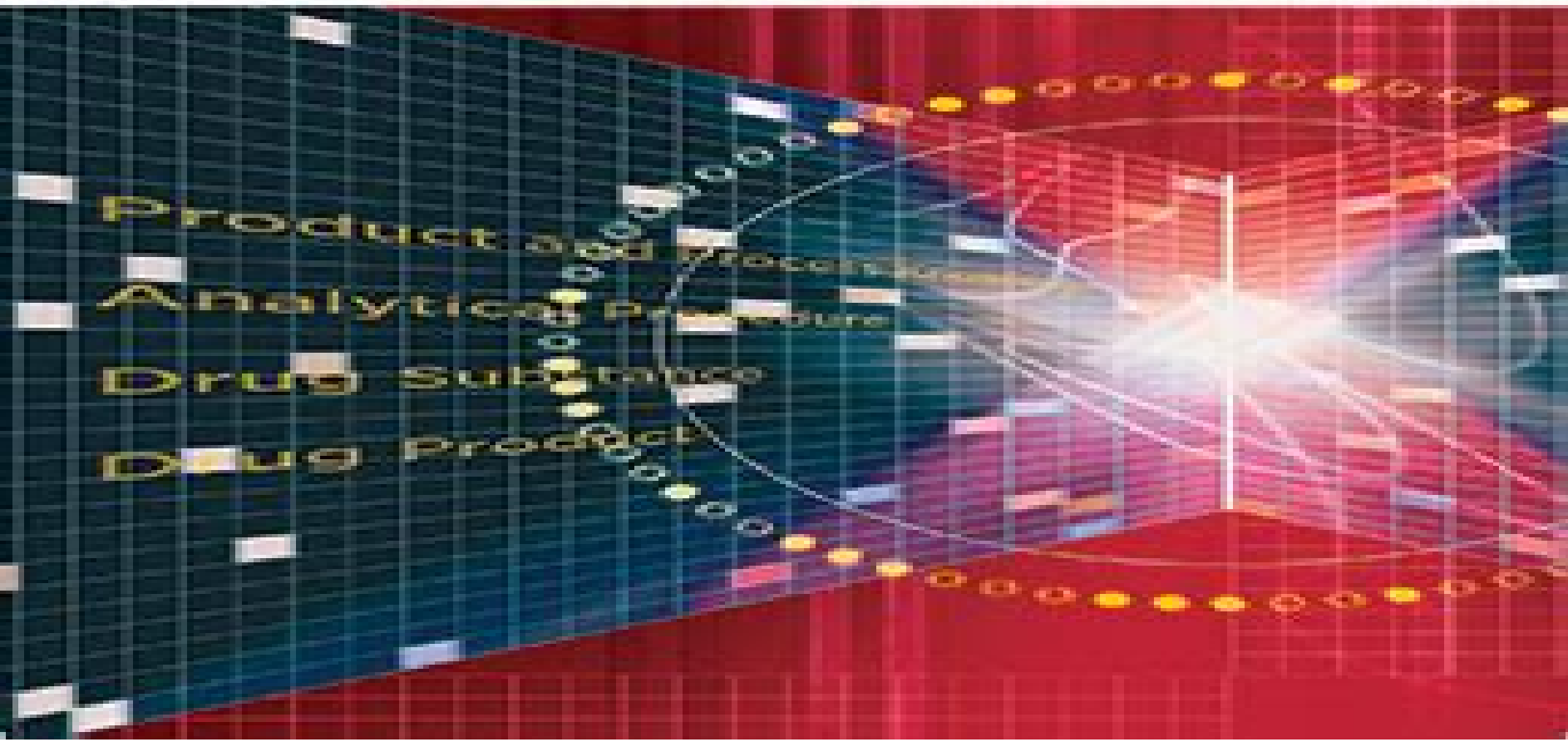




GOOD PRACTICE GUIDE:  
**Technology  
Transfer**

Third Edition



# Ispe Guidelines Technology Transfer

**Christopher M. Riley, Thomas W.  
Rosanske, George L. Reid**



## **Ispe Guidelines Technology Transfer:**

**ISPE Good Practice Guide** Ispe,2004-05      **ISPE Good Practice Guide** ISPE,2003-03-01      **Handbook of Pharmaceutical Analysis by HPLC** Satinder Ahuja,Michael Dong,2005-02-09 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 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 currents trends in HPLC ancillary techniques sample preparations and data handling      **Sterile Product Development** Parag Kolhe,Mrinal Shah,Nitin Rathore,2013-10-12 This comprehensive book encompasses various facets of sterile product development Key concepts relevant to the successful development of sterile products are illustrated through case studies and are covered under three sections in this book Formulation approaches that discuss a variety of dosage forms including protein therapeutics lipid based controlled delivery systems PEGylated biotherapeutics nasal dosage form and vaccines Process container closure and delivery considerations including freeze thaw process challenges best practices for technology transfer to enable commercial product development innovations and advancement in aseptic fill finish operations approaches to manufacturing lyophilized parenteral products pen auto injector delivery devices and associated container closure integrity testing hurdles for sterile product closures Regulatory and quality aspects in the areas of particulate matter and appearance evaluation sterile filtration admixture compatibility considerations sterilization process considerations microbial contamination investigations and validation of rapid microbiological methods and dry and moist heat sterilizers This book is a useful resource to scientists and researchers in both industry and academia and it gives process and product development engineers insight into current industry practices and evolving regulatory expectations for sterile product development      **Regulatory Affairs in Industrial Pharmacy in India** Madhu Verma,Iti Chauhan,2025-09-09 This book comprehensively explores the regulatory frameworks governing pharmaceutical manufacturing quality control and approvals in Indian pharmaceutical scenarios Tailored for industry professionals students and researchers it bridges the knowledge gaps in regulatory affairs in the pharmaceutical industry Covering key topics such as pilot plant scale up SUPAC Scale Up and Post Approval Changes technology transfer regulatory requirements and quality management systems it offers insights into navigating the complexities of Indian regulatory requirements A must read for those aiming to excel in pharmaceutical regulation the book serves as a roadmap for ensuring

efficiency safety and compliance in pharmaceutical industries operating in India      **Handbook of Analytical Validation** Michael E. Swartz,Ira S. Krull,2012-04-24 Written for practitioners in both the drug and biotechnology industries this handbook carefully compiles the current regulatory requirements to correctly and properly validate a new or modified analytical method The Handbook of Analytical Validation is designed to teach readers how to fully and correctly adapt new or modified analytical methods to meet regulatory requirements The contents offer the latest regulatory requirements for submitting applications for new drugs or other applications as regards analytical method validation The chapters apply to both small molecules in the conventional pharmaceutical industry as well the biotech industry      **Method Validation in Pharmaceutical Analysis** Joachim Ermer,Phil W. Nethercote,2025-03-06 New edition of the gold standard in the field of pharmaceutical analysis extensively updated to include the new ICH Guidelines Q2 R2 and Q14 Following a holistic lifecycle approach to analytical procedures Method Validation in Pharmaceutical Analysis provides hands on information for readers involved in development validation and continued maintenance and evaluation of analytical procedures in pharmaceutical analysis This newly revised and updated Third Edition includes much needed interpretation of the most recent ICH guidelines for validation and method development as well as recent publications of the USP on Analytical Procedure Lifecycle Management and the activities of the British Pharmacopeia AQbD Working Party It also addresses hot topics in the field such as data integrity and continuous monitoring of analytical performance Written by a team of highly qualified pharmaceutical professionals Method Validation in Pharmaceutical Analysis includes information on relevant topics such as Data governance data integrity and data quality as well as analytical instrument qualification and system validation lifecycle and continued HPLC performance qualification Analytical target profile decision rules and fitness for intended use and performance characteristics of analytical procedures Method selection development and optimization multivariate analytical procedures and risk assessment and analytical control strategy Implementation of compendial pharmacopeia test procedures transfer of analytical procedures and a lifecycle approach to transfer of analytical procedures Completely comprehensive in coverage Method Validation in Pharmaceutical Analysis is an essential reference for scientists researchers and professionals in the pharmaceutical industry analytical chemists QC and QA staff and public authorities tasked with relevant regulatory responsibilities      **Pharmaceutical and Biomedical Project Management in a Changing Global Environment** Scott D. Babler,2011-01-06 Pharmaceutical and Biomedical Portfolio Management in a Changing Global Environment explores some of the critical forces at work today in the complex endeavour of pharmaceutical and medical product development Written by experienced professionals and including real world approaches and best practice examples this new title addresses three key areas small molecules large molecules and medical devices and provides hard to find consolidated information relevant to and needed by pharmaceutical biotech and medical device company managers      **Technology Transfer** Ajay Babu Pazhayattil,Sanjay Sharma,Joe Paul Philip,Michelle Gischewski-Silva,Marzena Ingram,2023-06-16

Currently there are no textbooks on drug product manufacturing technology transfer that incorporate the latest regulatory expectations. Recent guidance from regulatory bodies such as the US FDA, EMEA, WHO and PIC S has adopted the ICH Lifecycle approach harmonizing concepts across regulatory guidance. This allows organizations to align their technology transfer activities for all regulated markets. However, there is a need for consensus and direction in approaching technology transfer, particularly in understanding how to manage the scale up effects to ensure regulatory compliance. This textbook offers technology transfer solutions and guidance to the pharmaceutical industry. The chapters provide a systematic understanding of applying the technology transfer concepts in pharmaceutical manufacturing, promoting standardization within the industry. Since Stage 1b is not specified in detail within the regulations, pharmaceutical organizations are left to determine the requirements of the stage. The need to justify the methodologies and utilization of sound science makes it more demanding. The textbook's authors provide innovative solutions for technology transfer challenges, making it a comprehensive reference document. The approaches can be applied to both small molecule and large molecule drug product manufacturing segments, addressing the unmet needs of the industry.

### **Good Quality Practice (GQP) in Pharmaceutical**

**Manufacturing: A Handbook** Jordi Botet, 2015-09-28. Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient. The entire chain comprises of several processes: auditing, materials purchase, procurement, production, storage, distribution, quality control, and quality assurance. The quality standard for pharmaceutical production is current good manufacturing practice (CGMP), which is applied within the frame of a pharmaceutical quality system (PQS). This implementation, however, requires a scientific approach and has to take into account several elements such as risk assessment, life cycle, patient protection, among other factors. Hence, pharmaceutical manufacturing is a complex subject in terms of regulation, given the technical and managerial requirements. This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance. The book gives details about basic quality control requirements such as risk management, quality hazards, and management systems, documentation, clean environments, personnel training, and gives guidelines on regulatory aspects. This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains, as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector.

Handbook of Stability Testing in Pharmaceutical Development Kim Huynh-Ba, 2008-11-16. This handbook is the first to cover all aspects of stability testing in pharmaceutical development. Written by a group of international experts, the book presents a scientific understanding of regulations and balances methodologies and best practices.

Pharmaceutical Analysis for Small Molecules Behnam Davani, 2017-07-12. A comprehensive introduction for scientists engaged in new drug development, analysis, and approvals.

Each year the pharmaceutical industry worldwide recruits thousands of recent science graduates especially chemistry analytical chemistry pharmacy and pharmaceutical majors into its ranks However because of their limited background in pharmaceutical analysis most of those new recruits find making the transition from academia to industry very difficult Designed to assist both recent graduates as well as experienced chemists or scientists with limited regulatory compendial or pharmaceutical analysis background make that transition *Pharmaceutical Analysis for Small Molecules* is a concise yet comprehensive introduction to the drug development process and analysis of chemically synthesized small molecule drugs It features contributions by distinguished experts in the field including editor and author Dr Behnam Davani an analytical chemist with decades of technical management and teaching experience in compendial regulatory and industry This book provides an introduction to pharmaceutical analysis for small molecules non biologics using commonly used techniques for drug characterization and performance tests The driving force for industry to perform pharmaceutical analyses is submission of such data and supporting documents to regulatory bodies for drug approval in order to market their products In addition related required supporting studies including good laboratory documentation practices including analytical instrument qualification are highlighted in this book Topics covered include Drug Approval Process and Regulatory Requirements private standards Pharmacopeias and Compendial Approval Process public standards Common methods in pharmaceutical analysis typically compendial Common Calculations for assays and impurities and other specific tests Analytical Method Validation Verification Transfer Specifications including how to handle out of specification OOS and out of trend OOT Impurities including organic inorganic residual solvents and elemental impurities Good Documentation Practices for regulatory environment Management of Analytical Laboratories Analytical Instrument Qualifications including IQ OQ PQ and VQ Due to global nature of pharmaceutical industry other topics on both regulatory ICH and Compendial harmonization are also highlighted *Pharmaceutical Analysis for Small Molecules* is a valuable working resource for scientists directly or indirectly involved with the drug development process including analytical chemists pharmaceutical scientists pharmacists and quality control quality assurance professionals It also is an excellent text reference for graduate students in analytical chemistry pharmacy pharmaceutical and regulatory sciences

WHO Expert Committee on Specifications for Pharmaceutical Preparations World Health Organization, 2008-05-05 The Expert Committee on Specifications for Pharmaceutical Preparations works towards standards and guidelines for medicines quality assurance The forty second meeting adopted 11 new monographs for inclusion in The International Pharmacopoeia Ph Int and seven related new International Chemical Reference Standards ICRS The specifications currently developed are internationally applicable test methodologies for antimalarial antituberculosis antiretroviral and specifically also medicines for children The main principles for selection of INNs for biologicals were endorsed In order to serve the WHO managed Prequalification Program two new procedures were adopted namely on prequalification of intrauterine devices IUDs and of male latex condoms together with a new guidance on

the assessment of active pharmaceutical ingredients for use in medicines Publisher's description

**Introduction to Modern Liquid Chromatography** Lloyd R. Snyder, Joseph J. Kirkland, John W. Dolan, 2011-09-20 The latest edition of the authoritative reference to HPLC High performance liquid chromatography HPLC is today the leading technique for chemical analysis and related applications with an ability to separate analyze and or purify virtually any sample Snyder and Kirkland's Introduction to Modern Liquid Chromatography has long represented the premier reference to HPLC This Third Edition with John Dolan as added coauthor addresses important improvements in columns and equipment as well as major advances in our understanding of HPLC separation our ability to solve problems that were troublesome in the past and the application of HPLC for new kinds of samples This carefully considered Third Edition maintains the strengths of the previous edition while significantly modifying its organization in light of recent research and experience The text begins by introducing the reader to HPLC its use in relation to other modern separation techniques and its history then leads into such specific topics as The basis of HPLC separation and the general effects of different experimental conditions Equipment and detection The column the heart of the HPLC system Reversed phase separation normal phase chromatography gradient elution two dimensional separation and other techniques Computer simulation qualitative and quantitative analysis and method validation and quality control The separation of large molecules including both biological and synthetic polymers Chiral separations preparative separations and sample preparation Systematic development of HPLC separations new to this edition Troubleshooting tricks techniques and case studies for both equipment and chromatograms Designed to fulfill the needs of the full range of HPLC users from novices to experts Introduction to Modern Liquid Chromatography Third Edition offers the most up to date comprehensive and accessible survey of HPLC methods and applications available

*Specification of Drug Substances and Products* Christopher M. Riley, Thomas W. Rosanske, George L. Reid, 2020-07-23 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     *Handbook of Modern Pharmaceutical Analysis* Satinder Ahuja, Stephen Scypinski, 2010-11-11

*Handbook of Modern Pharmaceutical Analysis* Second Edition synthesizes the complex research and recent changes in the field while covering the techniques and technology required for today's laboratories. The work integrates strategy case studies, methodologies and implications of new regulatory structures providing complete coverage of quality assurance from the point of discovery to the point of use. Treats pharmaceutical analysis QA 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     Clean-In-Place for Biopharmaceutical Processes Dale A. Seiberling, 2007-10-15 An invaluable source instruction on the principles instrumentation design implementation operation and maintenance of an effective clean in place system CIP. This guide illustrates best practices and successful applications of CIP in both pharmaceutical and biotechnology facilities. Offering reader friendly descriptions of the various types of equipment and materials found in typical CIP processes. Clean In Place For Biopharmaceutical Processes will take the guess work out of CIP development and illustrate all one needs to know for the establishment and optimal functioning of a CIP system     Charged Aerosol Detection for Liquid Chromatography and Related Separation Techniques Paul H. Gamache, 2017-05-08 The first book devoted exclusively to a highly popular relatively new detection technique. Charged Aerosol Detection for Liquid Chromatography and Related Separation Techniques presents a comprehensive review of CAD theory describes its advantages and limitations and offers extremely well informed recommendations for its practical use. Using numerous real world examples based on contributors professional experiences it provides priceless insights into the actual and potential applications of CAD across a wide range of industries. Charged aerosol detection can be combined with a variety of separation techniques and in numerous configurations. While it has been widely adapted for an array of industrial and research applications with great success it is still a relatively new technique and its fundamental performance characteristics are not yet fully understood. This book is intended as a tool for scientists seeking to identify the most effective and efficient uses of charged aerosol detection for a given application. Moving naturally from basic to advanced topics the author relates fundamental principles practical uses and applications across a range of industrial settings including pharmaceuticals petrochemicals biotech and more. Offers timely authoritative coverage of the theory experimental techniques and end user applications of charged aerosol detection. Includes contributions from experts from various fields of applications who explore CAD's advantages over traditional HPLC techniques as well its limitations. Provides a current theoretical and practical understanding of CAD derived from authorities on aerosol technology and

separation sciences Features numerous real world examples that help relate fundamental properties and general operational variables of CAD to its performance in a variety of conditions Charged Aerosol Detection for Liquid Chromatography and Related Separation Techniques is a valuable resource for scientists who use chromatographic techniques in academic research and across an array of industrial settings including the biopharmaceutical biotechnology biofuel chemical environmental and food and beverage industries among others

**Advances in Chromatography** Eli Grushka,Nelu

Grinberg,2011-03-04 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 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

**Developing Solid Oral Dosage**

**Forms** Yihong Qiu,Yisheng Chen,Geoff G.Z. Zhang,Lirong Liu,William Porter,2009-03-10 Developing Solid Oral Dosage Forms is intended for pharmaceutical professionals engaged in research and development of oral dosage forms It covers essential principles of physical pharmacy biopharmaceutics and industrial pharmacy as well as various aspects of state of the art techniques and approaches in pharmaceutical sciences and technologies along with examples and or case studies in product development The objective of this book is to offer updated or current knowledge and skills required for rational oral product design and development The specific goals are to provide readers with Basics of modern theories of physical pharmacy biopharmaceutics and industrial pharmacy and their applications throughout the entire process of research and development of oral dosage forms Tools and approaches of preformulation investigation formulation process design characterization and scale up in pharmaceutical sciences and technologies New developments challenges trends opportunities intellectual property issues and regulations in solid product development The first book ever that provides comprehensive and in depth coverage of what s required for developing high quality pharmaceutical products to meet international standards It covers a broad scope of topics that encompass the entire spectrum of solid dosage form development for the global market including the most updated science and technologies practice applications regulation intellectual property protection and new development trends with case studies in every chapter A strong team of more than

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