Method Validation Guidelines For Laboratory

This paper is an evaluation of the effectiveness of collaborative testing guidelines applied to two multi-laboratory method validation studies conducted for the U.S. Environmental Protection Agency (EPA). The guidelines were developed for EPA's Office of Toxic Substances and modeled after those of the Association of Official Analytical Chemists and The American Society for Testing and Materials. They were applied, to a greater or lesser extent, in the conduct of validation studies of the EPA's interim Ames test mutagenicity assay and Daphnia magna life-cycle toxicity assay. At the conclusion of the testing phase of the studies, each participant was requested to provide information related to key guideline elements. In addition, the organizers of each study indicated the degree to which they followed or did not follow the guidelines in administering their studies. Both participants and organizers were urged to provide recommendations for improving the way in which such studies are conducted in the future. The results are the basis for validation and appropriate revision of the collaborative testing guidelines. Results are presented and the implications of those results for future collaborative studies are discussed.

Guidance for the Validation of Analytical Methodology and Calibration of Equipment Used for Testing of Illicit Drugs in Seized Materials and Biological SpecimensA Commitment to Quality and Continuous ImprovementUnited Nations Publications

This book is a guide for quality control laboratories in pharmaceutical industry, and other labs using high performance liquid chromatography (HPLC). The book gives a biopharmaceutical industry point of view on the interpretation and implementation of the different guidelines and requirements for instrument qualification and analytical method validation. It overviews key topics like qualification process according to actual guidelines, method development with a focus on biological and protein sample analysis, method validation, change control, and instrument maintenance.

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

A Sampling of Current Approaches

Liquid Chromatography

Training in Statistical Quality Control for Medical Laboratories

Calibration and Validation of Analytical

Methods
Validation in Chemical Measurement
Method Validation in Pharmaceutical Analysis

Analytical chemical results touch everyone's lives: Can we eat the food? Do I have a disease? Did the defendant leave his DNA at the crime scene? Should I invest in that gold mine? When a chemist measures something, how do we know that the result is appropriate? What is "fit for purpose" in the context of analytical chemistry? Quality Assurance for the Analytical Chemistry Laboratory explains the practices that chemistry laboratories adopt so that we all can have confidence in the answers to these questions.

This Second Edition discusses ways to improve pharmaceutical product quality while achieving compliance with global regulatory standards. With comprehensive step-by-step instructions, practical recommendations, standard operating procedures (SOPs), checklists, templates, and graphics for easy incorporation in a laboratory. This title serves as a complete source to the subject, and explains how to develop and implement a validation strategy for routine, non-routine, and standard analytical methods, covering the entire equipment, hardware, and software qualification process. It also provides guidance on qualification of certified standards, in-house reference materials, and people qualification, as well as internal and third party laboratory audits and inspections.

Mass Spectrometry for the Clinical Laboratory is an accessible guide to mass spectrometry and the development, validation, and implementation of the most common assays seen in clinical labs. It provides readers with practical examples for assay development, and experimental design for validation to meet CLIA requirements, appropriate interference testing, measuring, validation of ion suppression/matrix effects, and quality control. These tools offer guidance on what type of instrumentation is optimal for each assay, what options are available, and the pros and cons of each. Readers will find a full set of tools that are either directly related to the assay they want to adopt or for an analogous assay they could use as an example. Written by expert users of the most common assays found in a clinical laboratory (clinical chemists, toxicologists, and clinical pathologists practicing mass spectrometry), the book lays out how experts in the field have chosen their mass spectrometers, purchased, installed, validated, and brought them on line for routine testing. The early chapters of the book covers what the practitioners have learned from years of experience, the challenges they have faced, and their recommendations on how to build and validate assays to avoid problems. These chapters also include recommendations for maintaining continuity of quality in testing. The later parts of the book focuses on specific types

of assays (therapeutic drugs, Vitamin D, hormones, etc.). Each chapter in this section has been written by an expert practitioner of an assay that is currently running in his or her clinical lab. Provides readers with the keys to choosing, installing, and validating a mass spectrometry platform Offers tools to evaluate, validate, and troubleshoot the most common assays seen in clinical pathology labs Explains validation, ion suppression, interference testing, and quality control design to the detail that is required for implementation in the lab

Analytical Methods for Agricultural Contaminants provides proven laboratory practices and methods necessary to control contaminants and residues in food and water. This reference provides insight into good laboratory practices and examples of methods used in individual specialist laboratories, thus enabling stakeholders in the agri-food industry to appreciate the importance of proven, reliable data and the associated quality assurance approaches for end product testing for toxic levels of contaminants and contaminant residues in food. The book offers standard operating procedures and tools for researchers, practitioners and students to confidently engage in using research methods with the aim to control contaminants. Users in a laboratory setting will find this to be a practical and useful reference on how to detect and control agricultural contaminants for a safe food supply. Provides coverage of

risk assessment and effective testing technologies Presents the most up-to-date information in research sample preparation and method validation to detect chemical residues Includes examples of each method for practical application Demonstrates proven, reliable research data and the associated quality assurance approaches for end product testing

Quality Assurance in the Analytical Chemistry Laboratory

OECD Series on Testing and Assessment Guidance Document on Good In Vitro Method Practices (GIVIMP)

Verification of Analytical Methods for GMO Testing when Implementing Interlaboratory Validated Methods

The Fitness for Purpose of Analytical Methods

Lifecycle Validation in Biopharmaceutical Quality Control Analysis

Analytical Method Validation and Instrument Performance Verification

In the past several decades, there has been a substantial increase in the availability of in vitro test methods for evaluating chemical safety in an international regulatory context. To foster confidence in in vitro alternatives to animal testing, the test methods and conditions under which ...

Liquid Chromatography: Fundamentals and Instrumentation, Second Edition, is a single source of authoritative information on all aspects of the practice of modern liquid chromatography. It gives those working in

both academia and industry the opportunity to learn, refresh, and deepen their understanding of new fundamentals and instrumentation techniques in the field. In the years since the first edition was published, thousands of papers have been released on new achievements in liquid chromatography, including the development of new stationary phases, improvement of instrumentation, development of theory, and new applications in biomedicine, metabolomics, proteomics, foodomics, pharmaceuticals, and more. This second edition addresses these new developments with updated chapters from the most expert researchers in the field. Emphasizes the integration of chromatographic methods and sample preparation Explains how liquid chromatography is used in different industrial sectors Covers the most interesting and valuable applications in different fields, e.g., proteomic, metabolomics, foodomics, pollutants and contaminants, and drug analysis (forensic, toxicological, pharmaceutical, biomedical) Includes references and tables with commonly used data to facilitate research, practical work, comparison of results, and decision-making

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.

The book introduces the new concepts of target measurement uncertainty and decision rules and explains how to use them to demonstrate a method is fit-for-purpose. As well, they can be used to set the acceptance criteria for a method validation clearly and quantitatively. Examples are given that illustrate the concepts so that the reader can easily apply decision rules and target measurement uncertainty to their methods. The book covers all aspects of method validation from stating the purpose of the method using a Decision Rule, calculating the target measurement uncertainty, deciding the required parameters that need to be included in the method validation, estimating the measurement uncertainty, and setting the acceptance criteria. With this approach the reader will fully understand the method, what its critical control points are and what to control and monitor during routine use. This approach fits in well with the lifecycle approach to analytical methods. The book covers the basics and advanced aspects of method validation so that it is useful for people new to method

validation and those with experience. The book is applicable for laboratories in many industries, from mining to pharmaceutical manufacturing to food analysis.
From Instrument Qualification and Method Validatin to Routine Use in a Biopharmaceutical Qc Laboratory
Bacteriological Analytical Manual
A Commitment to Quality and Continuous Improvement
Training in Analytical Quality Management for Medical Laboratories

A Practical Guide
With the publication of the Final CLIA Rule, new method validation responsibilities came to the laboratory. Previously, moderately complex methods did not need to be validated. But the Final Rule combined moderately and highly complex methods into a category of non-waived methods. Now Laboratories must validate all non-waived methods introduced after April 24, 2003. To help laboratory professionals comply with these new regulatory changes, a second edition of this manual was prepared. Book jacket.
Fit-for-purpose is a phrase familiar to all users of analytical data, who need to be assured that data provided by laboratories is both appropriate and of the required quality. Quality in the Food Analysis Laboratory surveys the procedures that a food analysis laboratory must consider to meet such requirements. The need to introduce quality assurance, the different quality models that are available and the legislative requirements are considered. Specific aspects of laboratory practice

and particular areas of accreditation which may cause problems for analytical laboratories are also discussed. Covering for the first time those areas of direct importance to food analysis laboratories, this unique book will serve as an aid to those laboratories when introducing new measures and justifying those chosen.

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 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.

Quality Assurance in Chemical Measurement, an advanced EURACHEM textbook, provides in-depth but easy-to-understand coverage for training, teaching and continuing studies. The CD-ROM accompanying the book contains course materials produced by ten experienced specialists, including more than 750 overheads (graphics and text) in ready-to-use PowerPoint® documents in English and German language. The book will serve as an advanced textbook for analytical chemistry students and professionals in industry and service labs and as a reference text and source of course materials for lecturers. The second edition has been completely revised according to the newest legislation.

Analytical Method Development and Validation

Principles and Practices of Method Validation

The International Pharmacopoeia

Handbook of Analytical Validation

Analytical Methods for Agricultural Contaminants

Basic QC Practices, 4th Edition

Principles and Practices of Method Validation is an overview

of the most recent approaches used for method validation in cases when a large number of analytes are determined from a single aliquot and where a large number of samples are to be analysed. Much of the content relates to the validation of new methods for pesticide residue analysis in foodstuffs and water but the principles can be applied to other similar fields of analysis. Different chromatographic methods are discussed, including estimation of various effects, eg. matrix-induced effects and the influence of the equipment set-up. The methods used for routine purposes and the validation of analytical data in the research and development environment are documented. The legislation covering the EU-Guidance on residue analytical methods, an extensive review of the existing in-house method validation documentation and guidelines for single-laboratory validation of analytical methods for trace-level concentrations of organic chemicals are also included. With contributions from experts in the field, any practising analyst dealing with method validation will find the examples presented in this book a useful source of technical information.

Technologies collectively called omics enable simultaneous measurement of an enormous number of biomolecules; for example, genomics investigates thousands of DNA sequences, and proteomics examines large numbers of proteins. Scientists are using these technologies to develop innovative tests to detect disease and to predict a patient's likelihood of responding to specific drugs. Following a recent case involving premature use of omics-based tests in cancer clinical trials at Duke University, the NCI requested that the IOM establish a committee to recommend ways to strengthen omics-based test development and evaluation. This report identifies best practices to enhance development, evaluation, and translation of omics-based tests while simultaneously reinforcing steps to ensure that these tests are appropriately

assessed for scientific validity before they are used to guide patient treatment in clinical trials.

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

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.

A Laboratory Guide to Method Validation and Related Topics

Application of Iso/Iec 17025 Technical Requirements in Industrial Laboratories

Guidance Document from the European Network of GMO Laboratories (ENGL).

Guidelines for Performance Criteria and Validation Procedures of Analytical Methods Used in Controls of Food Contact Materials

Validating Chromatographic Methods

A Guide to Best Practice

The validation of analytical methods and the calibration of equipment are important aspects of quality assurance in the laboratory. This manual deals with both of these within the context of testing of illicit drugs in seized materials and biological specimens. It provides an introduction and practical guidance to national authorities and analysts in the implementation of method validation and verification, and also in the calibration/performance verification of laboratory instrumentation and equipment within their existing internal quality assurance programmes. The procedures described represent a synthesis of the experience of scientists from several reputable laboratories around the world.

Validation describes the procedures used to analyze pharmaceutical products so that the data generated will comply with the requirements of regulatory bodies of the US, Canada, Europe and Japan. Calibration of Instruments describes the process of fixing, checking or correcting the graduations of instruments so that they comply with those regulatory bodies. This book provides a thorough explanation of both the

fundamental and practical aspects of biopharmaceutical and bioanalytical methods validation. It teaches the proper procedures for using the tools and analysis methods in a regulated lab setting. Readers will learn the appropriate procedures for calibration of laboratory instrumentation and validation of analytical methods of analysis. These procedures must be executed properly in all regulated laboratories, including pharmaceutical and biopharmaceutical laboratories, clinical testing laboratories (hospitals, medical offices) and in food and cosmetic testing laboratories.

This book provides useful information for bioanalytical / analytical scientists, analysts, quality assurance managers, and all personnel in bioanalytical laboratories through all aspects of bioanalytical technical and regulatory perspectives within bioanalytical operations and processes. Readers learn how to develop and implement strategies for routine, non-routine, and standard bioanalytical methods and on the entire equipment hardware and software qualification process. The book also gives guidelines on qualification of certified standards and in-house reference material as well as on people qualification. Finally, it guides readers through stressless internal and third party laboratory audits and inspections. It takes account to most national and international regulations and quality and accreditation standards, along with corresponding interpretation and inspection guides. The author elaborates on highly comprehensive content, making it easy not only to learn the subject but also to quickly implement the recommendations.

Adopting a practical approach, the authors provide a detailed interpretation of the existing regulations (GMP, ICH), while also discussing the appropriate calculations, parameters and

tests. The book thus allows readers to validate the analysis of pharmaceutical compounds while complying with both the regulations as well as the industry demands for robustness and cost effectiveness. Following an introduction to the basic parameters and tests in pharmaceutical validation, including specificity, linearity, range, precision, accuracy, detection and quantitation limits, the text focuses on a life-cycle approach to validation and the integration of validation into the whole analytical quality assurance system. The whole is rounded off with a look at future trends. With its first-hand knowledge of the industry as well as regulating bodies, this is an invaluable reference for analytical chemists, the pharmaceutical industry, pharmaceutists, QA officers, and public authorities.

Quality Assurance in Analytical Chemistry

Specification of Drug Substances and Products

Standard Methods for the Examination of Water and Wastewater

Fundamentals and Instrumentation

Evolution of Translational Omics

Chemical Analysis of Non-antimicrobial Veterinary Drug Residues in Food

This book seeks to introduce the reader to current methodologies in analytical calibration and validation. This collection of contributed research articles and reviews addresses current developments in the calibration of analytical methods and techniques and their subsequent validation. Section 1, "Introduction," contains the Introductory Chapter, a broad overview of analytical calibration and validation, and a brief synopsis of the following chapters. Section 2 "Calibration Approaches" presents five chapters covering calibration schemes for some modern analytical methods and techniques. The last chapter

in this section provides a segue into Section 3, "Validation Approaches," which contains two chapters on validation procedures and parameters. This book is a valuable source of scientific information for anyone interested in analytical calibration and validation.

Application of Sampling and Detection Methods in Agricultural Plant Biotechnology describes detection methods for seed, plants and grain derived from biotechnology. This international handbook, based on a series of workshops carried out for governments in collaboration with ILSI and Co-published in partnership with the Cereals & Grains Association, provides the technical and practical information needed to develop, validate and use detection methods. This useful resource provides readers with the tools necessary to carry out reliable sampling, detection and interpretation of data. Presents a review of the technologies and approaches used for sampling and detecting biotechnology products in seed, plants, grain, food and feed Serves as a GM detection manual for international regulators and government agencies, testing laboratories, and academic and industrial professionals Contains case studies, applications, literature reviews and coverage of recent developments

Test methods for materials and articles in contact with foodstuffs are required to determine the concentration of residues of monomers in the materials themselves or to determine the concentration of individual or groups of substances in food (or food simulants) which have migrated from the food contact materials. The Community Reference Laboratory and National Reference Laboratories for food contact materials (FCM) prepared the present Guidelines to illustrate the required performance criteria for the analytical methods applied in the laboratories for FCM and provide procedures for method validation in order to estimate their

performance characteristics. The scope of these guidelines is to provide rules for the performance of the analytical methods to be used in the verification of compliance with the migration limits defined in Directive 2002/72/EC, as amended, and in accordance with Directive 82/711/EEC, as amended, and others defined in the European legislation, in order to ensure the quality and comparability of the analytical results. The document presents 4 approaches, according to the different purpose of performance assessment. These guidelines are intended as a dynamic document and they will evolve and expand into further editions. This is the first edition. These guidelines have been endorsed by the European Union official Network of National Reference Laboratories and approved by the EU Commission competent service DG SANCO. This work also highlights an important deliverable for the Network of NRLs. In particular, the members of the task force "Method Performance" that have dedicated time and effort to provide input into the development of these guidelines. They are gratefully acknowledged here for their contribution: NRL-BE (Fabien Bolle, Tina n'Goy), NRL-DE (Oliver Kappenstein), NRL-DK (Jens Petersen), NRL-ES (Juana Bustos), NRL-FR1 (Patrick Sauvegrain), NRL-EL (Timokleia Togkalidou), NRL-IT (Maria Rosaria Milana), NRL-NL (Durk Schakel, Dita Kalsbeek-van Wijk), NRL-PL (Kazimiera Cwiek-Ludwicka), NRL-SI (Viviana Golja), NRL-UK (Emma Bradley). Special thanks are extended to Emma Bradley for her contribution to the editing of the document

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

Advances in Clinical Chemistry

Validation of Collaborative Testing Guidelines

Application of Sampling and Detection Methods in Agricultural Plant Biotechnology

Quality in the Food Analysis Laboratory

Lessons Learned and the Path Forward

Regulated Bioanalytical Laboratories

In the EU, method validation is an essential part of the process that regulates the introduction of new GMOs as food and/or feed into the market. When the inter-laboratory validation

study is completed, the method is ready to be implemented in routine testing laboratories. When implementing the new method, the laboratory has to verify that the method can be used for its intended purpose (method verification). The scope of this document is to provide guidance on how to carry out the method verification. Despite the fact that several guidelines on method verification have been published, no specific guidelines are available for GMO detection. The aim of this guidance document is to harmonise the in-house verification of inter-laboratory validated methods for the qualitative and quantitative detection of GMOs, including element-, construct-, and event-specific methods. Considering that the Polymerase Chain Reaction (PCR) is the method of choice in the EU for the identification and quantification of GMOs, this document refers exclusively to real time PCR. However, if novel methods are subsequently developed that fulfill legal requirements, then this document will be amended accordingly.

Volume 47 in the internationally

acclaimed Advances in Clinical Chemistry contains chapters submitted from leading experts from academia and clinical laboratory science. Authors are from a diverse field of clinical chemistry disciplines and diagnostics, ranging from basic biochemical exploration to cutting-edge microarray technology. Leading experts from academia and clinical laboratory science Volume emphasizes novel laboratory advances with application to clinical laboratory diagnostics and practical basic science studies

A collection of recommended procedures for analysis and specifications for the determination of pharmaceutical substances, excipients and dosage forms intended to serve as source material for reference by any WHO member state.

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.

Guidance for the Validation of Analytical Methodology and Calibration of Equipment Used for Testing of Illicit Drugs in Seized Materials and Biological Specimens

Guideline for Submitting Samples and Analytical Data for Methods Validation

Mass Spectrometry for the Clinical Laboratory

Training and Teaching

Technical and Regulatory Aspects from Global Perspectives

Basic Method Validation and Verification, 4th Edition

Describes analytical methods development, optimization and validation, and provides examples of successful methods development and validation in high-performance liquid chromatography (HPLC) areas. The text presents an overview of Food and Drug Administration (FDA)/International Conference on Harmonization (ICH) regulatory guidelines,

compliance with validation requirements for regulatory agencies, and methods validation criteria stipulated by the US Pharmacopia, FDA and ICH.

"The signature undertaking of the Twenty-Second Edition was clarifying the QC practices necessary to perform the methods in this manual. Section in Part 1000 were rewritten, and detailed QC sections were added in Parts 2000 through 7000. These changes are a direct and necessary result of the mandate to stay abreast of regulatory requirements and a policy intended to clarify the QC steps considered to be an integral part of each test method. Additional QC steps were added to almost half of the sections."--Pref. p. iv.

The need to validate an analytical or bioanalytical method is encountered by analysts in the pharmaceutical industry on an almost daily basis, because adequately validated methods are a necessity for approvable regulatory filings. What constitutes a validated method, however, is subject to analyst interpretation because there is no universally accepted industry practice for assay validation. This book is intended to serve as a guide to the analyst in terms of the issues and parameters that must be considered in the development and validation of analytical methods. In addition to the critical issues surrounding method validation, this book also deals with other

related factors such as method development, data acquisition, automation, cleaning validation and regulatory considerations. The book is divided into three parts. Part One, comprising two chapters, looks at some of the basic concepts of method validation. Chapter 1 discusses the general concept of validation and its role in the process of transferring methods from laboratory to laboratory. Chapter 2 looks at some of the critical parameters included in a validation program and the various statistical treatments given to these parameters. Part Two (Chapters 3, 4 and 5) of the book focuses on the regulatory perspective of analytical validation. Chapter 3 discusses in some detail how validation is treated by various regulatory agencies around the world, including the United States, Canada, the European Community, Australia and Japan. This chapter also discusses the International Conference on Harmonization (ICH) treatment of assay validation. Chapters 4 and 5 cover the issues and various perspectives of the recent United States vs. Barr Laboratories Inc. case involving the retesting of samples. Part Three (Chapters 6 - 12) covers the development and validation of various analytical components of the pharmaceutical product development process. This part of the book contains specific chapters dedicated to bulk drug substances and finished products, dissolution studies, robotics and automated workstations,

biotechnology products, biological samples, analytical methods for cleaning procedures and computer systems and computer-aided validation. Each chapter goes into some detail describing the critical development and related validation considerations for each topic. This book is not intended to be a practical description of the analytical validation process, but more of a guide to the critical parameters and considerations that must be attended to in a pharmaceutical development program. Despite the existence of numerous guidelines including the recent attempts by the ICH to be implemented in 1998, the practical part of assay validation will always remain, to a certain extent, a matter of the personal preference of the analyst or company. Nevertheless, this book brings together the perspectives of several experts having extensive experience in different capacities in the pharmaceutical industry in an attempt to bring some consistency to analytical method development and validation.

Validation of Analytical Methods for Pharmaceutical Analysis

Validation and Qualification in Analytical Laboratories, Second Edition

Guidance Document from the European Network of GMO Laboratories (ENGL) : JRC Scientific and Technical Reports

Development and Validation of Analytical Methods
Basic Method Validation