File Type PDF Api Q2 Specification For Quality Management System

As recognized, adventure as with ease as experience practically lesson, amusement, as capably as conformity can be gotten by just checking out a ebook **Api Q2 Specification For Quality Management System** next it is not directly done, you could tolerate even more vis--vis this life, vis--vis the world.

We have the funds for you this proper as competently as easy pretentiousness to acquire those all. We manage to pay for Api Q2 Specification For Quality Management System and numerous book collections from fictions to scientific research in any way. along with them is this Api Q2 Specification For Quality Management System that can be your partner.

VZFLO2 - BOONE MELODY

Quality management (QM) practices are the basis for the successful implementation and maintenance of any QM system. Quality control (QC) is identified as a QM component. Therefore, QM effectiveness is dependent on the QC strategy. QC practice is more or less complex depending on the type of production. The book is focused on new trends and developments in QM and QC in several types of industries from a worldwide perspective. Its content has been organized into two sections and seven chapters written by well-recognized researchers worldwide. Several approaches are debated based on sample traceability, analytical method validation, required parameters, class of exponential regression-type estimators of the population means, determination of impurities, viewpoints, and case studies.

This book explains task management concepts and outlines practical knowledge to help pharmaceutical analytical scientists become productive and enhance their career. •Presents broad topics such as product development process, regulatory requirement, task and project management, innovation mindset, molecular recognition, separation science, degradation chemistry, and statistics. •Provokes thinking through figures, tables, and case studies to help understand how the various functions integrate and how analytical development can work efficiently and effectively by applying science and creativity in their work. •Discusses how to efficiently develop a fit-for-purpose HPLC method without screening dozens of columns, gradients, or mobile phase combinations each time, since the extra effort may not provide enough of a benefit to justify the cost and time in a fast-paced product development environment. This book explains task management concepts and outlines practical knowledge to help pharmaceutical analytical scientists become productive and enhance their career. •Presents broad topics such as product development process, regulatory requirement, task and project management, innovation mindset, molecular recognition, separation science, degradation chemistry, and statistics. •Provokes thinking through figures, tables, and case studies to help understand how the various functions integrate and how analytical development can work efficiently and effectively by applying science and creativity in their work. •Discusses how to efficiently develop a fit--for-purpose HPLC method without screening dozens of columns, gradients, or mobile phase combinations each time, since the extra effort may not provide enough of a benefit to justify the cost and time in a fast-paced product development environment.

This book provides practical and detailed advice on how to implement data governance and data integrity for regulated analytical laboratories working in the pharmaceutical and allied industries.

Describes the potential environmental impacts of the Proposed Final 2012-2017 Outer Continental Shelf (OCS) Oil and Gas Leasing Program (PFP), which establishes a schedule that is used as a basis for considering where and when oil and gas leasing might be appropriate over a 5-year period.

The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear, independent and practical standards and guidelines for the quality assurance of medicines. Standards are developed by the Committee through worldwide consultation and an international consensus-building process. The following new guidelines were adopted and recommended for use, in addition to 20 monographs and general texts for inclusion in The International Pharmacopoeia and 11 new International Chemical Reference Substances. The International Pharmacopoeia - updating mechanism for the section on radiopharmaceuticals; WHO good manufacturing practices for pharmaceutical products: main principles; Model quality assurance system for procurement agencies; Assessment tool based on the model quality assurance system for procurement agencies: aide-memoire for inspection; Guidelines on submission of documentation for prequalification of finished pharmaceutical products approved by stringent regulatory authorities; and Guidelines on submission of documentation for a multisource (generic) finished pharmaceutical product: quality part.

In recent years, due to advancing technology and diagnostic and therapeutic techniques, medicine and health care have become more patient-oriented. This concept of personalized medicine or theranostics can be traced back to the beginnings of nuclear medicine when radioisotopes were uncovered as diagnostic and therapeutic tools. Nowadays, the field of theranostics is in flux, as new techniques and materials allow a growing range of applications beneficial for patients. This book examines new developments in theranostics and provides a comprehensive overview of the state of the art in this exciting discipline.

In your day-to-day planning, design, operation, and optimization of pipelines, wading through complex formulas and theories is not the way to get the job done. Gas Pipeline Hydraulics acts as a quick-reference guide to formulas, codes, and standards encountered in the gas industry. Based on the author's 30 years of experience in manufacturing and the oil and gas industry, the book presents a step-by-step introduction to the concepts in a practical approach illustrated by real-world examples, case studies, and a wealth of problems at the end of each chapter. Avoiding overly complex equations and theorems, Gas Pipeline Hydraulics demonstrates the calculation of pressure drop using various commonly accepted formulas. The author extends this discussion to determine total pressure required under various configurations, the necessity of pressure regulators and control valves, the comparative pros and cons of adding compressor stations versus pipe loops, mechanical strength of the pipeline, and thermal hydraulic analysis. He also introduces transient pressure analysis along with references for more in-depth study. The text concludes with the economic aspects of pipeline systems. Containing valuable appendices that provide conversions from USCS to SI units, tables of properties of natural gas, commonly used pipe sizes, and allowable internal and hydrotest pressures, this is the most easy-to-use, hands-on reference for gas pipelines available.

Analytical chemists in the pharmaceutical industry are always looking for more-efficient techniques to meet the analytical challenges of today’s pharmaceutical industry. One technique that has made steady advances in pharmaceutical analysis is supercritical fluid chromatography (SFC). SFC is meeting the chromatography needs of the industry by providing efficient and selective testing capabilities on the analytical and preparative scale. The supercritical fluid mobile phase, consisting mainly of CO2, facilitates cost reduction costs and helps the industry in meeting green chemistry standards. This book provides a comprehensive overview of the use of SFC in pharmaceutical analysis. Supercritical Fluid Chromatography reviews the use of SFC in drug-discovery applications and describes its application in drug development. When a drug is developed and brought to market, it is tested many times for impurities and degradants, enantiomeric purity, and analytical and preparative isolations—it is tested during discovery and development and for under-regulated and unregulated methodologies. The book describes the use of SFC for each of these applications and discusses more in--depth topics, such as the use of SFC in mass spectrometric and polarographic detection. The book also sheds light on the role of SFC in drug development from natural products and the advancement of SFC with new technologies and its use in pilot-scale operations as a chromatographic technique.

Following the Semi-solid Microstructure Workshop sponsored by BASF and hosted by the Rutgers Center for Dermal Research, a pharmaceutical product development working group was formed. The group, known as the Q3 Working Group, selected the following five areas of focus: Particle/Globule Size and Distribution, Viscosity/Rheology/Spreadability, In Vitro Testing, State of API, State of Excipients. A committee was appointed for each of these five areas. The committees were tasked to review the literature, identify best practices, list experimental details required for an independent lab to duplicate the test, and propose scientific studies that may meaningfully advance this specific area of focus. Each committee has a chair (or co-chairs) that are the lead author(s) of the chapter. The Q3 Working Group members serve as the critical reviewers of each chapter, making suggestions that improve the quality of the document and that make each of the five chapters uniform in scope and content.Pharmaceutical development scientists that formulate topical products (creams, lotions, gels suspensions, foams, etc) and all the allied raw material suppliers, packaging suppliers, contract laboratories including CROs, CMOs and regulators need access to this book. Overall, the topic of semi-solid microstructure is of equal importance to the generic pharmaceutical companies (filing Abbreviated New Drug Applications or ANDAs) and pharmaceutical companies filing New Drug Applications (NDAs). In addition to products applied to the skin, hair, and nails, The Role of Microstructure in Topical Drug Product Development’ crosses over and is essential reading to developers of oral suspensions, ophthalmic ointments and gels, otic suspension, vaginal semisolids and retention enemas.

Advances in Industrial Mixing is a companion volume and update to the Handbook of Industrial Mixing. The second volume fills in gaps for a number of industries that were not covered in the first edition. Significant changes in five of the fundamental areas are covered in entirely updated or new chapters. The original text is provided as a searchable pdf file on the accompanying USB. This book explains industrial mixers and mixing problems clearly and concisely. Gives practical insights by the top professionals in the field, combining industrial design standards with fundamental insight. Details applications in 14 key industries. Six of these are new since the first edition. Provides the professional with information he/she did not receive in school. Five completely rewritten chapters on mixing fundamentals where significant advances have happened since the first edition and seven concise update chapters which summarize critical technical information.

Examining the implications and practical implementation of multi-disciplinary International Conference on Harmonization (ICH) topics, this book gives an integrated view of how the guidelines inform drug development strategic planning and decision-making. • Addresses a consistent need for interpretation, training, and implementation examples of ICH guidelines via case studies • Offers a primary reference point for practitioners addressing the dual challenge of interpretation and practical implementation of ICH guidelines • Uses case studies to help readers understand and apply ICH guidelines • Provides valuable insights into guidelines development, with chapters by authors involved in generating or with experience implementing the guidelines • Includes coverage of stability testing, analytical method validation, impurities, biotechnology drugs and products, and good manufacturing practice (GMP)

InfoWorld is targeted to Senior IT professionals. Content is segmented into Channels and Topic Centers. InfoWorld also celebrates people, companies, and projects.

The API Individual Certification Programs (ICPs) are well established worldwide in the oil, gas, and petroleum industries. This Quick Guide is unique in providing simple, accessible and well-structured guidance for anyone studying the API 570 Certified Pipework Inspector syllabus by: Summarising and helping them through the syllabus Providing multiple example questions and worked answers Technical standards covered include the full API ‘body of knowledge’ for the examination, i.e. API570 Piping inspection code; API RP 571 Damage mechanisms affecting fixed equipment in the refining industry; API RP 574 Inspection practices for piping system components; API RP 577 Welding and metallurgy; API RP 578 Material verification program for new and existing alloy piping systems; ASME V Non-destructive examination; ASME IX Welding qualifications; ASME B16.5 Pipe flanges and flanged fittings; and ASME B 31.3 Process piping. Provides simple, accessible and well-structured guidance for anyone studying the API 570 Certified Pipework Inspector syllabus Summarizes the syllabus and provides the user with multiple example questions and worked answers Technical standards covered include the full API ‘body of knowledge’ for the examination

About 4000 medical compounds are being used in the drugs applied today. It is estimated that worldwide consumption of active compounds amounts to some 100,000 tons or more per year. Consequently, there is a need to highlight the most important questions and issues related to presence of pharmaceuticals in the environment. Pharmaceuticals in the Environment: current knowledge and need assessment to reduce presence and impact brings together results of previous and on-going EU projects with published data from both governmental sources and scientific literature and manufacturers’ data on production and usage of pharmaceuticals. This book puts together the current knowledge and emphasises questions that deserve attention such as: What is the spectrum of most relevant pharmaceutical products (PPs) for the aquatic environment? Which indicators for supporting environmental managers, health authorities? What is the efficiency of urban and industrial sewage treatment plants over a year? What is the fate and behaviour of PPs in sewage treatment plants? If receiving waters are used for potable water supplies, does the presence of these compounds represent a potential hazard to human health? Could we solve some problems by environmental or cleaner technologies? What regulatory approaches, incentives, prevention actions can be implemented in order to lower PPs concentration in the environment? Does a European practical guidance can be developed? Can the impacts of PPs on the environment be reduced through the use of eco-pharmaco-stewardship approaches including the use of clean synthesis, classification and labelling, and better communication of methods of 'good practice'? How can we better monitor the environmental impact of a pharmaceutical once it has received a marketing authorisation?

Peptide therapy has become a key strategy in innovative drug development, however, one of the potential barriers for the development of novel peptide drugs in the clinic is their deficiencies in clearly defined chemistry, manufacturing and controls (CMC) strategy from clinical development to commercialization. CMC can often become a rate-limiting step due to lack of knowledge and lack of a formal policy or guidelines on CMC for peptide-based drugs. Regulators use a risk-based approach, reviewing applications on a case-by-case basis. Peptide Therapeutics: Strategy and Tactics for Chemistry, Manufacturing, and Controls covers efficient manufacturing of peptide drug substances, a review of the process for submitting applications to the regulatory authority for drug approval, a holistic approach for quality attributes and quality control from a regulatory perspective, emerging analytical

tools for the characterisation of impurities, and the assessment of stability. This book is an essential reference work for students and researchers, in both academia and industry, with an interest in learning about CMC, and facilitating development and manufacture of peptide-based drugs.
The next enterprise computing era will rely on the synergy between both technologies: semantic web and model-driven software development (MDSD). The semantic web organizes system knowledge in conceptual domains according to its meaning. It addresses various enterprise computing needs by identifying, abstracting and rationalizing commonalities, and checking for inconsistencies across system specifications. On the other side, model-driven software development is closing the gap among business requirements, designs and executables by using domain-specific languages with custom-built syntax and semantics. It focuses on using modeling languages as programming languages. Among many areas of application, we highlight the area of configuration management. Consider the example of a telecommunication company, where managing the multiple configurations of network devices (routers, hubs, modems, etc.) is crucial. Enterprise systems identify and document the functional and physical characteristics of network devices, and control changes to those characteristics. Applying the integration of semantic web and model-driven software development allows for (1) explicitly specifying configurations of network devices with tailor-made languages, (2) for checking the consistency of these specifications (3) for defining a vocabulary to share device specifications across enterprise systems. By managing configurations with consistent and explicit concepts, we reduce cost and risk, and enhance agility in response to new requirements in the telecommunication area. This book examines the synergy between semantic web and model--driven software development. It brings together advances from disciplines like ontologies, description logics, domain-specific modeling, model transformation and ontology engineering to take enterprise computing to the next level.

Covers the Fundamentals of Chiral Separation, Available Chiral Selectors, and Numerous Applications of Chiral Separation by Capillary Electrophoresis Since the 1980s, modern analytical tools have enabled capillary electrophoresis to become a standard part of the chemist’s toolkit. With contributions from international experts, Chiral Separations by Capillary Electrophoresis provides a general overview of the principles of chiral separation by capillary electrophoresis and the different chiral selectors available. The book discusses the most important as well as several new chiral selectors used in capillary electrophoresis. It reviews recent pharmaceutical and biomedical applications and explores novel techniques, such as capillary electrophoresis coupled to mass spectrometry and microchip technology. The book also examines the quantitative aspects of capillary electrophoresis, the possibilities of capillary electrochromatography, and the various chiral columns available. Capillary electrophoresis has proven to be an effective tool for chiral separation. This book explains how this technique can be used in the separation of molecules, offering insight into both existing and emerging applications.
Pharma Interview Questions and Answers. This book contain all the information that will help you crack any Pharmaceutical interview as well as Questions and Answers. This book is suitable for Production, Quality assurance, Quality control, Regulatory affairs, Research and development, product development and Pharmacovigilance etc.
"Applications of Neural Networks in High Assurance Systems" is the first book directly addressing a key part of neural network technology: methods used to pass the tough verification and validation (V&V) standards required in many safety-critical applications. The book presents what kinds of evaluation methods have been developed across many sectors, and how to pass the tests. A new adaptive structure of V&V is developed in this book, different from the simple six sigma methods usually used for large-scale systems and different from the theorem-based approach used for simplified component subsystems.
Few books in computing have had as profound an influence on software management as Peopleware . The unique insight of this longtime best seller is that the major issues of software development are human, not technical. They’re not easy issues; but solve them, and you’ll maximize your chances of success. “Peopleware has long been one of my two favorite books on software engineering. Its underlying strength is its base of immense real experience, much of it quantified. Many, many varied projects have been reflected on and distilled; but what we are given is not just lifeless distillate, but vivid examples from which we share the authors’ inductions. Their premise is right: most software project problems are sociological, not technological. The insights on team jelling and work environment have changed my thinking and teaching. The third edition adds strength to strength.” — Frederick P. Brooks, Jr., Kenan Professor of Computer Science, University of North Carolina at Chapel Hill, Author of The Mythical Man-Month and The Design of Design “Peopleware is the one book that everyone who runs a software team needs to read and reread once a year. In the quarter century since the first edition appeared, it has become more important, not less, to think about the social and human issues in software develop¿ment. This is the only way we’re going to make more humane, productive workplaces. Buy it, read it, and keep a stock on hand in the office supply closet.” —Joel Spolsky, Co-founder, Stack Overflow “When a book about a field as volatile as software design and use extends to a third edition, you can be sure that the authors write of deep principle, of the fundamental causes for what we readers experience, and not of the surface that everyone recognizes. And to bring people, actual human beings, into the mix! How excellent. How rare. The authors have made this third edition, with its additions, entirely terrific.” —Lee Devin and Rob Austin, Co-authors of The Soul of Design and Artful Making For this third edition, the authors have added six new chapters and updated the text throughout, bringing it in line with today’s development environments and challenges. For example, the book now discusses pathologies of leadership that hadn’t previously been judged to be pathological; an evolving culture of meetings; hybrid teams made up of people from seemingly incompatible generations; and a growing awareness that some of our most common tools are more like anchors than propellers. Anyone who needs to manage a software project or software organization will find invaluable advice throughout the book.
This book constitutes the refereed proceedings of the 20th International Working Conference on Requirements Engineering: Foundation for Software Quality, REFSQ 2014, held in Essen, Germany, in April 2013. The 23 papers presented together with 1 keynote were carefully reviewed and selected from 62 submissions. The REFSQ'15 conference is organized as a three-day symposium. The REFSQ'15 has chosen a special conference theme “I heard it first at RefsQ”. Two conference days were devoted to presentation and discussion of scientific papers. The two days connect to the conference theme with a keynote, an invited talk and poster presentations. There were two parallel tracks on the third day: the Industry Track and the new Research Methodology Track. REFSQ 2015 seeks reports of novel ideas and techniques that enhance the quality of RE’s products and processes, as well as reflections on current research and industrial RE practices.
As we all know by now, wireless networks offer many advantages over fixed (or wired) networks. Foremost on that list is mobility, since going wireless frees you from the tether of an Ethernet cable at a desk. But that's just the tip of the cable-free iceberg. Wireless networks are also more flexible, faster and easier for you to use, and more affordable to deploy and maintain.The de facto standard for wireless networking is the 802.11 protocol, which includes Wi-Fi (the wireless standard known as 802.11b) and its faster cousin, 802.11g. With easy-to-install 802.11 network hardware available everywhere you turn, the choice seems simple, and many people dive into wireless computing with less thought and planning than they'd give to a wired network. But it's wise to be familiar with both the capabilities and risks associated with the 802.11 protocols. And 802.11 Wireless Networks: The Definitive Guide, 2nd Edition is the perfect place to start.This updated edition covers everything you'll ever need to know about wireless technology. Designed with the system administrator or serious home user in mind, it's a no-nonsense guide for setting up 802.11 on Windows and Linux. Among the wide range of topics covered are discussions on: deployment considerations network monitoring and performance tuning wireless security issues how to use and select access points network monitoring essentials wireless card configuration security issues unique to wireless networks With wireless technology, the advantages to its users are indeed plentiful. Companies no longer have to deal with the hassle and expense of wiring buildings, and households with several computers can avoid fights over who's online. And now, with 802.11 Wireless Networks: The Definitive Guide, 2nd Edition, you can integrate wireless technology into your current infrastructure with the utmost confidence.
This is the second book in the series of three. These three books will be based upon the idea to tailor PMI’s Project Management methodologies to the typical pharmaceutical projects. This book mainly discusses launch of drug products in EU market which are manufactured in countries like India or china by supplier manufacturer. It is specially designed for Project Managers, team members and pharmacy students. Format of book is purposely kept simple. This book includes various useful flow charts and templates that can be used during the project life cycle. Information provided in this book is obtained from highly authentic sources, and links of data sources is provided for reference. Surely this is the kind of book every pharmaceutical personnel will want to be on their shelf.
The API Individual Certification Programs (ICPs) are well established worldwide in the oil, gas, and petroleum industries. This Quick Guide is unique in providing simple, accessible and well-structured guidance for anyone studying the API 510 Certified Pressure Vessel Inspector syllabus by summarizing and helping them through the syllabus and providing multiple example questions and worked answers. Technical standards are referenced from the API ‘body of knowledge’ for the examination, i.e. API 510 Pressure vessel inspection, alteration, rerating; API 572 Pressure vessel inspection; API RP 571 Damage mechanisms; API RP 577 Welding; ASMEVIII Vessel design; ASMEV NDE; and ASME IX Welding qualifications. Provides simple, accessible and well-structured guidance for anyone studying the API 510 Certified Pressure Vessel Inspector syllabus Summarizes the syllabus and provides the user with multiple example questions and worked answers Technical standards are referenced from the API ‘body of knowledge’ for the examination

Specification of Drug Substances and Products: Development and Validation of Analytical Methods is a comprehensive and critical analysis of the requirements and approaches to setting specifications for new pharmaceutical products, with an emphasis on phase-appropriate development and validation of analytical methods. This book is intended as more than a review of new regional guidelines, existing regulatory guidance, and industry practices. It provides a hands-on guide to understanding and applying these in practice. The authors discuss critical issues, novel approaches, and future directions while also providing insight into how International Guidelines were developed and the rationale behind them. Guide to industry best practices of analytical methodologies used in the specification of new drug substances and products (e.g. DOE, QbD) Critical assessment of the application of ICH guidelines on method validation and specification setting, written by experts involved in the development and application of the guidelines to aid understanding of requirements and what is expected by regulatory authorities Direct applicability to the day-to-day activities in drug development and the potential to increase productivity
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.
The Gas Turbine Engineering Handbook has been the standard for engineers involved in the design, selection, and operation of gas turbines. This revision includes new case histories, the latest techniques, and new designs to comply with recently passed legislation. By keeping the book up to date with new, emerging topics, Boyce ensures that this book will remain the standard and most widely used book in this field. The new Third Edition of the Gas Turbine Engineering Hand Book updates the book to cover the new generation of Advanced gas Turbines. It examines the benefit and some of the major problems that have been encountered by these new turbines. The book keeps abreast of the environmental changes and the industries answer to these new regulations. A new chapter on case histories has been added to enable the engineer in the field to keep abreast of problems that are being encountered and the solutions that have resulted in solving them. Comprehensive treatment of Gas Turbines from Design to Operation and Maintenance. In depth treatment of Compressors with emphasis on surge, rotating stall, and choke; Combustors with emphasis on Dry Low NOx Combustors; and Turbines with emphasis on Metallurgy and new cooling schemes. An excellent introductory book for the student and field engineers A special maintenance section dealing with the advanced gas turbines, and special diagnostic charts have been provided that will enable the reader to troubleshoot problems he encounters in the field The third edition consists of many Case Histories of Gas Turbine problems. This should enable the field engineer to avoid some of these same generic problems
Pharmaceutical Quality by Design: Principles and Applications discusses the Quality by Design (QbD) concept implemented by regulatory agencies to ensure the development of a consistent and high--quality pharmaceutical product that safely provides the maximum therapeutic benefit to patients. The book walks readers through the QbD framework by covering the fundamental principles of QbD, the current regulatory requirements, and the applications of QbD at various stages of pharmaceutical product development, including drug substance and excipient development, analytical development, formulation development, dissolution testing, manufacturing, stability studies, bioequivalence testing, risk and assessment, and clinical trials. Contributions from global leaders in QbD provide specific insight in its application in a diversity of pharmaceutical products, including nanopharmaceuticals, biopharmaceuticals, and vaccines. The inclusion of illustrations, practical examples, and case studies makes this book a useful reference guide to pharmaceutical scientists and researchers who are engaged in the formulation of various delivery systems and the analysis of pharmaceutical product development and drug manufacturing process. Discusses vital QbD precepts and fundamental aspects of QbD implementation in the pharma, biopharma and biotechnology industries Provides helpful illustrations, practical examples and research case studies to explain QbD concepts to readers Includes contributions from global leaders and experts from academia, industry and regulatory agencies

This edited volume brings together the expertise of numerous specialists on the topic of particles –

their physical, chemical, pharmacological and toxicological characteristics – when they are a component of pharmaceutical products and formulations. The book discusses in detail properties such as the composition, size, shape, surface properties and porosity of particles with respect to how they impact the formulations and products in which they are used and the effective delivery of pharmaceutical active ingredients. It considers all dosage forms of pharmaceuticals involving particles, from powders to tablets, creams to ointments, and solutions to dry-powder inhalers, also including the latest nanomedicine products. Further, it discusses examples of particle toxicity, as well as the important subject of pharmaceutical industry regulations, guidelines and legislation. The book is of interest to researchers and practitioners who work on testing and developing pharmaceutical dosage and delivery systems.

Since the early 2000s, there has been increasing interest within the pharmaceutical industry in the application of Bayesian methods at various stages of the research, development, manufacturing, and health economic evaluation of new health care interventions. In 2010, the first Applied Bayesian Biostatistics conference was held, with the primary objective to stimulate the practical implementation of Bayesian statistics, and to promote the added-value for accelerating the discovery and the delivery of new cures to patients. This book is a synthesis of the conferences and debates, providing an overview of Bayesian methods applied to nearly all stages of research and development, from early discovery to portfolio management. It highlights the value associated with sharing a vision with the regulatory authorities, academia, and pharmaceutical industry, with a view to setting up a common strategy for the appropriate use of Bayesian statistics for the benefit of patients. The book covers: Theory, methods, applications, and computing Bayesian biostatistics for clinical innovative designs Adding value with Real World Evidence Opportunities for rare, orphan diseases, and pediatric development Applied Bayesian biostatistics in manufacturing Decision making and Portfolio management Regulatory perspective and public health policies Statisticians and data scientists involved in the research, development, and approval of new cures will be inspired by the possible applications of Bayesian methods covered in the book. The methods, applications, and computational guidance will enable the reader to apply Bayesian methods in their own pharmaceutical research.

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 (PA) as an integral partner to the drug development process rather than as a service to it Covers method development, validation, selection, testing, modeling, and simulation studies combined with advanced exploration of assays, impurity testing, biomolecules, and chiral separations Features detailed coverage of QA, ethics, and regulatory guidance (quality by design, good manufacturing practice), as well as high-tech methodologies and technologies from "lab-on-a-chip" to LC-MS, LC-NMR, and LC-NMR-MS

This book is an excellent reference for learning and applying basic quality auditing principles. Examples and checklists throughout the book help make this one of the best single-source reference guides. Quality practitioners, registrars, and those preparing for certification exams will find this book to be a useful tool. the new edition expands on established techniques and addresses both internal and supplier auditing as it relates to any quality management system, including ISO 9001, GMP, automotive, and others.

Crispin and Gregory define agile testing and illustrate the tester's role with examples from real agile teams. They teach you how to use the agile testing quadrants to identify what testing is needed, who should do it, and what tools might help. The book chronicles an agile software development iteration from the viewpoint of a tester and explains the seven key success factors of agile testing.

Based on the popular Artech House classic, Digital Communication Systems Engineering with Software-Defined Radio, this book provides a practical approach to quickly learning the software-defined radio (SDR) concepts needed for work in the field. This up-to-date volume guides readers on how to quickly prototype wireless designs using SDR for real-world testing and experimentation. This book explores advanced wireless communication techniques such as OFDM, LTE, WLA, and hardware targeting. Readers will gain an understanding of the core concepts behind wireless hardware, such as the radio frequency front-end, analog-to-digital and digital-to-analog converters, as well as various processing technologies. Moreover, this volume includes chapters on timing estimation, matched filtering, frame synchronization message decoding, and source coding. The orthogonal frequency division multiplexing is explained and details about HDL code generation and deployment are provided. The book concludes with coverage of the WLAN toolbox with OFDM beacon reception and the LTE toolbox with downlink reception. Multiple case studies are provided throughout the book. Both MATLAB and Simulink source code are included to assist readers with their projects in the field.

NEW from the bestselling HBR’s 10 Must Reads series. To innovate profitably, you need more than just creativity. Do you have what it takes? If you read nothing else on inspiring and executing innovation, read these 10 articles. We’ve combed through hundreds of articles in the Harvard Business Review archive and selected the most important ones to help you innovate effectively. Leading experts such as Clayton Christensen, Peter Drucker, and Rosabeth Moss Kanter provide the insights and advice you need to: • Decide which ideas are worth pursuing • Innovate through the front lines—not just from the top • Adapt innovations from the developing world to wealthier markets • Tweak new ventures along the way using discovery-driven planning • Tailor your efforts to meet customers’ most pressing needs • Avoid classic pitfalls such as stifling innovation with rigid processes Looking for more Must Read articles from Harvard Business Review? Check out these titles in the popular series: HBR’s 10 Must Reads: The Essentials HBR’s 10 Must Reads on Communication HBR’s 10 Must Reads on Collaboration HBR’s 10 Must Reads on Leadership HBR’s 10 Must Reads on Making Smart Decisions HBR’s 10 Must Reads on Managing Yourself HBR’s 10 Must Reads on Strategic Marketing HBR’s 10 Must Reads on Teams