Equipment Hold Time For Cleaning Validation

CHOI PITTS

Sterile Manufacturing John Wiley & Sons
This report presents the recommendations of an international group of experts convened by the World Health Organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms. The report is complemented by a number of annexes. These include: a list of available international chemical reference substances and international infrared spectra; supplementary guidelines on good manufacturing practices for heating, ventilation and air-conditioning systems for non-sterile pharmaceutical dosage forms; updated supplementary guidelines on good manufacturing practices for the manufacture of herbal medicines; supplementary guidelines on good manufacturing practices for validation; good distribution practices for pharmaceutical products; a model quality assurance system for procurement agencies (recommendations for quality assurance systems focusing on prequalification of products and manufacturers, purchasing, storage and distribution of pharmaceutical products); multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability; a proposal to waive in vivo bioequivalence requirements for WHO Model List of Essential Medicines immediate-release, solid oral dosage forms; and additional guidance for organizations performing in vivo bioequivalence studies. ...This is an excellent book with a misleading title... a good reference work for anyone seeking to understand the concept of validation and looking for general guidance on validation for both Active Pharmaceutical Ingredients (API) and finished pharmaceutical products. Annex 5 on Good distribution practices (GDP) for pharmaceutical products is an excellent Annex that splits the task of GDP into 20, small, easy to digest sections that guide the reader through the process of understanding the complexity of controlling distribution of pharmaceutical products. It contains a comprehensive glossary of terms used in GDP... a useful reference book for anyone involved in Quality Assurance, Manufacturing of marketed products, Clinical Manufacturing and Development. - Industrial Pharmacy

Engineering Practice, Validation, and Compliance in Regulated Environments World Health Organization
The third edition of this popular work is revised to include the latest developments in this fast-changing field. Its interdisciplinary approach elegantly combines the chemistry and engineering to explore the fundamentals and optimization processes involved.

A Practical Lifecycle Approach Cleaning Method Validation of Solid Dosage FormTo establish sufficient documented evidence to assure that, cleaning procedures can repeatedly and reproducibly remove residue of the subjected product-within established acceptance limit. The acceptance limit is maximum allowable quantity of product residue, which does not affect quality and safety of the subsequent product to be manufactured, by using same equipment and facility. To establish acceptable time limit for storage of cleaned equipment, utensils and components after cleaning (Cleaned Equipment Hold Time Study). Equipment are not expected to be free from all microorganisms, particularly when the final stage in cleaning does not involve final rinsing with sterile water for injection. The objective shall be to demonstrate that there is no microbial proliferation in equipments during storage.Cleaning ValidationPractical Compliance Solutions for Pharmaceutical ManufacturingPharmaceutical Microbiological Quality Assurance and ControlPractical Guide for Non-Sterile Manufacturing

Describes 250 occupations which cover approximately 107 million jobs.

Practical Guide for Non-Sterile Manufacturing Quality Press
The purpose of this handbook is to assist individuals for the Certified Pharmaceutical Good Manufacturing Practices Professional (CPGP) examination and provide a reference for the practitioner. The second edition reflects the Body of Knowledge which was updated in 2015. This edition has also incorporated additional information including updated references. The updates reflect the current trends and expectations of the evolving pharmaceutical industry driven by consumer expectations and regulatory oversight. This handbook covers compliance with good manufacturing practices (GMPs), as regulated and guided by national and international agencies for the pharmaceutical industry. It covers finished human and veterinary drugs and biologics, and combination devices, as well as their component raw materials (including active pharmaceutical ingredients (APIs) and excipients), and packaging and labeling operations.

Fermentation, Biocatalysis, and Bioseparation John Wiley & Sons
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.

The Gentle Art of Swedish Death Cleaning Butterworth-Heinemann
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.

Fortieth Report John Wiley & Sons
"The greater our knowledge increases, the more our ignorance unfolds. " U. S. President John F. Kennedy, speech, Rice University, September 12, 1962 My primary purpose for writing this book was much more than to provide another information source on Chemistry, Manufacturing & Controls (CMC) that would rapidly become out of date. My primary purpose was to provide insight and practical suggestions into a common sense business approach to manage the CMC regulatory compliance requirements for biopharmaceuticals. Such a common sense business approach would need (1) to be applicable for all types of biopharmaceutical products both present and future, (2) to address the needs of a biopharmaceutical manufacturer from the beginning to the end of the clinical development stages and including post market approval, and (3) to be adaptable to the constantly changing CMC regulatory compliance requirements and guidance. Trying to accomplish this task was a humbling experience for this author! In Chapter 1, the CMC regulatory process is explained, the breadth of products included under the umbrella ofbiopharmaceuticals are identified, and the track record for the pharmaceutical and biopharmaceutical industry in meeting CMC regulatory compliance is discussed. In Chapter 2, while there are many CMC commonalities between biopharmaceuticals and chemically-synthesized pharmaceuticals, the significant differences in the way the regulatory agencies handle them are examined and the reasons for why such differences are necessary is discussed. Also, the importance of CMC FDA is stressed.

Dictionary of Occupational Titles John Wiley & Sons
Applications, Processes, and Controls is the second volume in the Handbook for Critical Cleaning, Second Edition. Should you clean your product during manufacturing? If so, when and how? Cleaning is essential for proper performance, optimal quality, and increased sales. Inadequate cleaning of product elements can lead to catastrophic failure of the entire system and serious hazards to individuals and the general public. Gain a competitive edge with proven cleaning and contamination-control strategies A decade after the bestselling original, the Handbook for Critical Cleaning, Second Edition helps manufacturers meet today's challenges, providing practical information and perspective about cleaning chemistries, equipment, processes, and applications. With 90% new or revised chapters plus supplementary online material, the handbook has grown into two comprehensive volumes: Cleaning Agents and Systems, and Applications, Processes, and Controls. Helping manufacturers become more efficient and productive, these books: Show how to increase profitability and meet both existing and expected product demand Clarify the sea of print and Internet information about cleaning chemistries and techniques Address challenges of performance, miniaturization, and cost, as well as regulatory and supply chain pressures Offer clearly written guidance from the viewpoints of more than 70 leading industry contributors in technical, management, academic, and regulatory disciplines Overview chapters by the editors, industry icons Barbara and Ed Kanegsberg, meld the different viewpoints and compile and critique the options. The result is a complete, cohesive, balanced perspective that helps manufacturers better select, implement, and maintain a quality, value-added cleaning process. The second volume, Handbook for Critical Cleaning: Applications, Processes, and Controls, addresses how to implement, validate, monitor, and maintain a critical cleaning process. Topics include cleanrooms, materials compatibility, worker safety, sustainability, and environmental constraints. The book shows readers how to draw from diverse disciplines—including aerospace, art conservation, electronics, food, life sciences, military, optics, and semiconductors—to achieve superior productivity.
Applications, Processes, and Controls, Second Edition Elsevier
This is the third edition of the Society of Dairy Technology's highly successful volume on Cleaning-in-Place (CIP). Already a well-established practice in dairy technology, CIP has become increasingly relevant in the processed food industry during the last 10-15 years, and the beverage industry has seen increased demands from customers regarding CIP verification and validation to provide improvements in plant hygiene and related efficiency. The book addresses the principles of cleaning operations, water supply issues and the science of detergents and disinfectants. Aspects of equipment design relevant to ease of cleaning are covered in a special chapter, as is the assessment of cleaning efficiency and the management of cleaning operations. This third edition features for the first time a chapter on membrane cleaning - a relatively new area requiring very specialised cleaning products and procedures. Useful data on fluid flow dynamics and laboratory test methods are also included in separate chapters. Authors have been selected from within industry, allied suppliers and academia to provide a balanced, leading edge assessment of the subject matter. Cleaning-in-Place is directed at dairy scientists and technologists in industry and academia, general food scientists and food technologists, food microbiologists and equipment manufacturers.
Pharmaceutical Manufacturing Handbook John Wiley & Sons
Describes the methodologies and best practices of the sterile manufacture of drug products Thoroughly trained personnel and carefully designed, operated, and maintained facilities and equipment are vital for the sterile manufacture of medicinal products using aseptic processing. Professionals in pharmaceutical and biopharmaceutical manufacturing facilities must have a clear understanding of current good manufacturing practice (cGMP) and preapproval inspection (PAI) requirements. Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments provides up-to-date coverage of aseptic processing techniques and sterilization methods. Written by a recognized expert with more than 20 years of industry experience in aseptic manufacturing, this practical resource illustrates a comprehensive approach to sterile manufacturing engineering that can achieve drug manufacturing objectives and goals. Topics include sanitary piping and equipment, cleaning and manufacturing process validation, computerized automated systems, personal protective equipment (PPE), clean-in-place (CIP) systems, barriers and isolators, and guidelines for statistical procedure. Offering authoritative guidance on the key aspects of sterile manufacturing engineering, this volume: Covers fundamentals of aseptic techniques, quality by design, risk assessment and management, and operational requirements Addresses various regulations and guidelines instituted by the FDA, ISPE, EMA, MHRA, and ICH Provides techniques for systematic process optimization and good manufacturing practice Emphasizes the importance of attention to detail in process development and validation Features real-world examples highlighting different aspects of drug manufacturing Sterile Processing of Pharmaceutical Products: Engineering Practice, Validation, and Compliance in Regulated Environments is an indispensable reference and guide for all chemists, chemical engineers, pharmaceutical professionals and engineers, and other professionals working in pharmaceutical sciences and manufacturing.
Formulation and Process Development Strategies for Manufacturing Biopharmaceuticals Springer Science & Business Media
A real-world guide to the production and manufacturing of biopharmaceuticals While much has been written about the science of biopharmaceuticals, there is a need for practical, up-to-date information on key issues at all stages of developing and manufacturing commercially viable biopharmaceutical drug products. This book helps fill the gap in the field, examining all areas of biopharmaceuticals manufacturing, from development and formulation to production and packaging. Written by a group of experts from industry and academia, the book focuses on real-world methods for maintaining product integrity throughout the commercialization process, clearly explaining the fundamentals and essential pathways for all development stages. Coverage includes: Research and early development phase–appropriate approaches for ensuring product stability Development of commercially viable formulations for liquid and lyophilized dosage forms Optimal storage, packaging, and shipping methods Case studies relating to therapeutic monoclonal antibodies, recombinant proteins, and plasma fractions Useful analysis of successful and failed products Formulation and Process Development Strategies for Manufacturing Biopharma-ceuticals is an essential resource for scientists and engineers in the pharmaceutical and biotech industries, for government and regulatory agencies, and for anyone with an interest in the latest developments in the field.
Sterile Processing of Pharmaceutical Products Academic Press
Cleaning Method Validation of Solid Dosage Form
How to Validate a Pharmaceutical Process John Wiley & Sons
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
The Delineator 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 final form on January 24, 2011. The book also provides guidelines and current practices, as well as industrial 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.
Microbial Contamination Control in the Pharmaceutical Industry World Health Organization
Rules of Thumb for Chemical Engineers, Fifth Edition, provides solutions, common sense techniques, shortcuts, and calculations to help chemical and process engineers deal with practical on-the-job problems. It discusses physical properties for proprietary materials, pharmaceutical and biopharmaceutical sector heuristics, and process design, along with closed-loop heat transfer systems, heat exchangers, packed columns, and structured packings. Organized into 27 chapters, the book begins with an overview of formulae and data for sizing piping systems for incompressible and compressible flow. It then moves to a discussion of design recommendations for heat exchangers, practical equations for solving fractionation problems, along with design of reactive absorption processes. It also considers different types of pumps and presents narrative as well as tabular comparisons and application notes for various types of fans, blowers, and compressors. The book also walks the reader through the general rules of thumb for vessels, how cooling towers are sized based on parameters such as return temperature and supply temperature, and specifications of refrigeration systems. Other chapters focus on pneumatic conveying, blending and agitation, energy conservation, and process modeling. Chemical engineers faced with fluid flow problems will find this book extremely useful. Rules of Thumb for Chemical Engineers brings together solutions, information and work-arounds that engineers in the process industry need to get their job done. New material in the Fifth Edition includes physical properties for proprietary materials, six new chapters, including pharmaceutical, biopharmaceutical sector heuristics, process design with simulation software, and guidelines for hazardous materials and processes Now includes SI units throughout alongside
Volume 34 Lippincott Williams & Wilkins
Offshore Pipelines covers the full scope of pipeline development from pipeline designing, installing, and testing to operating. It gathers the authors' experiences gained through years of designing, installing, testing, and operating submarine pipelines. The aim is to provide engineers and management personnel a guideline to achieve cost-effective management in their offshore and deepwater pipeline development and operations. The book is organized into three parts. Part I presents design practices used in developing submarine oil and gas pipelines and risers. Contents of this part include selection of pipe size, coating, and insulation. Part II provides guidelines for pipeline installations. It focuses on controlling bending stresses and pipe stability during laying pipelines. Part III deals with problems that occur during pipeline operations. Topics covered include pipeline testing and commissioning, flow assurance engineering, and pigging operations. This book is written primarily for new and experienced engineers and management personnel who work on oil and gas pipelines in offshore and deepwater. It can also be used as a reference for college students of undergraduate and graduate levels in Ocean Engineering, Mechanical Engineering, and Petroleum Engineering. * Pipeline design engineers will learn how to design low-cost pipelines allowing long-term operability and safety. * Pipeline operation engineers and management personnel will learn how to operate their pipeline systems in a cost effective manner. * Deepwater pipelining is a new technology developed in the past ten years and growing quickly.
How to Free Yourself and Your Family from a Lifetime of Clutter Simon and Schuster
This text lists the necessary steps for meeting compliance requirements during the drug development process. It presents comprehensive approaches for validating analytical methods for pharmaceutical applications.
Good Design Practices for GMP Pharmaceutical Facilities, Second Edition Butterworth-Heinemann
The third edition of A Guide to Hygiene and Sanitation in Aviation addresses water, food, waste disposal, cleaning and disinfection, vector control and cargo safety, with the ultimate goal of assisting all types of airport and aircraft operators and all other responsible bodies in achieving high standards of hygiene and sanitation, to protect travellers and crews engaged in air transport. Each topic is addressed individually, with guidelines that provide procedures and quality specifications that are to be achieved. The guidelines apply to domestic and international air travel for all developed and developing countries.
Principles of Parenteral Solution Validation CRC Press
Biocontamination Control for Pharmaceuticals and Healthcare outlines a biocontamination strategy that tracks bio-burden control and reduction at each transition in classified areas of a facility. This key part of controlling risk escalation can lead to the contamination of medicinal products, hence necessary tracking precautions are essential. Regulatory authorities have challenged pharmaceutical companies, healthcare providers, and those in manufacturing practice to adopt a holistic approach to contamination control. New technologies are needed to introduce barriers between personnel and the environment, and to provide a rapid and more accurate assessment of risk. This book offers guidance on building a complete biocontamination strategy. Provides the information necessary for a facility to build a complete biocontamination strategy Helps facilities understand the main biocontamination risks to medicinal products Assists the reader in navigating regulatory requirements Provides insight into developing an environmental monitoring program Covers the types of rapid microbiological monitoring methods now available, as well as current legislation
Pharmaceutical Microbiological Quality Assurance and Control CRC Press
This authoritative reference presents an up-to-date review of the testing methods, emerging technologies, and analytical systems and procedures used to prevent the microbial contamination of pharmaceutical processes, products, and environments. It identifies new tools for sample analysis and evaluation and the

impact of these advancements on the continuous supply and manufacturing of pharmaceutical products. With more than 100 tables and 430 current references, the book contains a detailed analysis of microbial contamination recalls for nonsterile and sterile pharmaceutical products, demonstrating the distribution of microorganisms worldwide and the identification by geographical regions.

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