purification practices, training and compliance. It describes such technologies as viral retentive filters, membrane chromatography, downstream processing, cell harvesting, and sterile filtration. Features: Addresses recent biotechnology-related processes and advanced technologies such as viral retentive filters, membrane chromatography, downstream processing, cell harvesting, and sterile filtration of medium, buffer and end product. Presents detailed updates on the latest FDA and EMA regulatory requirements involving filtration and decontamination, as well as discussions on best industry quality standards and certification. Provides guidance for compliance, not just from an end-user perspective, but also supplier requirement. It discusses the advantages of single-use process technologies and the qualification needs. Sterilization grade filtration qualification and process validation is presented in detail to gain the understanding of the regulatory needs. The book has been compiled by highly experienced contributors in the field of pharmaceutical and biopharmaceutical processing. Each specific topic has been thoroughly examined by a subject matter expert.

Validation of Pharmaceutical Processes 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.

Validation Standard Operating Procedures When a pharmaceutical company decides to build a Quality System, it has to face the fact that there aren't any guidelines that define exactly how such a system has to be built. With terms such as quality system, quality assurance, and quality management used interchangeably, even defining the system's objectives is a problem. This book provides a practical approach to developing and implementing a sustainable pharmaceutical process validation program. The latest volume in the Expertise in Pharmaceutical Process Technology Series, this book illustrates the methods and reasoning behind processes and protocols. It also addresses practical problems and offers solutions to qualify and validate a pharmaceutical process. Understanding the "why" is critical to a successful and defensible process validation, making this book an essential research companion for all practitioners engaged in pharmaceutical process validation. Thoroughly referenced and based on the latest research and literature, this book illustrates the most common issues related to developing and implementing a sustainable process validation program and provides examples on how to be successful. Covers important topics such as the lifecycle approach, quality by design, risk assessment, critical process parameters, US and international regulatory guidelines, and more.

Pharmaceutical Process Validation This practical book in instrumental analytics conveys an overview of important methods of analysis and enables the reader to realistically learn the (principally technology-independent) working techniques of the analytical chemist to use in developing methods and conduct validation. What is to be conveyed to the student is the fact that analysts in their capacity as problem-solvers perform services for certain groups of customers, i.e., the solution to the problem should be in such a way to be "fit for purpose". The book presents sixteen experiments in analytical chemistry laboratory courses. They consist of the classical curriculum used at universities and universities of applied sciences with chromatographic procedures, atom spectrometric methods, sensors and special methods (e.g. field flow fractionation, flow injection analysis and N-determination according to Kjeldahl). The carefully chosen combination of theoretical description of the methods of analysis and the detailed instructions given are what characterizes this book. The instructions to the experiments are so detailed that the measurements can, for the most part, be taken without the help of additional literature. The book is complemented with tips for effective literature and database research on the topics of organization and the practical workflow of experiments in analytical laboratory, on the topic of the use of laboratory logs as well as on writing technical reports and grading them (Evaluation Guidelines for Laboratory Experiments). A small introduction to Quality Management, a brief glance at the history of analytical chemistry as well as a detailed appendix on the topic of safety in analytical laboratories and a short introduction to the new system of grading and marking chemicals using the "Globally Harmonized System of Classification and Labelling of Chemicals (GHS)" round off this book. This book is therefore an indispensable workbook for students, internship assistants and lecturers (in the area of chemistry, biotechnology, food technology and environmental technology) in the basic training program of technology at universities and universities of applied sciences.

Pharmaceutical Process Validation, Second Edition A quality product or service is the successful and profitable outcome of organizing resources, as judged by the final customer. Every business unit needs processes in order to do this effectively; and all processes must be documented so that achievements can be measured and future improvements planned and implemented. Pharmaceutical Process Design and Management takes a step-wise approach to process management. It presents the various elements comprising a process (man, machine, materials, method and environment); it looks at quality control and quality assurance, tools for quality improvements and ways of structuring a process into discrete, fully accountable elements; it proposes that for processes to run successfully, all operators must be the initial problem-solvers; finally, it illustrates how, with the right tools, every problem can be broken down into solvable elements. Learn how to deploy a science and risk-based approach to pharmaceutical manufacturing, by taking a fundamental approach to process design and management and, as a consequence, keep your customers satisfied and your profits healthy.

Advanced Aseptic Processing Technology The unexpected results from an investigation into hereditary congenital anorectal malformations of pig embryos have demonstrated the weakness of earlier interpretations and constructions and underlined the need for a new inquiry into the normal development of the area in human embryos. It demonstrated that although data from malformations may offer extra information about the normal development of the area, great care has to be taken in using that information for the reconstruction of its normal development which should be firmly based on the observation of the evolving microscopic anatomy of the region in the first place.

Modelling Survival Data in Medical Research, Second Edition A major new work on all aspects of water, the most used raw material ingredient in the pharmaceutical and biotechnology industries-used as an excipient in pharmaceutical formulations, as a cleaning agent, and as a separately packaged product diluent. Drawing on the author's extensive field experience with more than 400 pharmaceutical and related water systems, this book provides a practical approach to developing and implementing a sustainable pharmaceutical process validation program. The book illustrates the methods and reasoning behind processes and protocols. It also addresses practical problems and offers solutions to qualify and validate a pharmaceutical process. Understanding the "why" is critical to a successful and defensible process validation, making this book an essential research companion for all practitioners engaged in pharmaceutical process validation. Thoroughly referenced and based on the latest research and literature, this book illustrates the most common issues related to developing and implementing a sustainable process validation program and provides examples on how to be successful. Covers important topics such as the lifecycle approach, quality by design, risk assessment, critical process parameters, US and international regulatory guidelines, and more.

Equipment Qualification in the Pharmaceutical Industry The third edition of Pharmaceutical Process Scale-Up deals with the theory and practice of scale-up in the pharmaceutical industry. This thoroughly revised edition reflects the rapid changes in the field and includes: New material on tabletting scale-up and compaction. Regulatory appendices that cover FDA and EU Guidelines. New chapters on risk evaluation and validation as related to scale-up. Practical advice on scale-up solutions from world renowned experts in the field. Pharmaceutical Process Scale-Up, Third Edition will provide an excellent insight in to the practical aspects of the process scale-up and will be an invaluable source of information on batch enlargement techniques for formulators, process engineers, validation specialists and quality assurance personnel, as well as production managers. It will also provide interesting reading material for anyone involved in Process Analytical Technology (PAT), technology transfer and product globalization.

Drug Discovery and Development No other area of regulatory compliance receives more attention and scrutiny by regulatory authorities than the regulation of sterile products, for obvious reasons. With the increasing number of potent products, drug discovery and development are critical to successfully bringing new medicines to market. Pharmaceutical Process Scale-Up, Third Edition will provide an excellent insight into the practical aspects of the process scale-up and will be an invaluable source of information on batch enlargement techniques for formulators, process engineers, validation specialists and quality assurance personnel, as well as production managers. It will also provide interesting reading material for anyone involved in Process Analytical Technology (PAT), technology transfer and product globalization.

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randomization, and the different types of clinical trials but also deals with various methods of data analysis, group sequential procedures for interim analysis, efficacy data evaluation, analysis of safety data, and more. Throughout, the book: * Surveys current and emerging clinical issues and newly developed statistical methods * Presents a critical review of statistical methodologies in various therapeutic areas * Features case studies from actual clinical trials * Minimizes the mathematics involved, making the material widely accessible * Offers each chapter as a self-contained entity * Includes illustrations to highlight the text This monumental reference on all facets of clinical trials is important reading for physicians, clinical and medical researchers, pharmaceutical scientists, clinical programmers, biostatisticians, and anyone involved in this burgeoning area of clinical research. It can also be used as a textbook in graduate-level courses in the field.

Sterility, Sterilisation and Sterility Assurance for Pharmaceuticals This book is the definitive work on the theory and practice of pharmaceutical tablet and tablet coating. It describes both the practical and theoretical aspects of tablet coating, including the equipment and methods used in laboratory development, scale-up and production systems. Moreau well as automation and validation. This book also discusses the problems of conforming to world-wide regulations, and the hazards of environmental pollution.

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

The Development of the Perinum in the Human 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.

Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing It is very important for scientists all over the globe to enhance drug discovery research for better human health. This book demonstrates that various expertise are essential for drug discovery including clinical case studies of natural drugs, clinical pharmacology, receptor identification, drug metabolism, pharmacodynamic and pharmacokinetic research. The following 5 sections cover diverse chapter topics in drug discovery: Natural Products as Sources of Leading Molecules in Drug Discovery; Oncology and Drug Discovery; Receptors Involvement in Drug Discovery; Management and Development of Drugs against Infectious Diseases; Advanced Methodology.

Pharmaceutical Dosage Forms - Parenteral Medications This volume explores the application of Quality by Design (QbD) to biopharmaceutical drug product development. Twenty-eight comprehensive chapters cover dosage forms, liquid and lyophilized drug products. The introductory chapters of this book define key elements of QbD and examine how these elements are integrated into drug product development. These chapters also discuss lessons learned from the FDA Office of Biotechnology Products pilot program. Following chapters demonstrate how QbD is used for formulation development ranging from screening of formulations to developability assessment to development of lyophilized and liquid formats. The next few chapters study the use of small-scale and surrogate models as well as QbD application to drug product processes such as drug substance freezing and thawing, mixing, sterile filtration, filling, lyophilization, inspection and shipping and handling. Later chapters describe more specialized applications of QbD in the drug product realm. This includes the use of QbD in primary containers, devices and combination product development. The volume also explores QbD applied to vaccine development, automation, mathematical modeling and monitoring, and controlling processes and defining control strategies. It concludes with a discussion on the application of QbD to biopharmaceutical product transfer as well as overall regulatory considerations and lifecycle management. Quality by Design for Biopharmaceutical Drug Product Development is an authoritative resource for scientists and researches interested in expanding their knowledge on QbD principles and uses in creating better drugs.

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

Statistical Applications for Chemistry, Manufacturing and Controls (CMC) in the Pharmaceutical Industry Many modern pharmaceutical and biological products, e.g., blood derivatives, vaccines, cytostatic drugs, antibiotics, bacteria cultures but also consumer goods such as soluble coffee are freeze-dried to transform perishable substances into a form that can be stored and reconstituted to their almost original state without loss of quality. The book describes the up-to-date fundamentals of freeze-drying, not just presenting the process in all its seven steps theoretically, but explaining it with many practical examples. Many years of experience in freeze-drying allow the authors to supply valuable criteria for the selection of laboratory, pilot and production plants, discussing the advantages, drawbacks and limitations of different plant designs. In this second, completely revised edition, process and plant automation are introduced in a separate section and methods to transfer pilot plant qualifications and process data to production are presented. The guidelines for process and plant evaluation and qualifications have been updated and enlarged. Trouble shooting is concentrated in a section of its own and literature has been updated with 100 more quotations to include references as recent as 2002, and 100 new tables and figures have been added.


Fermentation and Biochemical Engineering Handbook, 2nd Ed. This book examines statistical techniques that are critically important to Chemistry, Manufacturing, and Control (CMC) activities. Statistical methods are presented with a focus on applications unique to the CMC in the pharmaceutical industry. The target audience consists of statisticians and other scientists who are responsible for performing statistical analyses within a CMC environment. Basic statistical concepts are addressed in Chapter 2 followed by applications to specific topics related to development and manufacturing. The mathematical level assumes an elementary understanding of statistical methods. The ability to use Excel or statistical packages such as Minitab, JMP, SAS, or R will provide more value to the reader. The motivation for this book came from an American Association of Pharmaceutical Scientists (AAPS) short course on statistical methods applied to CMC applications presented by four of the
authors. One of the course participants asked us for a good reference book, and the only book recommended was written over 20 years ago by Chow and Liu (1995). We agreed that a more recent book would serve a need in our industry. Since we began this project, an edited book has been published on the same topic by Zhang (2016). The chapters in Zhang discuss statistical methods for CMC as well as drug discovery and nonclinical development. We believe our book complements Zhang by providing more detailed statistical analyses and examples.

Freeze-Drying Updated to reflect current good manufacturing practice (CGMP) regulations, this text discusses current concepts in validation. New topics covered include: validation of cleaning systems and computer systems; equipment and water systems validation; and lyophilized and aerosol product validation.

Reliable Design of Medical Devices This third edition provides chemical engineers with process control techniques that are used in practice while offering detailed mathematical analysis. Numerous examples and simulations are used to illustrate key theoretical concepts. New exercises are integrated throughout several chapters to reinforce concepts. Up-to-date information is also included on real-time optimization and model predictive control to highlight the significant impact these techniques have on industrial practice. And chemical engineers will find two new chapters on biosystems control to gain the latest perspective.

Drugs Sets forth tested and proven risk management practices indrug manufacturing Risk management is essential for safe and efficient pharmaceutical and biopharmaceutical manufacturing, control, and distribution. With this book as their guide, readers involved inall facets of drug manufacturing have a single, expertly written, and organized resource to guide them through all facets of risk management and analysis. It sets forth a solid foundation in risk management concepts and then explains how these concepts are applied to drug manufacturing. Risk Management Applications in Pharmaceutical and Biopharmaceutical Manufacturing features contributions from leading international experts in risk management and drug manufacturing. These contributions reflect the latest research, practices, and industry standards as well as the authors' firsthand experience. Readers can turn to the book for: Basic foundation of risk management principles, practices, and applications. Tested and proven tools and methods for managing risk in pharmaceutical and biopharmaceutical product manufacturing processes. Recent FDA guidelines, EU regulations, and international standards governing the application of risk management to drug manufacturing. Case studies and detailed examples demonstrating the use and results of applying risk management principles to drug product manufacturing. Bibliography and extensive references leading to the literature and helpful resources in the field. With its unique focus on the application of risk management to pharmaceutical and pharmaceutical manufacturing, this book is an essential resource for pharmaceutical and process engineers as well as safety and compliance professionals involved in drug manufacturing.

Quality by Design for Biopharmaceutical Drug Product This three-volume set of Pharmaceutical Dosage Forms: Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacture of parenteral dosage forms, effectively balancing theoretical considerations with the practical aspects of their development. As such, it is recommended for scientists and engineers in the pharmaceutical industry and academia, and will also serve as an excellent reference and training tool for regulatory scientists and quality assurance professionals. First published in 1984 (as two volumes) and then last revised in 1993 (when it grew to three volumes), this latest revision will address the plethora of changes in the science and considerable advances in the technology associated with these products and routes of administration. The third edition of this book maintains the features that made the last edition so popular but comprises several brand new chapters, revisions to all other chapters, as well as high-quality illustrations. Volume two presents: • Chapters on aseptic facility design, environmental monitoring, and cleanroom operations. • A comprehensive chapter on pharmaceutical water systems. • A discussion of quality attributes of sterile dosage forms, including particulate matter, endotoxin, and sterility testing. • A detailed chapter on processing of parenteral drug products (SVPs and LVPs). • Presentations on widely used sterilization technologies – steam, gas / chemical, radiation, filtration and dry heat. • An in-depth chapter on lyophilization.

Animal Cell Technology: From Target to Market Pharmaceutical science deals with the whole spectrum of drug development from start to finish. There are many different facets to the pharmaceutical industry, from initial research to the finished product, including the equipment used, trials performed, and regulations that must be followed. Presenting an overview of all of these different aspects, the Encyclopedia of Pharmaceutical Science and Technology, Fourth Edition is a must-have reference guide for all laboratories and libraries in the pharmaceutical field. Bringing together leaders from every specialty related to pharmaceutical science and technology, this is the single-source reference at the forefront of pharmaceutical R&D. The strength of this work is not only its breadth but also the caliber of contributing writers, all experts in their field, writing on all aspects of pharmaceutical science and technology. The fourth edition offers 29 new chapters ranging from biomarkers, computational chemistry, and contamination control to high-throughput screening, orally disintegrating tablets, and quality by design. The encyclopedia details best practices of equipment used, methods for manufacturing, options for packaging, and routes for drug delivery. The volumes also provide a thorough understanding of the choices behind each method. In addition, the regulations, safety aspects, patent guidance, and methods of analysis are presented. Key Areas Covered: • Analytics • Biomarkers and Dosage Forms • Drug Delivery • Formulation • Informatics • Manufacturing Processes • Pharmaceutical Water Systems • Packaging • Processing • Regulatory Affairs • Systems Validation This is an authoritative reference source for those practicing in any area of pharmaceutical science and technology, enabling the pharmaceutical specialist and novice alike to keep abreast of developments in this constantly evolving and highly competitive field. Online version coming soon. Contact us to inquire about subscription options and print/online combination packages. US: (Tel) 1.888.318.2367 / (Email) e-reference@taylorandfrancis.com International: (Tel) +44 (0) 20 7017 6062 / (Email) online.sales@tandf.co.uk

Microbial Limit and Bioburden Tests In recent years, the field of pharmaceutical microbiology has experienced numerous technological advances, accompanied by the publication of new and harmonized compendial methods. It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical/biopharmaceutical products to keep abreast of the latest changes. Microbial Limit and Bioburden Tests: Validation Approaches and Global Requirements guides readers through the various microbiological methods listed in the compendia with easy-to-follow diagrams and approaches to validations of such test methodologies. Includes New and Updated Material Now in its second edition, this work is the culmination of research and discussions with technical experts, as well as USP and FDA representatives on various topics of interest to the pharmaceutical microbiologist and those responsible for the microbial quality of products, materials, equipment, and manufacturing facilities. New in this edition is an entire chapter dedicated to the topic of biofilms and their impact on pharmaceutical and biopharmaceutical operations. The subject of rapid methods in microbiology has been expanded and includes a discussion on the validation of alternative microbiological methods and a case study on microbial identification in support of a product contamination investigation. Substantially updated and revised, this book assists readers in understanding the fundamental issues associated with pharmaceutical microbiology and provides them with tools to create effective microbial contamination control and microbial testing programs for the areas under their responsibility.

Pharmaceutical Quality Systems The preparation of sterile products using aseptic processing is considered perhaps the most critical process in the pharmaceutical industry and has witnessed continual improvement over the last half century. New approaches that have transformed classical aseptic processing methods are appearing almost daily. This book reviews emerging technologies for aseptic processing that will markedly reduce the level of contamination risk for sterile products and includes coverage on: The use of isolator and barrier concepts for aseptic processing and assembly. The application of robotics as an alternative to manual processing. The increasing reliance on automation to minimize or eliminate operator intervention. The design, operational, monitoring and compliance changes necessary for success with advanced aseptic processing. Advanced Aseptic Technology is an essential reference for anyone working with sterile products, and is recommended for individuals in manufacturing, compliance, regulatory affairs, microbiology, environmental monitoring, sterility testing, sterilization, validation, engineering, development, facility and equipment design, component and equipment suppliers, automation, and robotics.

Pharmaceutical Water Failure to adequately control any microbial challenge associated within process or product by robust sterilisation will result in a contaminated marketed product, with potential harm to the patient. Sterilisation is therefore of great
importance to healthcare and the manufacturers of medical devices and pharmaceuticals. Sterility, sterilisation and sterility assurance for pharmaceuticals examines different means of rendering a product sterile by providing an overview of sterilisation methods including heat, radiation and filtration. The book outlines and discusses sterilisation technology and the biopharmaceutical manufacturing process, including aseptic filling, as well as aspects of the design of containers and packaging, as well as addressing the cleanroom environments in which products are prepared. Consisting of 18 chapters, the book comprehensively covers sterility, sterilisation and microorganisms; pyrogenicity and bacterial endotoxins; regulatory requirements and good manufacturing practices; and gamma radiation. Later chapters discuss e-beam; dry heat sterilisation; steam sterilisation; sterilisation by gas; vapour sterilisation; and sterile filtration, before final chapters analyse depyrogenation; cleanrooms; aseptic processing; media simulation; biological indicators; sterility testing; auditing; and new sterilisation techniques. Covers the main sterilisation methods of physical removal, physical alteration and inactivation Includes discussion of medical devices, aseptically filled products and terminally sterilised products Describes bacterial, pyrogenic, and endotoxin risks to devices and products

Process Dynamics and Control NOTE: This set consists of two volumes: Cleaning Agents and Systems and Applications, Processes, and Controls. Updated, expanded, re-organized, and rewritten, this two-volume handbook covers cleaning processes, applications, management, safety, and environmental concerns. The editors rigorously examine technical issues, cleaning agent options and systems, chemical and equipment integration, and contamination control, as well as cleanliness standards, analytical testing, process selection, implementation and maintenance, specific application areas, and regulatory issues. A collection of international contributors gives the text a global viewpoint. Color illustrations, video clips, and animation are available online to help readers better understand presented material.

Validation of Aseptic Pharmaceutical Processes The third edition of this text contains additional chapters which cover troubleshooting procedures, validation in contract manufacturing and current harmonization trends.

Handbook of Pharmaceutical Manufacturing Formulations Equipment Qualification in the Pharmaceutical Industry provides guidance and basic information for the preparation of a quality qualification program. It has been noted that there is a general lack of understanding in the industry, especially for those new to the industry, as to what constitutes a compliant qualification program. Even experienced professionals have felt a lack of security in reaching a compliant state. This book outlines a guideline for the preparation and execution of qualification protocols including the installation (IQ), operational (OQ), and performance (PQ) protocols. It discusses the importance of related qualification programs (e.g., quality systems, commissioning, computer system, and cleaning) and how to incorporate them into a fully compliant qualification program. Furthermore, it provides matrices of what could be included in each type of protocol for major types of process equipment. While primarily for people entering the pharmaceutical industry, those established in the field will benefit from the multiple examples and matrices as well as integration of related systems. Equipment Qualification in the Pharmaceutical Industry provides students and pharmaceutical scientists a guideline for the preparation and execution of qualification (installation, operational, and performance) protocols. Incorporates good manufacturing processes into a compliant qualification program Provides examples of protocol layout Includes matrices for major process equipment, installation quality, operational quality, and performance quality requirements

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