life cycle requirements for computerised system validation, the book then develops into a guide on planning, specifying, managing risk, configuring and testing a chromatography data system before release. This is followed by operational aspects such as training, integration and IT support and finally retirement. All areas are discussed in detail with case studies and practical examples provided as appropriate. The book has been carefully written and is right up to date including recently released FDA data integrity guidance. It provides detailed guidance on good practice and expands on the first edition making it an invaluable addition to a chromatographer's book shelf.

Chromatography is a major analytical technique that is used throughout research, development and manufacturing in the pharmaceutical, medical device and associated industries. To

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demonstrate fitness for purpose with the applicable regulations, the systems must be validated. Validation of Chromatography Data Systems: Meeting Business and Regulatory Requirements introduces the basics of computer validation. It looks in detail at the requirements throughout the life cycle of a CDS for any regulated laboratory, from its concept, through writing the user requirements specification to selecting the system, testing and operational release, including using electronic signatures. This logical and uniquely organised book provides the background to the regulatory requirements, interpretation of the regulations and documented evidence needed to support a claim that a system is validated. Development of the system, risk management, operation and finally system retirement and data migration are discussed. Case studies and practical examples are provided where appropriate. Validation of Chromatography Data Systems: Meeting Business and Regulatory Requirements is ideal for the chromatographer working in analytical laboratories in the regulated pharmaceutical, contract research, biotechnology and medical device industries seeking the practical guidance required for validating their chromatography data systems in order to meet regulatory requirements. It will also be welcomed by consultants or those in regulatory agencies. Practical approaches to ensure that analytical methods and instruments meet GMP standards and requirements

Complementing the authors' first book, Analytical Method Validation and Instrument Performance Verification, this new volume provides coverage of more advanced topics, focusing on additional and supplemental methods, instruments, and electronic systems that are used in pharmaceutical, biopharmaceutical, and clinical testing. Readers will gain new and valuable insights that enable them to avoid common pitfalls in order to seamlessly conduct analytical method

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validation as well as instrument operation qualification and performance verification. Part 1, Method Validation, begins with an overview of the book's risk-based approach to phase appropriate validation and instrument qualification; it then focuses on the strategies and requirements for early phase drug development, including validation of specific techniques and functions such as process analytical technology, cleaning validation, and validation of laboratory information management systems Part 2, Instrument Performance Verification, explores the underlying principles and techniques for verifying instrument performance—coverage includes analytical instruments that are increasingly important to the pharmaceutical industry, such as NIR spectrometers and particle size analyzers—and offers readers a variety of alternative approaches for the successful verification of instrument performance based on the needs of their labs At the end of each chapter, the authors examine important practical problems and share their solutions. All the methods covered in this book follow Good Analytical Practices (GAP) to ensure that reliable data are generated in compliance with current Good Manufacturing Practices (cGMP). Analysts, scientists, engineers, technologists, and technical managers should turn to this book to ensure that analytical methods and instruments are accurate and meet GMP standards and requirements.

The second edition of the popular Chromatographic Integration Methods has been completely revised and updated. Written by an expert with many years' experience with two of the world's largest manufacturers of computing integrators, it has been expanded to include a new section on validation of integrators in response to regulatory requirements for quality and validation. A new literature survey, additional diagrams and Author Index have also been added. Well illustrated and easily read, this is an excellent

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source book for those who wish to increase their understanding of integrators. Chromatographic Integration Methods describes and discusses both manual and electronic techniques used, with the aim of aiding analysts to obtain more data from their chromatograms, and assist them with understanding how integrators work so that results are never accepted unquestioningly. As with the first edition, this book will be welcomed by all those in the chromatography field, particularly those at the bench.

Written for practitioners in both the drug and biotechnology industries, the Handbook of Analytical Validation carefully compiles current regulatory requirements on the validation of new or modified analytical methods. Shedding light on method validation from a practical standpoint, the handbook: Contains practical, up-to-date guidelines for analytical data integrity is the hottest topic in the pharmaceutical industry. Global regulatory agencies have issued guidance, after guidance after guidance in the past few years, most of which does not offer practical advice on how to implement policies, procedures and processes to ensure integrity. These guidances state what but not how. Additionally, key stages of analysis that impact data integrity are omitted entirely. The aim of this book is to provide practical and detailed help on how to implement data integrity and data governance for regulated analytical laboratories working in or for the pharmaceutical industry. It provides clarification of the regulatory issues and trends, and gives practical methods for meeting regulatory requirements and guidance. Using a data integrity model as a basis, the principles of data integrity and data governance are expanded into practical steps for regulated laboratories to implement. The author uses case study examples to illustrate his points and provides instructions for applying the principles of data integrity and data governance to individual laboratory needs. This book is

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a useful reference for analytical chemists and scientists, management and senior management working in regulated laboratories requiring either an understanding about data integrity or help in implementing practical solutions. Consultants will also benefit from the practical guidance provided.

Chromatography is a major analytical technique that is used throughout research, development and manufacturing in the pharmaceutical, medical device and associated industries. To demonstrate fitness for purpose with the applicable regulations, the systems must be validated. Validation of Chromatography Data Systems: Meeting Business and Regulatory Requirements introduces the basics of computer validation. It looks in detail at the requirements throughout the life cycle of a CDS for any regulated laboratory, from its concept, through writing the user requirements specification to selecting the.

Completely revised and updated to reflect the significant advances in pharmaceutical production and regulatory expectations, this third edition of Validation of Pharmaceutical Processes examines and blueprints every step of the validation process needed to remain compliant and competitive. The many chapters added to the prior compilation examine va

This book is a comprehensive compilation of modern and cutting-edge chromatographic techniques written by pharmaceutical industry experts, academics, and vendors in the field. This book is an

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inclusive guide to developing all chromatographic methods (such as liquid chromatography and gas chromatography). It covers modern techniques for developing methods using chromatographic development software, requirements for validations, discussion on orthogonality, and how to transfer methods from HPLC to UHPLC. The text introduces some newer techniques that are heavily employed by chemists analyzing proteins and RNAi, as well as novel techniques such as counter current chromatography. This book is valuable for both the novice starting out in undergraduate labs and those who are new to the pharmaceutical industry and is a useful reference for seasoned analysts.

Contains an outline of the principles and characteristics of relevant instrumental techniques, provides an overview of various aspects of direct additive analysis by focusing on an array of applications in R ampD, production, quality control, and technical service.

This second edition of a global bestseller has been completely redesigned and extensively rewritten to take into account the new Quality by Design (QbD) and lifecycle concepts in pharmaceutical manufacturing. As in the first edition, the fundamental requirements for analytical method validation are covered, but the second edition describes how these are applied systematically throughout the entire analytical lifecycle. QbD

principles require adoption of a systematic approach to development and validation that begin with predefined objectives. For analytical methods these predefined objectives are established as an Analytical Target Profile (ATP). The book chapters are aligned with recently introduced standards and guidelines for manufacturing processes validation and follow the three stages of the analytical lifecycle: Method Design, Method Performance Qualification, and Continued Method Performance Verification. Case studies and examples from the pharmaceutical industry illustrate the concepts and guidelines presented, and the standards and regulations from the US (FDA), European (EMA) and global (ICH) regulatory authorities are considered throughout. The undisputed gold standard in the field.

Written for practitioners in both the drug and biotechnology industries, the Handbook of Analytical Validation carefully compiles current regulatory requirements on the validation of new or modified analytical methods. Shedding light on method validation from a practical standpoint, the handbook: Contains practical, up-to-date guidelines for analytical method validation Summarizes the latest regulatory requirements for all aspects of method validation, even those coming from the USP, but undergoing modifications Covers development, optimization, validation, and transfer of many different types of methods used in the regulatory

environment Simplifying the overall process of method development, optimization and validation, the guidelines in the Handbook apply to both small molecules in the conventional pharmaceutical industry, as well as well as the biotech industry. High-temperature liquid chromatography has attracted much interest in recent years but has not yet recognized its full potential in the chromatographic community. There is a widespread reluctance in industry to use temperature to speed up the separation process, influence the selectivity of a separation or implement novel detection techniques. However, the technology has now matured and could revolutionize chromatography as we see it today. Better equipment, such as heating systems able to generate faster heating rates, is becoming more readily available. Also, columns based on silica gel, which can withstand higher temperatures for an extended period, are now being introduced. Nevertheless, further technological and methodical efforts are needed to establish the method in a regulated environment like the pharmaceutical industry. This is the only text to cover all the practical aspects, as well as the underlying theoretical principles, of setting up an HPLC system for high temperature operation. It is not intended solely for academics but will also benefit the researcher interested in more practical considerations. The author is a recognized expert

and has conducted several studies with partners from industry to validate the method. Many real examples from these studies have been included in the book. The aim is to support practitioners in the creation of their own protocols without the need to rely solely on trial and error. The book starts with a brief definition of high temperature liquid chromatography before going on to cover: system set up; the heating system; mobile phase considerations; suitable stationary phases; method development using temperature programming; analyte stability, and special hyphenation techniques using superheated water as a mobile phase. In each chapter, experimental data is used to illustrate the main statements and the advantages over conventional HPLC are evaluated. The book concludes with a critical outlook on further developments and applications underlining the necessary advances needed to make high temperature HPLC more robust.

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