Quality Management Systems Process Validation Guidance

The Book of Chinese Medicine, Volume 2
The Biotech Business Handbook
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Biochemistry, Manufacture and Medical Applications
Clinical Engineering Handbook
A Complete Guide to Quality Management in the Medical Device Industry, Second Edition
The Basics, Volume 1
Plastics in Medical Devices
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The Science and Practice of Pharmacy
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Designing A World-Class Quality Management System For FDA Regulated Industries
Parenteral Medications, Fourth Edition
Insights Into Pharmaceutical Processes, Management and Regulatory Affairs
Cost Management in Plastics Processing
Science and Technology

Strategies, Targets, Techniques, and Tools

WENDY ZAYDEN

The Book of Chinese Medicine, Volume 2 Cambridge Scholars Publishing
Written in a clear and concise style by an experienced author, this attractively-priced book covers regulatory affairs in all major global markets for pharmaceuticals and medical devices, making it the most comprehensive in its field. Following a look at drug development, complete sections are devoted to national and EU regulatory issues, manufacturing license application and retention, and regulation in the USA. Other topics dealt with include CDER, CBER and marketing and manufacturing licenses, the ICH process and Good Laboratory/Clinical/Manufacturing Practices. Everything pharmacologists, bioengineers, pharma engineers, students in pharmacy and those working in the pharmaceutical industry need to know about medical regulatory affairs.

The Biotech Business Handbook Academic Press
One comment often repeated to me by coworkers in the biotechnology industry deals with their frustration at not understanding how their particular roles fit into their company's overall scheme for developing, manufacturing, and marketing biomedical products. Although these workers know their fields of specialty and responsibilities very well, whether it be in product research and development, regulatory affairs, manufacturing, packaging, quality control, or marketing and sales, they for the most part lack an understanding of precisely how their own contributory pieces fit into the overall scheme of the corporate biotechnology puzzle. The Biotech Business Handbook was written to assist the biotechnologist-whether a tech nician, senior scientist, manager, marketing representative, or college student interested in entering the field-in building a practical knowledge base of the rapidly expanding and maturing biotechnology segment of the healthcare industry. Because biotechnology in the United States and abroad covers many disciplines, much of the information presented in this book deals with the biomedical diagnostic aspects of the industry. Business subjects for the most part unfamiliar to technically oriented people, such as the types of biotechnology corpo rations, their business and corporate structures, their financing, patent, and trademark mat ters, their special legal issues, and the contributions of their consultants are treated in a manner designed to make them clear and understandable.

Pharmaceutical Product Development CRC Press
Process Validation in Manufacturing of Biopharmaceuticals, Third Edition delves into the key aspects and current practices of 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 PVG, issued in

Sterile Manufacturing CRC Press
The Handbook of Pharmaceutical Manufacturing Formulations, Third Edition: Volume Two, Uncompressed Solid Products is an authoritative and practical guide to the art and science of formulating drugs for commercial

manufacturing. With thoroughly revised and expanded content, this second volume of a six-volume set, compiles data from FDA and EMA new drug applications, patents and patent applications, and other sources of generic and proprietary formulations including author's own experience, to cover the broad spectrum of cGMP formulations and issues in using these formulations in a commercial setting. A must-have collection for pharmaceutical manufacturers, educational institutions, and regulatory authorities, this is an excellent platform for drug companies to benchmark their products and for generic companies to formulate drugs coming off patent. Features: Largest source of authoritative and practical formulations, cGMP compliance guidance and self-audit suggestions Differs from other publications on formulation science in that it focuses on readily scalable commercial formulations that can be adopted for cGMP manufacturing Tackles common difficulties in formulating drugs and presents details on stability testing, bioequivalence testing, and full compliance with drug product safety elements Written by a well-recognized authority on drug and dosage form development including biological drugs and alternative medicines

Biochemistry, Manufacture and Medical Applications AuthorHouse

Latex and Synthetic Polymer Dispersions 2013Smithers Rapra

Clinical Engineering Handbook William Andrew

Principles of Parenteral Solution Validation: A Practical Lifecycle Approach covers all aspects involved in the development and process validation of a parenteral product. By using a lifecycle approach, this book discusses the latest technology, compliance developments, and regulatory considerations and trends, from process design, to divesting. As part of the Expertise in Pharmaceutical Process Technology series edited by Michael Levin, this book incorporates numerous case studies and real-world examples that address timely problems and offer solutions to the daily challenges facing practitioners in this area. Discusses international and domestic regulatory considerations in every section Features callout boxes that contain points-of-interest for each segment of the audience so readers can quickly find their interests and needs Contains important topics, including risk management, the preparation and execution of properly designed studies, scale-up and technology transfer activities, problem-solving, and more

A Complete Guide to Quality Management in the Medical Device Industry, Second Edition CRC Press

The 8th Smithers Rapra conference on Latex and Synthetic Polymer Dispersions gave a very broad picture of the industry. These proceedings cover all the presentations from the two day event which included: The scientific principles underlying latex dipping were described by Professor C. C. Ho, and Dr, Aik Hwee Eng of Ansell spoke about a modern result of dipping - the antimicrobial glove. Very interesting observations about the allergenic potential of synthetic latex gloves compared to those dipped from natural rubber were made by Hardi Tamm of Korymbos. The use of gamma radiation from the very start of the process, as a means of prevulcanization, to the end of the production process, in sterilization, was described by Dr. Rosamma Alex of the Rubber Research Institute of India and Eric Beers of Nordion respectively. The

versatility of natural latex was demonstrated in a paper by Dr. Azura of Universiti Sains Malaysia, who showed us how it can be used for the cleaning of compression moulds. Innovative polymer synthesis in the manufacture of latex dispersions was presented by Dr. Joachim Storsberg of the Fraunhofer Institute, and Dr. Soeren Butz of Synthomer told how more clever chemistry could be used to &quote;tailor-make&quote; pressure sensitive adhesives. The environmental side of the industry was not forgotten, with two presentations from the Malaysian Rubber Board - Muhammad D Syraarani describing an environmentally friendly method for the analysis of magnesium in latex and Dr. Devaraj Veerasamy presenting the use of ultrafiltration to process latex. In a similar vein, Prof. Khairah Haji Badri, of the Universiti Tun Abdul Rahman showed how natural resources such as palm oil can be used to create useful polymers. David Hill of David Hill and Associates described how to carry out Process Validation of dipped condoms and gloves, and the delegates were told how the newest latex for dipping - synthetic polyiosprene - compares with the oldest - natural rubber - by Dr. Bert Krutzer of Kraton. The conference ended with Dr. Siby Varghese of the Rubber Research Institute of India, and Prof. Sabu Thomas of the Mahatma Gandhi University describing recent advances and applications in the field of nanotechnology.

The Basics, Volume 1 Elsevier

The Biomedical Quality Auditor Handbook was developed by the ASQ Biomedical Division in support of its mission to promote the awareness and use of quality principles, concepts, and technologies in the biomedical community. This third edition correlates to the 2013 exam Body of Knowledge (BoK) and reference list for ASQ□s Certified Biomedical Auditor program. It includes updates and corrections to errors and omissions in the second edition. Most notably it has been re-organized to align more closely with the BoK.

Plastics in Medical Devices Springer

This book highlights key ideas and factors to coach and guide professionals involved in learning about Sterile Manufacturing and operational requirements. It covers regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH, emphasizing good manufacturing practice and inspection requirements in the manufacturing of medicinal products. Additionally, this book provides the fundamentals of aseptic techniques, quality by design, risk assessment, and management in support of sterile operations applications. It creates a link to the implementation of business practices in drug manufacturing and healthcare and forms a correlation between design strategies including a step-by-step process to ensure reliability, safety, and efficacy of healthcare products for human and animal use. The book also provides a connection between drug production and regulated applications by offering a review of the basic elements of sterile processing, and how to remain viable with solid strategic planning. The book is a concise reference for professionals and learners in the field of sterile operations that governs primarily, pharmaceutical and medical device space, but can also extend to food and cosmetics that require clean (aseptic) manufacturing applications. It also helps compounding pharmacists and GMP inspectors and auditors.

Handbook of Pharmaceutical Manufacturing Formulations, Third Edition John Wiley & Sons
Pharmaceutical product development is a multidisciplinary activity involving extensive efforts in systematic product development and optimization in compliance with regulatory authorities to ensure the quality, efficacy and safety of resulting products. Pharmaceutical Product Development equips the pharmaceutical formulation scientist with extensive and up-to-date knowledge of drug product development and covers all steps from the beginning of product conception to the final packaged form that enters the market and lifecycle management thereof. Applications of core scientific principles for product development are also thoroughly discussed in conjunction with the latest approaches involving design of experiment and quality by design with comprehensive illustrations based on practical case studies of several dosage forms. The book presents pharmaceutical product development information in an easy-to-read mode with simplified theories, case studies and guidelines for students, academicians and professionals in the pharmaceutical industry. It is an invaluable resource and hands-on guide covering managerial, regulatory and practical aspects of pharmaceutical product lifecycle management.

From Research to Application Independently Published
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 Timeless Science of Balance and Harmony for Modern Life Springer Science & Business Media
Currently there are no process validation (PV) textbooks addressing the lifecycle concepts (Stage 1, 2, 3). Recent regulatory guidance's such as US FDA, EMEA, WHO, PIC/S have adopted the ICH lifecycle approach. The concepts are now harmonized across regulatory guidance's and organizations have an opportunity to align PV activities for all regulated markets. Therefore a need exists for consensus and direction on how to approach solid dose manufacturing process validation for regulatory compliance. Solid Dose Process Validation: The Basics, Volume One and companion Solid Dose Process Validation: Lifecycle Approach Application, Volume Two, also available as a set, provide directions and solutions for these unmet needs for the pharmaceutical industry. The topics and chapters give a systematic understanding for the application of lifecycle concepts in solid dose pharmaceutical manufacturing. All approaches meet the regulatory requirements enlisted in the guidance’s, which is the precursor to applying the concepts. This set is published as a comprehensive solution for solid dose process validation. Since solid dose formulations encompass majority of the pharmaceutical preparations, it is essential information for pharmaceutical professionals who use the process validation lifecycle approach.

The Science and Practice of Pharmacy John Wiley & Sons
Clinical Engineering Handbook, Second Edition, covers modern clinical engineering topics, giving experienced

professionals the necessary skills and knowledge for this fast-evolving field. Featuring insights from leading international experts, this book presents traditional practices, such as healthcare technology management, medical device service, and technology application. In addition, readers will find valuable information on the newest research and groundbreaking developments in clinical engineering, such as health technology assessment, disaster preparedness, decision support systems, mobile medicine, and prospects and guidelines on the future of clinical engineering. As the biomedical engineering field expands throughout the world, clinical engineers play an increasingly important role as translators between the medical, engineering and business professions. In addition, they influence procedures and policies at research facilities, universities, and in private and government agencies. This book explores their current and continuing reach and its importance. Presents a definitive, comprehensive, and up-to-date resource on clinical engineering Written by worldwide experts with ties to IFMBE, IUPESM, Global CE Advisory Board, IEEE, ACCE, and more Includes coverage of new topics, such as Health Technology Assessment (HTA), Decision Support Systems (DSS), Mobile Apps, Success Stories in Clinical Engineering, and Human Factors Engineering

Cytogenetic Laboratory Management John Wiley & Sons

Remington: The Science and Practice of Pharmacy, Twenty Third Edition, offers a trusted, completely updated source of information for education, training, and development of pharmacists. Published for the first time with Elsevier, this edition includes coverage of biologics and biosimilars as uses of those therapeutics have increased substantially since the previous edition. Also discussed are formulations, drug delivery (including prodrugs, salts, polymorphism. With clear, detailed color illustrations, fundamental information on a range of pharmaceutical science areas, and information on new developments in industry, pharmaceutical industry scientists, especially those involved in drug discovery and development will find this edition of Remington an essential reference. Intellectual property professionals will also find this reference helpful to cite in patents and resulting litigations. Additional graduate and postgraduate students in Pharmacy and Pharmaceutical Sciences will refer to this book in courses dealing with medicinal chemistry and pharmaceutics. Contains a comprehensive source of principles of drug discovery and development topics, especially for scientists that are new in the pharmaceutical industry such as those with trainings/degrees in chemistry and engineering Provides a detailed source for formulation scientists and compounding pharmacists, from produg to excipient issues Updates this excellent source with the latest information to verify facts and refresh on basics for professionals in the broadly defined pharmaceutical industry

CRC Press

Parenteral Medications is an authoritative, comprehensive reference work on the formulation and manufacturing of parenteral dosage forms, effectively balancing theoretical considerations with practical aspects of their development. Previously published as a three-volume set, all volumes have been combined into one comprehensive publication that addresses the plethora of changes in the science and considerable advances in the technology

associated with these products and routes of administration. Key Features: Provides a comprehensive reference work on the formulation and manufacturing of parenteral dosage forms Addresses changes in the science and advances in the technology associated with parenteral medications and routes of administration Includes 13 new chapters and updated chapters throughout Contains the contributors of leading researchers in the field of parenteral medications Uses full color detailed illustrations, enhancing the learning process The fourth edition not only reflects enhanced content in all the chapters but also highlights the rapidly advancing formulation, processing, manufacturing parenteral technology including advanced delivery and cell therapies. The book is divided into seven sectionss: Section 1 - Parenteral Drug Administration and Delivery Devices; Section 2 - Formulation Design and Development; Section 3 - Specialized Drug Delivery Systems; Section 4 - Primary Packaging and Container Closure Integrity; Section 5 - Facility Design and Environmental Control; Section 6 - Sterilization and Pharmaceutical Processing; Section 7 - Quality Testing and Regulatory Requirements

Solid Oral Dose Process Validation CRC Press

Nonthermal Processing Technologies for Food offers a comprehensive review of nonthermal processing technologies that are commercial, emerging or over the horizon. In addition to the broad coverage, leading experts in each technology serve as chapter authors to provide depth of coverage. Technologies covered include: physical processes, such as high pressure processing (HPP); electromagnetic processes, such as pulsed electric field (PEF), irradiation, and UV treatment; other nonthermal processes, such as ozone and chlorine dioxide gas phase treatment; and combination processes. Of special interest are chapters that focus on the "pathway to commercialization" for selected emerging technologies where a pathway exists or is clearly identified. These chapters provide examples and case studies of how new and nonthermal processing technologies may be commercialized. Overall, the book provides systematic knowledge to industrial readers, with numerous examples of process design to serve as a reference book. Researchers, professors and upper level students will also find the book a valuable text on the subject.

Practical Pharmaceutical Engineering John Wiley & Sons

Hydrogels are very important for biomedical applications because they can be chemically manipulated to alter and control the hydrogel’s interaction with cells and tissues. Their flexibility and high water content is similar to that of natural tissue, making them extremely suitable for biomaterials applications. Biomedical hydrogels explores the diverse range and use of hydrogels, focusing on processing methods and novel applications in the field of implants and prostheses. Part one of this book concentrates on the processing of hydrogels, covering hydrogel swelling behaviour, superabsorbent cellulose-based hydrogels and regulation of novel hydrogel products, as well as chapters focusing on the structure and properties of hydrogels and different fabrication technologies. Part two covers existing and novel applications of hydrogels, including chapters on spinal disc and cartilage replacement implants,

hydrogels for ophthalmic prostheses and hydrogels for wound healing applications. The role of hydrogels in imaging implants in situ is also discussed. With its distinguished editor and international team of contributors, Biomedical hydrogels is an excellent reference for biomedical research scientists and engineers in industry and academia, as well as others involved in research in this area, such as research clinicians. Examines the diverse range and use of hydrogels, focusing on processing methods and novel applications Comprehensive book explores the structure and properties of hydrogels and different fabrication technologies Covers important areas such as processing of hydrogels, covering hydrogel swelling behaviour, superabsorbent cellulose-based hydrogels and regulation of novel hydrogel products

Regulations, Processes, and Guidelines Quality Press

Pharmaceuticals companies, biotech companies, and CROs, regardless of size, all face the same challenge of managing costs and operational execution associated with bringing a valuable drugs and devices to market. Because of timeline pressures and cost as well as the growing interest in "neglected diseases" and diseases affecting the emerging nations, clinical trials are increasingly conducted in emerging markets and developing countries where infrastructure, leadership, skilled personnel and a governance are at a premium. Working with academics, regulatory professionals, safety officers, experts from the pharma industry and CROs, the editors have put together this up-to-date, step-by-step guide book to building and enhancing global clinical trial capacity in emerging markets and developing countries. This book covers the design, conduct, and tools to build and/or enhance human capacity to execute such trials, appealing to individuals in health ministries, pharmaceutical companies, world health organizations, academia, industry, and non-governmental organizations (NGOs) who are managing global clinical trials. Gives medical professionals the business tools needed to effectively execute clinical trials throughout the world Provides real world international examples which illustrate the practical translation of principles Includes forms, templates, and additional references for standardization in a number of global scenarios

Food Preservation by Pulsed Electric Fields Elsevier

Plastics in Medical Devices is a comprehensive overview of the main types of plastics used in medical device applications. It focuses on the applications and properties that are most important in medical device design, such as chemical resistance, sterilization capability and biocompatibility. The roles of additives, stabilizers, and fillers as well as the synthesis and production of polymers are covered and backed up with a wealth of data tables. Since the first edition the rate of advancement of materials technology has been constantly increasing. In the new edition Dr. Sastri not only provides a thorough update of the first edition chapters with new information regarding new plastic materials, applications and new requirements, but also adds two chapters – one on market and regulatory aspects and supplier controls, and one on process validation. Both chapters meet an urgent need in the industry and make the book an all-encompassing

reference not found anywhere else. Comprehensive coverage of uses of polymers for medical devices. Unique coverage of medical device regulatory aspects, supplier control and process validation. Invaluable guide for engineers, scientists and managers involved in the development and marketing of medical devices and materials for use in medical devices.

Principles of Parenteral Solution Validation Quality Press

For the past decade, process validation issues ranked within the top six of Food and Drug Administration (FDA) form 483 observation findings issued each year. This poses a substantial problem for the medical device industry and is the reason why the authors wanted to write this book. The authors will share their collective knowledge: to help organizations improve patient safety and increase profitability while maintaining a state of compliance with regulations and standards. The intent of this book is to provide manufacturing quality professionals working in virtually any industry a quick, convenient, and comprehensive guide to properly conduct process validations that meet regulatory and certification requirements. It will aid quality technicians, engineers, managers, and others that need to plan, conduct, and monitor validation activities.

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