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Hvac Ispe Good Practice Guide

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Veterinary Vaccines
Developing a Protocol for Observational Comparative Effectiveness Research: A User's Guide
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A Risk-based Approach to Compliant GxP Computerized Systems
A Guide to Best Practice
Sterile Product Development
Handbook of Stability Testing in Pharmaceutical Development

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A SOURCEBOOK FOR INDUSTRY

Royal Society of Chemistry
Over the last few years, financial statement scandals, cases of fraud and corruption, data protection violations, and other legal violations have led to numerous liability cases, damages claims, and losses of reputation. As a reaction to these developments, several regulations have been issued: Corporate Governance, the Sarbanes-Oxley Act, IFRS, Basel II and III, Solvency II and BilMoG, to name just a few. In this book, compliance is understood as the process, mapped not only in an internal control system, that is intended to guarantee conformity with legal requirements but also with internal policies and enterprise objectives (in particular, efficiency and profitability). The current literature primarily confines itself to mapping controls in SAP ERP and auditing SAP systems. Maxim Chuprunov not only addresses this subject but extends the aim of internal controls from legal compliance to include efficiency and profitability and then well beyond, because a basic understanding of the processes involved in IT-supported compliance management processes are not delivered along with the software. Starting with the requirements for compliance (Part I), he not only answers compliance-relevant questions in the form of an audit guide for an SAP ERP system and in the form of risks and control descriptions (Part II), but also shows how to automate the compliance management process based on SAP GRC (Part III). He thus addresses the current need for solutions for implementing an integrated GRC system in an organization, especially focusing on the continuous control monitoring topics. Maxim Chuprunov mainly targets compliance experts, auditors, SAP project managers and consultants responsible for GRC products as readers for his book. They will find indispensable information for their daily work from the first to the last page. In addition, MBA, management information system students as well as senior managers like CIOs and CFOs will find a wealth of valuable information on compliance in the SAP ERP environment, on GRC in general and its implementation in particular.
Oral Solid Dosage Forms ISPE Good Practice GuideTechnology TransferISPE Good Practice GuideCold Chain ManagementISPE Good Practice GuideProcess GasesISPE Good Practice GuideHeating, Ventilation, and Air Conditioning (HVAC)ISPE Good Practice GuideMaintenanceGood Design Practices for GMP Pharmaceutical Facilities, Second Edition
This revised publication serves as a handy and current reference for professionals engaged in planning, designing, building, validating and maintaining modern cGMP pharmaceutical manufacturing facilities in the U.S. and internationally. The new edition expands on facility planning, with a focus on the ever-growing need to modify existing legacy facilities, and on current trends in pharmaceutical manufacturing which include strategies for sustainability and LEED building ratings. All chapters have been re-examined with a fresh outlook on current good design practices.
Production and Processes CRC Press
Drug Utilization Research (DUR) is an eclectic scientific discipline, integrating descriptive and analytical methods for the quantification, understanding and evaluation of the processes of prescribing, dispensing and consumption of medicines and for the testing of interventions to enhance the quality of these processes. The discipline is closely related and linked mainly to the broader field of pharmacoepidemiology, but also to health outcomes research, pharmacovigilance and health economics. Drug Utilization Research is a unique, practical guide to the assessment and evaluation of prescribing practices and to interventions to improve the use of medicines in populations. Edited by an international expert team from the International Society for Pharmacoepidemiology (ISPE), DUR is the only title to cover both the methodology and applications of drug utilization research and covers areas such as health policy, specific populations, therapeutics and adherence.
Practical Implementation in Regulated Laboratories National Academies Press
Packed with case studies and problem calculations, Handbook of Food Processing: Food Safety, Quality, and Manufacturing Processes presents the information necessary to design food processing operations and describes the equipment needed to carry them out in detail. It covers the most common and new food manufacturing processes while addressing rele
Fifty-Third Report Wiley-Interscience
Spanning every critical element of validation for any pharmaceutical, diagnostic, medical device or equipment, and biotech product, this Second Edition guides readers through each step in the correct execution of validating processes required for non-aseptic and aseptic pharmaceutical production. With 14 exclusive environmental performance evaluati

Registries for Evaluating Patient Outcomes

John Wiley & Sons
Provides a concise and authoritative reference on the use of vaccines against diseases of livestock Compiled by Senior Animal Health Officers at The Food and Agriculture Organization of the United Nations, and with contributions from international leading experts, Veterinary Vaccines: Principles and Applications is a concise and authoritative reference featuring easily readable reviews of the latest research in vaccinology and vaccine immune response to pathogens of major economic impact to livestock. It covers advice and recommendations for vaccine production, quality control, and effective vaccination schemes including vaccine selection, specifications, vaccination programs, vaccine handling in the field, application, failures, and assessment of herd protection. In addition, the book presents discussions on the current status and potential future developments of vaccines and vaccination against selected transboundary animal diseases. Provides a clear and comprehensive guide on using veterinary vaccines to protect livestock from diseases Teaches the principles of vaccinology and vaccine immune response Highlights the vaccine production schemes and standards for quality control testing Offers easy-to-read reviews of the most current research on the subject Gives readers advice and recommendations on which vaccination schemes are most effective Discusses the today’s state of vaccines and vaccination against selected transboundary animal diseases as well as possible future developments in the field Veterinary Vaccines: Principles and Applications is an important resource for veterinary practitioners, animal health department officials, vaccine scientists, and veterinary students. It will also be of interest to professional associations and NGO active in livestock industry.
A Step by Step Guide for Achieving Compliance in the Pharmaceutical, Medical Device, and Biotech Industries John Wiley & Sons
ISPE Good Practice GuideTechnology TransferISPE Good Practice GuideCold Chain ManagementISPE Good Practice GuideProcess GasesISPE Good Practice GuideHeating, Ventilation, and Air Conditioning (HVAC)ISPE Good Practice GuideMaintenanceGood Design Practices for GMP Pharmaceutical Facilities, Second EditionCRC Press
Veterinary Vaccines Springer Science & Business Media
This User’s Guide is intended to support the design, implementation, analysis, interpretation, and quality evaluation of registries created to increase understanding of patient outcomes. For the purposes of this guide, a patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes. A registry database is a file (or files) derived from the registry. Although registries can serve many purposes, this guide focuses on registries created for one or more of the following purposes: to describe the natural history of disease, to determine clinical effectiveness or cost-effectiveness of health care products and services, to

measure or monitor safety and harm, and/or to measure quality of care. Registries are classified according to how their populations are defined. For example, product registries include patients who have been exposed to biopharmaceutical products or medical devices. Health services registries consist of patients who have had a common procedure, clinical encounter, or hospitalization. Disease or condition registries are defined by patients having the same diagnosis, such as cystic fibrosis or heart failure. The User's Guide was created by researchers affiliated with AHRQ's Effective Health Care Program, particularly those who participated in AHRQ's DEcIDE (Developing Evidence to Inform Decisions About Effectiveness) program. Chapters were subject to multiple internal and external independent reviews.

Developing a Protocol for Observational Comparative Effectiveness Research: A User's Guide

John Wiley & Sons
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.

Calibration Management

Ispe Headquarters
Pharmaceutical Isolators is a new indispensable guide to the design, construction, commissioning, maintenance, use and monitoring of pharmaceutical isolators. The current validation protocols are explained and the book includes some useful technical appendices. Written through the combined technical expertise of the Isolator Working Party, this new title will assist both experienced and new users to understand and manage this technology. The book will also be a useful reference source for auditors, inspectors and all those involved in standard setting and monitoring.

Pharmaceutical Manufacturing Handbook

CRC Press
This book covers several aspects of perinatal tissue-derived stem cells, from theoretical concepts to clinical applications. Topics include functions and different sources, immunomodulatory properties, translational point of view, GMP facility design and manufacturing for clinical translation, therapeutic potentials, and finally ethical considerations. The text provides a brief review of each type of perinatal stem cells and then focuses on their multi- or pluripotent properties, regenerative capacity, and future therapeutic potential in regenerative medicine. Additionally, the book discusses GMP compliance in stem cell facilities and the manufacture of stem cells for clinical translation. The chapters are authored by world-renowned experts in the perinatal stem cell field. Perinatal Tissue-Derived Stem Cells: Alternative Sources of Fetal Stem Cells, part of Springer's Stem Cell Biology and Regenerative Medicine series, is essential reading for basic and clinical scientists, clinicians, and pharmaceutical experts working or conducting research in the fields of stem cell biology, molecular aspects of stem cell research, tissue engineering, regenerative medicine, and cellular therapy.

U.S. Department of Energy
Provides a concise and authoritative reference on the use of vaccines against diseases of livestock Compiled by Senior Animal Health Officers at The Food and Agriculture Organization of the United Nations, and with contributions from international leading experts, Veterinary Vaccines: Principles and Applications is a concise and authoritative reference featuring easily readable reviews of the latest research in vaccinology and vaccine immune response to pathogens of major economic impact to livestock. It covers advice and recommendations for vaccine production, quality control, and effective vaccination schemes including vaccine selection, specifications, vaccination programs, vaccine handling in the field, application, failures, and assessment of herd protection. In addition, the book presents discussions on the current status and potential future developments of vaccines and vaccination against selected transboundary animal diseases. Provides a clear and comprehensive guide on using veterinary vaccines to protect livestock from diseases Teaches the principles of vaccinology and vaccine immune response Highlights the vaccine production schemes and standards for quality control testing Offers easy-to-read reviews of the most current research on the subject Gives readers advice and recommendations on which vaccination schemes are most effective Discusses the today's state of vaccines and vaccination against selected transboundary animal diseases as well as possible future developments in the field Veterinary Vaccines: Principles and Applications is an important resource for veterinary practitioners, animal health department officials, vaccine scientists, and veterinary students. It will also be of interest to professional associations and NGO active in livestock industry.
Design, Manufacturing, Behavior and Performance Pharmaceutical Press
This comprehensive book encompasses various facets of sterile product development. Key concepts relevant to the successful development of sterile products are illustrated through case studies and are covered under three sections in this book: • Formulation approaches that discuss a variety of dosage forms including protein therapeutics, lipid-based controlled delivery systems, PEGylated biotherapeutics, nasal dosage form, and vaccines • Process, container closure and delivery considerations including freeze-thaw process challenges, best practices for technology transfer to enable commercial product development, innovations and advancement in aseptic fill-finish operations, approaches to manufacturing lyophilized parenteral products, pen / auto-injector delivery devices, and associated container closure integrity testing hurdles for sterile product closures • Regulatory and quality aspects in the areas of particulate matter and appearance evaluation, sterile filtration, admixture compatibility considerations, sterilization process considerations, microbial contamination investigations and validation of rapid microbiological methods, and dry and moist heat sterilizers This book is a useful resource to scientists and researchers in both industry and academia, and it gives process and product development engineers insight into current industry practices and evolving regulatory expectations for sterile product development.
A Risk-based Approach to Compliant GxP Computerized Systems John Wiley & Sons
A Practical, On-the-Job HVAC Guide Applicable to residential, commercial, and industrial jobs, this essential handbook puts a wealth of real-world information at your fingertips. HVAC Troubleshooting Guide shows you how to read, interpret, and prepare schedules, mechanical plans, and electrical schematics. This handy resource will aid you in your everyday tasks and keep you up to date with the latest facts, figures, and devices. The book includes numerous illustrations, tables, and charts, troubleshooting tips, safety precautions, resource directories, and a glossary of terms. HVAC Troubleshooting Guide helps you: Identify and safely use tools and equipment (both new and old) Use heat pumps and hot air furnaces Calculate ventilation requirements Work with refrigeration equipment and the new refrigerants Utilize control devices, including solenoids and relays Operate, select, and repair electric motors Work with condensers, compressors, and evaporators Monitor the flow of refrigerant with valves, tubing, and filters Comply with the Section 608 refrigerant recycling rule Program thermostats Insulate with batts, sheet, tubing covers, and foam Work with solid-state controls Understand electrical and electronic symbols used in schematics
A Guide to Best Practice CRC Press
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.
Sterile Product Development World Health Organization
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.

Handbook of Stability Testing in Pharmaceutical Development

John Wiley & Sons
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.
ISPE Good Practice Guide CRC Press
Written by a researcher with experience designing, establishing, and validating biological manufacturing facilities worldwide, this is the first comprehensive introduction to disposable systems for biological drug manufacturing. It reviews the current state of the industry; tackles questions about safety, costs, regulations, and waste disposal; and guides readers to choose disposable components that meet their needs. This practical manual covers disposable containers, mixing systems, bioreactors, connectors and transfers, controls and sensors, downstream processing systems, filling and finishing systems, and filters. The author also shares his predictions for the future, calling disposable bioprocessing technology a "game changer."
Food Safety, Quality, and Manufacturing Processes Springer
Guidelines for Laboratory Design: Health and Safety Considerations, Third Edition provides reliable design information related to specific health and safety issues that need to be considered when building or renovating laboratories.".
Heating, Ventilation, and Air Conditioning (HVAC) CRC Press
With its coverage of Food and Drug Administration regulations, international regulations, good manufacturing practices, and process analytical technology, this handbook offers complete coverage of the regulations and quality control issues that govern pharmaceutical manufacturing. In addition, the book discusses quality assurance and validation, drug stability, and contamination control, all key aspects of pharmaceutical manufacturing that are heavily influenced by regulatory guidelines. The team of expert authors offer you advice based on their own firsthand experience in all phases of pharmaceutical manufacturing.

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