Api Spec Q2 Quality

A step-by-step guide to interpreting and implementing the new international technical specification, ISO/TS 16949. The guide includes details of the certification scheme, the differences with existing standards, check lists, questionnaires, tips for implementers, flow charts and a glossary of terms.

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.

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.

Data integrity is the hottest topic in the pharmaceutical industry. Global regulatory agencies have issued guidance, after guidance after guidance in the past few years, most of which does not offer practical advice on how to implement policies, procedures and processes to ensure integrity. These guidances state what but not how. Additionally, key stages of analysis that impact data integrity are omitted entirely. The aim of this book is to provide practical and detailed help on how to implement data integrity and data governance for regulated analytical laboratories working in or for the pharmaceutical industry. It provides clarification of the regulatory issues and trends, and gives practical methods for meeting regulatory requirements and guidance. Using a data integrity model as a basis, the principles of data integrity and data governance are expanded into practical steps for regulated laboratories to implement. The author uses case study examples to illustrate his points and provides instructions for applying the principles of data integrity and data governance to individual laboratory needs. This book is a useful reference for analytical chemists and scientists, management and senior management working in regulated laboratories requiring either an understanding about data integrity or help in implementing practical solutions. Consultants will also benefit from the practical guidance provided.

This book is a printed edition of the Special Issue "Air Quality Monitoring and Forecasting" that was published in Atmosphere

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.

A guide for constructing and using composite indicators for policy makers, academics, the media and other interested parties. In particular, this handbook is concerned with indicators which compare and rank country performance.

Diluted bitumen has been transported by pipeline in the United States for more than 40 years, with the amount increasing recently as a result of improved extraction technologies and resulting increases in production and exportation of Canadian diluted bitumen. The increased importation of Canadian diluted bitumen to the United States has strained the existing pipeline capacity and contributed to the expansion of pipeline mileage over the past 5 years. Although rising North American crude oil production has resulted in greater transport of crude oil by rail or tanker, oil pipelines continue to deliver the vast majority of crude oil supplies to U.S. refineries. Spills of Diluted Bitumen from Pipelines examines the current state of knowledge and identifies the relevant properties and characteristics of the transport, fate, and effects of diluted bitumen and commonly transported crude oils when spilled in the environment. This report assesses whether the differences between properties of diluted bitumen and those of other commonly transported crude oils warrant modifications to the regulations governing spill response plans and cleanup. Given the nature of pipeline operations, response planning, and the oil industry, the recommendations outlined in this study are broadly applicable to other modes of transportation as well.

Supercritical Fluid Chromatography (SFC) provides a timely overview of SFC application areas which were unimaginable just a decade ago. This two-volume series opens with an overview of the history and expectant future of SFC and continues with recent applications in the pharmaceutical industry and other fascinating areas of science. SFC has found its place in the pharmaceutical industry with an increasing body of applications for chiral and achiral molecules in both the research and development phases of the drug discovery process. As illustrated in this two-volume series, the current interest in SFC extends well beyond the pharmaceutical industry. Chapters encompassing applications for polar and non-polar mixtures of importance are covering widely disparate areas in substance abuse, natural products including cannabinoids, bioactive lipids, flavor and fragrance. With its broad balance and coverage, this two-volume book constitutes a unique educational platform to students and scientists for many years to come. The major objective of this book editions is to inspire and stimulate readers to continue exploring the possibilities of exploiting supercritical fluids as a particular media for analysis, purifications and synthesis

Biopharmaceutical Processing: Development, Design, and Implementation of Manufacturing Processes covers bioprocessing from cell line development to bulk drug substances.

The methods and strategies described are essential learning for every scientist, engineer or manager in the biopharmaceutical and vaccines industry. The integrity of the bioprocess ultimately determines the quality of the product in the biotherapeutics arena, and this book covers every stage including all technologies related to downstream purification and upstream processing fields. Economic considerations are included throughout, with recommendations for lowering costs and improving efficiencies. Designed for quick reference and easy accessibility of facts, calculations and guidelines, this book is an essential tool for industrial scientists and managers in the biopharmaceutical industry. Offers a comprehensive, go-to reference for daily work decisions Covers both upstream and downstream processes Includes case studies that emphasize financial outcomes Presents summaries, decision grids, graphs and overviews for quick reference

This handbook features contributions from a team of expert authors representing the many disciplines within science, engineering, and technology that are involved in pharmaceutical manufacturing. They provide the information and tools you need to design, implement, operate, and troubleshoot a pharmaceutical manufacturing system. The editor, with more than thirty years' experience working with pharmaceutical and biotechnology companies, carefully reviewed all the chapters to ensure that each one is thorough, accurate, and clear.

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.

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.

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

Once thought of as niche technology, operators today are utilizing more opportunities with casing and liners as formations and environments grow in difficulty, especially with the unconventional oil and gas boom. Casing and liners for Drilling and Completions, 2nd Edition provides the engineer and well designer with up-to-date information on critical properties, mechanics, design basics and newest applications for today’s type of well. Renovated and simplified to cover operational considerations, pressure loads, and selection steps, this handbook gives you the knowledge to execute the essential and fundamental features of casing and liners. Bonus features include: Additional glossary added to explain oil field terminology New appendix on useful every day formulas such as axial stress, shear stress in tubes and principal stress components Listing section of acronyms, notations, symbols and constants for quick reference Concise step-by-step basic casing design procedure with examples Thorough coverage and tips on important field practice for installation topics Advanced methods for critical and horizontal well casing design including hydraulic fracturing Exhaustive appendices on foundational topics: units & nomenclature, solid mechanics, hydrostatics, borehole environment & rock mechanics, and a summary of useful formulas

Data is at the center of many challenges in system design today. Difficult issues need to be figured out, such as scalability, consistency, reliability, efficiency, and maintainability. In addition,

we have an overwhelming variety of tools, including relational databases, NoSQL datastores, stream or batch processors, and message brokers. What are the right choices for your application? How do you make sense of all these buzzwords? In this practical and comprehensive guide, author Martin Kleppmann helps you navigate this diverse landscape by examining the pros and cons of various technologies for processing and storing data. Software keeps changing, but the fundamental principles remain the same. With this book, software engineers and architects will learn how to apply those ideas in practice, and how to make full use of data in modern applications. Peer under the hood of the systems you already use, and learn how to use and operate them more effectively Make informed decisions by identifying the strengths and weaknesses of different tools Navigate the trade-offs around consistency, scalability, fault tolerance, and complexity Understand the distributed systems research upon which modern databases are built Peek behind the scenes of major online services, and learn from their architectures

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.

Get past the myths of testing in agile environments - and implement agile testing the RIGHT way. * * For everyone concerned with agile testing: developers, testers, managers, customers, and other stakeholders. * Covers every key issue: Values, practices, organizational and cultural challenges, collaboration, metrics, infrastructure, documentation, tools, and more. * By two of the world's most experienced agile testing practitioners and consultants. Software testing has always been crucial, but it may be even more crucial in agile environments that rely heavily on repeated iterations of software capable of passing tests. There are, however, many myths associated with testing in agile environments. This book helps agile team members overcome those myths -- and implement testing that truly maximizes software quality and value. Long-time agile testers Lisa Crispin and Janet Gregory offer powerful insights for three large, diverse groups of readers: experienced testers who are new to agile; members of newly-created agile teams who aren't sure how to perform testing or work with testers; and test/QA managers whose development teams are implementing agile. Readers will learn specific agile testing practices and techniques that can mean the difference between success and failure; discover how to transition 'traditional' test teams to agile; and learn how to integrate testers smoothly into agile teams. Drawing on extensive experience, the authors illuminate topics ranging from culture to test planning to automated tools. They cover every form of testing: business-facing tests, technology-facing tests, exploratory tests, context-driven and scenario tests, load, stability, and endurance tests, and more. Using this book's techniques, readers can improve the effectiveness and reduce the risks of any agile project or initiative.

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.

Authored by two of the leading authorities in the field, this guide offers readers the knowledge and skills needed to achieve proficiency with embedded software.

Presents instructions on using MySQL, covering such topics as installation, querying, user management, security, and backups and recovery.

Class-tested and coherent, this textbook teaches classical and web information retrieval, including web search and the related areas of text classification and text clustering from basic concepts. It gives an up-to-date treatment of all aspects of the design and implementation of systems for gathering, indexing, and searching documents; methods for evaluating systems; and an introduction to the use of machine learning methods on text collections. All the important ideas are explained using examples and figures, making it perfect for introductory courses in information retrieval for advanced undergraduates and graduate students in computer science. Based on feedback from extensive classroom experience, the book has been carefully structured in order to make teaching more natural and effective. Slides and additional exercises (with solutions for lecturers) are also available through the book's supporting website to help course instructors prepare their lectures.

44 reusable patterns to develop and deploy reliable production-quality microservices-based applications, with worked examples in Java Key Features 44 design patterns for building and deploying microservices applications Drawing on decades of unique experience from author and microservice architecture pioneer Chris Richardson A pragmatic approach to the benefits and the drawbacks of microservices architecture Solve service decomposition, transaction management, and inter-service communication Purchase of the print book includes a free eBook in PDF, Kindle, and ePub formats from Manning Publications. About The Book Microservices Patterns teaches you 44 reusable patterns to reliably develop and deploy production-quality microservices-based applications. This invaluable set of design patterns builds on decades of distributed system experience, adding new patterns for composing services into systems that scale and perform under real-world conditions. More than just a patterns catalog, this practical guide with worked examples offers industry-tested advice to help you design, implement, test, and deploy your microservices-based application. What You Will Learn How (and why!) to use microservices architecture Service decomposition strategies Transaction management and querying patterns Effective testing strategies Deployment patterns This Book Is Written For Written for enterprise developers familiar with standard enterprise application architecture. Examples are in Java. About The Author Chris Richardson is a Java Champion, a JavaOne rock star, author of Manning’s POJOs in Action, and creator of the original CloudFoundry.com. Table of Contents Escaping monolithic hell Decomposition strategies Interprocess communication in a microservice architecture Managing transactions with sagas Designing business logic in a microservice architecture Developing business logic with event sourcing Implementing queries in a microservice architecture External API patterns Testing microservices: part 1 Testing microservices: part 2 Developing production-ready services Deploying microservices Refactoring to microservices

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.
Software services are established as a programming concept, but their impact on the overall architecture of enterprise IT and business operations is not well-understood. This has led to problems in deploying SOA, and some disillusionment. The SOA Source Book adds to this a collection of reference material for SOA. It is an invaluable resource for enterprise architects working with SOA.The SOA Source Book will help enterprise architects to use SOA effectively. It explains: What SOA is How to evaluate SOA features in business terms How to model SOA How to use The Open Group Architecture Framework (TOGAF™) for SOA SOA governance This book explains how TOGAF can help to make an Enterprise Architecture. Enterprise Architecture is an approach that can help management to understand this growing complexity.
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.
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.
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.
For decades gas chromatography has been and will remain an irreplaceable analytical technique in many research areas for both quantitative analysis and qualitative characterization/identification, which is still supplementary with HPLC. This book highlights a few areas where significant advances have been reported recently and/or a revisit of basic concepts is deserved. It provides an overview of instrumental developments, frontline and modern research as well as practical industrial applications. The topics include GC-based metabolomics in biomedical, plant and microbial research, natural products as well as characterization of aging of synthetic materials and industrial monitoring, which are contributions of several experts from different disciplines. It also contains best hand-on practices of sample preparation (derivatization) and data processing in daily research. This book is recommended to both basic and experienced researchers in gas chromatography.
This monograph reviews all relevant technologies based on mass spectrometry that are used to study or screen biological interactions in general. Arranged in three parts, the text begins by reviewing techniques nowadays almost considered classical, such as affinity chromatography and ultrafiltration, as well as the latest techniques. The second part focusses on all MS-based methods for the study of interactions of proteins with all classes of biomolecules. Besides pull down-based approaches, this section also emphasizes the use of ion mobility MS, capture-compound approaches, chemical proteomics and interactomics. The third and final part discusses other important technologies frequently employed in interaction studies, such as biosensors and microarrays. For pharmaceutical, analytical, protein, environmental and biochemists, as well as those working in pharmaceutical and analytical laboratories.
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)
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.
PLEASE PROVIDE DESCRIPTION
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

The Big Picture of Business, Book 4 offers a creative approach to strategy development and planning for companies in today’s turbulent business environment that prepares them for an unknowable tomorrow. Each year, one-third of the U.S. Gross National Product goes toward cleaning up problems, damages and other high costs caused by companies that failed to take proper actions. Look no further than the cost of the current financial crisis for an example. The costs of band-aid surgery for their problems and make-good work cost business six times that of proper planning, oversight and accountability. 92% of all problems in organizations stem from poor management decisions. The Big Picture of Business, Book 4 takes a fresh look at change and growth, utilizing full-scope planning as a means of navigating through uncertain waters toward richer success. It is based upon Hank Moore’s trademarked approach to growing and strengthening businesses, tested by his actual work in guiding corporations over three decades. Moore shows how to master change and readies companies to face the future.