



GOOD PRACTICE GUIDE:
**Heating, Ventilation, and
Air Conditioning**

Second Edition



Hvac Ispe Good Practice Guide

**Samia Metwally, Gerrit Viljoen, Ahmed
El Idrissi**



Hvac Ispe Good Practice Guide:

ISPE Good Practice Guide: Heating, Ventilation, and Air Conditioning (HVAC) Ispe,2013-07-18 Good Quality Practice (GQP) in Pharmaceutical Manufacturing: A Handbook Jordi Botet,2015-09-28 Pharmaceutical manufacturing can be viewed as a supply chain which spans from the production and purchase of the starting and packaging materials through the manufacture of dosage forms until the safe reception of the finished product by the patient The entire chain comprises of several processes auditing materials purchase procurement production storage distribution quality control and quality assurance The quality standard for pharmaceutical production is current good manufacturing practice CGMP which is applied within the frame of a pharmaceutical quality system PQS This implementation however requires a scientific approach and has to take into account several elements such as risk assessment life cycle patient protection among other factors Hence pharmaceutical manufacturing is a complex subject in terms of regulation given the technical and managerial requirements This comprehensive handbook describes CGMP for new professionals who want to understand and apply the elements which build up pharmaceutical quality assurance The book gives details about basic quality control requirements such as risk management quality hazards and management systems documentation clean environments personnel training and gives guidelines on regulatory aspects This is an ideal handbook for undergraduates studying pharmaceutical or industrial manufacturing and supply chains as well for entrepreneurs and quality control professionals seeking to learn about CGMP standards and implementing quality assurance systems in the pharmaceutical sector Good Design Practices for GMP Pharmaceutical Facilities Terry Jacobs,Andrew A. Signore,2016-08-19 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 *HVAC Site Acceptance Testing for Pharmaceutical Plants: Ensuring Quality, Compliance, and Efficiency* Charles Nehme, Preface for HVAC Site Acceptance Test for Pharmaceutical Plants Introduction The HVAC Heating Ventilation and Air Conditioning systems play a crucial role in pharmaceutical plants ensuring that environmental conditions are tightly controlled to meet stringent regulatory requirements The integrity of these systems directly impacts the quality and safety of pharmaceutical products Therefore a thorough and meticulously documented site acceptance test SAT is essential before commissioning any HVAC system in a pharmaceutical plant Purpose The purpose of this document is to outline the procedures and criteria for conducting the HVAC site acceptance test SAT in pharmaceutical plants The SAT ensures that the installed HVAC system operates according to the specified design meets regulatory standards and fulfills the requirements for maintaining controlled environments critical for pharmaceutical production Scope

This document covers the SAT procedures for HVAC systems including testing methodologies performance criteria documentation requirements and acceptance standards It is intended for use by project managers validation engineers quality assurance personnel and HVAC contractors involved in the commissioning and qualification of HVAC systems in pharmaceutical plants Importance of HVAC Systems in Pharmaceutical Plants Environmental Control HVAC systems maintain temperature humidity and air quality within specified ranges essential for product stability and compliance with good manufacturing practices GMP Contamination Control Properly functioning HVAC systems prevent cross contamination and ensure a sterile environment which is vital for the production of drugs and medical products Regulatory Compliance Compliance with regulatory standards such as those set by the FDA EMA and other global health authorities is mandatory for pharmaceutical plants The SAT is a critical step in demonstrating that the HVAC system meets these stringent requirements Product Quality The consistent operation of HVAC systems is essential to ensure the quality and efficacy of pharmaceutical products Any deviations can lead to compromised product integrity and potential recalls Objectives The primary objectives of the HVAC SAT are Verification of System Installation Ensure that the HVAC system is installed according to design specifications and manufacturer guidelines Operational Performance Testing Validate that the HVAC system operates within specified parameters for temperature humidity airflow and filtration Compliance with Regulations Confirm that the HVAC system meets all relevant regulatory standards and guidelines Documentation and Reporting Provide comprehensive documentation and reports to support the validation process and facilitate regulatory inspections Structure of the Document This document is structured as follows Preparation for SAT Overview of pre test preparations including reviewing design specifications regulatory requirements and preparing test protocols SAT Procedures Detailed procedures for conducting the SAT including test methods instrumentation and data collection Performance Criteria Specification of the performance criteria and acceptable limits for various parameters such as temperature humidity and airflow Documentation Requirements Guidelines for documenting the SAT process including test results deviations and corrective actions Acceptance and Approval Criteria for acceptance and the process for approval by relevant stakeholders Conclusion The HVAC site acceptance test is a critical component in the commissioning of pharmaceutical plants ensuring that the environmental conditions necessary for product quality and regulatory compliance are met This document provides a comprehensive framework for conducting the SAT emphasizing the importance of meticulous testing and documentation to achieve a validated and reliable HVAC system

Process Architecture in Biomanufacturing Facility Design Jeffery Odum, Michael C. Flickinger, 2018-01-26 Essential information for architects designers engineers equipment suppliers and other professionals who are working in or entering the biopharmaceutical manufacturing field Biomanufacturing facilities that are designed and built today are radically different than in the past The vital information and knowledge needed to design and construct these increasingly sophisticated biopharmaceutical manufacturing facilities is difficult to find in published literature and it is rarely taught in

architecture or design schools This is the first book for architects and designers that fills this void Process Architecture in Biomanufacturing Facility Design provides information on design principles of biopharmaceutical manufacturing facilities that support emerging innovative processes and technologies use state of the art equipment are energy efficient and sustainable and meet regulatory requirements Relying on their many years of hands on design and operations experience the authors emphasize concepts and practical approaches toward design construction and operation of biomanufacturing facilities including product process facility relationships closed systems and single use equipment aseptic manufacturing considerations design of biocontainment facility and process based laboratory and sustainability considerations as well as an outlook on the facility of the future Provides guidelines for meeting licensing and regulatory requirements for biomanufacturing facilities in the U S A and WHO especially in emerging global markets in India China Latin America and the Asia Pacific regions Focuses on innovative design and equipment to speed construction and time to market increase energy efficiency and reduce footprint construction and operational costs as well as the financial risks associated with construction of a new facility prior to the approval of the manufactured products by regulatory agencies Includes many diagrams that clarify the design approach Process Architecture in Biomanufacturing Facility Design is an ideal text for professionals involved in the design of facilities for manufacturing of biopharmaceuticals and vaccines biotechnology and life science industry including architects and designers of industrial facilities construction equipment vendors and mechanical engineers It is also recommended for university instructors advanced undergraduates and graduate students in architecture industrial engineering mechanical engineering industrial design and industrial interior design

Instrument Engineers' Handbook, Volume 3 Bela G. Liptak, Halit Eren, 2018-10-08 Instrument Engineers Handbook Volume 3 Process Software and Digital Networks Fourth Edition is the latest addition to an enduring collection that industrial automation AT professionals often refer to as the bible First published in 1970 the entire handbook is approximately 5 000 pages designed as standalone volumes that cover the measurement Volume 1 control Volume 2 and software Volume 3 aspects of automation This fourth edition of the third volume provides an in depth state of the art review of control software packages used in plant optimization control maintenance and safety Each updated volume of this renowned reference requires about ten years to prepare so revised installments have been issued every decade taking into account the numerous developments that occur from one publication to the next Assessing the rapid evolution of automation and optimization in control systems used in all types of industrial plants this book details the wired wireless communications and software used This includes the ever increasing number of applications for intelligent instruments enhanced networks Internet use virtual private networks and integration of control systems with the main networks used by management all of which operate in a linked global environment Topics covered include Advances in new displays which help operators to more quickly assess and respond to plant conditions Software and networks that help monitor control and optimize industrial processes to determine the

efficiency energy consumption and profitability of operations Strategies to counteract changes in market conditions and energy and raw material costs Techniques to fortify the safety of plant operations and the security of digital communications systems This volume explores why the holistic approach to integrating process and enterprise networks is convenient and efficient despite associated problems involving cyber and local network security energy conservation and other issues It shows how firewalls must separate the business IT and the operation automation technology or AT domains to guarantee the safe function of all industrial plants This book illustrates how these concerns must be addressed using effective technical solutions and proper management policies and practices Reinforcing the fact that all industrial control systems are in general critically interdependent this handbook provides a wide range of software application examples from industries including automotive mining renewable energy steel dairy pharmaceutical mineral processing oil gas electric power utility and nuclear power

Perinatal Tissue-Derived Stem Cells Babak Arjmand, 2016-12-01 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

Instrument Engineers' Handbook Bela G. Liptak, Halit Eren, 2011-08-19 Instrument Engineers Handbook Volume 3 Process Software and Digital Networks Fourth Edition is the latest addition to an enduring collection that industrial automation AT professionals often refer to as the bible First published in 1970 the entire handbook is approximately 5 000 pages designed as standalone volumes that cover the measurement Volume 1 control Volume 2 and software Volume 3 aspects of automation This fourth edition of the third volume provides an in depth state of the art review of control software packages used in plant optimization control maintenance and safety Each updated volume of this renowned reference requires about ten years to prepare so revised installments have been issued every decade taking into account the numerous developments that occur from one publication to the next Assessing the rapid evolution of automation and optimization in control systems used in all types of industrial plants this book details the wired wireless communications and software used This includes the ever increasing number of applications for intelligent instruments enhanced networks Internet use virtual private networks and integration of control systems with the main networks used by management all of

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Handbook of Validation in Pharmaceutical Processes, Fourth Edition James Agalloco, Phil DeSantis, Anthony Grilli, Anthony Pavell, 2021-10-28 Revised to reflect significant advances in pharmaceutical production and regulatory expectations Handbook of Validation in Pharmaceutical Processes Fourth Edition examines and blueprints every step of the validation process needed to remain compliant and competitive This book blends the use of theoretical knowledge with recent technological advancements to achieve applied practical solutions As the industry's leading source for validation of sterile pharmaceutical processes for more than 10 years this greatly expanded work is a comprehensive analysis of all the fundamental elements of pharmaceutical and bio pharmaceutical production processes Handbook of Validation in Pharmaceutical Processes Fourth Edition is essential for all global health care manufacturers and pharmaceutical industry professionals Key Features Provides an in depth discussion of recent advances in sterilization Identifies obstacles that may be encountered at any stage of the validation program and suggests the newest and most advanced solutions Explores distinctive and specific process steps and identifies critical process control points to reach acceptable results New chapters include disposable systems combination products nano technology rapid microbial methods contamination control in non sterile products liquid chemical sterilization and medical device manufacture

WHO Expert Committee on Specifications for Pharmaceutical Preparations World Health Organization, 2019-05-29 The Expert Committee on Specifications for Pharmaceutical Preparations works towards clear independent and practical standards and guidelines for the quality assurance of medicines Standards are developed by the Committee through worldwide consultation and an international consensus building process The following new guidelines were adopted and recommended for use Procedure for development of the WHO medicines quality assurance guidelines Guidelines on Good Manufacturing Practices GMP for heating ventilation and air conditioning systems HVAC illustrative part Guidance on GMP

for Validation including the general main text analytical procedure validation validation of computerized systems and qualification in the area of interchangeability of multisource medicines the Protocol to conduct equilibrium solubility experiments for the purpose of biopharmaceutics classification systembased classification of active pharmaceutical ingredients for biowaiver Guidelines on Import Procedures for pharmaceutical products and the Good Practice Guidance document on implementing the collaborative procedures All of the above are included in this report and recommended for implementation *ISPE Good Practice Guide* International Society for Pharmaceutical Engineering,2009 *Dietary Supplement Good Manufacturing Practices* William J. Mead,2016-04-19 Dietary Supplement GMP is a one stop how to road map to the final dietary supplement GMP regulations recently issued by the FDA covering the manufacture packaging and holding of dietary supplement products The recent regulations outlining broad goals intentionally avoid specifics to allow for future technological advances leaving implementati

Veterinary Vaccines Samia Metwally,Gerrit Viljoen,Ahmed El Idrissi,2021-04-01 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

Guidelines for Laboratory Design Louis J. DiBerardinis,Janet S. Baum,Melvin W. First,Gari T. Gatwood,Anand K. Seth,2013-04-08 Proven and tested guidelines for designing ideal labs for scientific investigations Now in its Fourth Edition Guidelines for Laboratory Design continues to enable readers to design labs that make it possible to conduct scientific investigations in a safe and healthy environment The book brings together all the professionals who are critical to a successful lab design discussing the roles of architects engineers health and safety professionals and laboratory researchers

It provides the design team with the information needed to ask the right questions and then determine the best design while complying with current regulations and best practices. Guidelines for Laboratory Design features concise straightforward advice organized in an easy to use format that facilitates the design of safe efficient laboratories. Divided into five sections the book records some of the most important discoveries and achievements in Part IA Common Elements of Laboratory Design sets forth technical specifications that apply to most laboratory buildings and modules. Part IB Common Elements of Renovations offers general design principles for the renovation and modernization of existing labs. Part II Design Guidelines for a Number of Commonly Used Laboratories explains specifications best practices and guidelines for nineteen types of laboratories with three new chapters covering nanotechnology engineering and autopsy labs. Part III Laboratory Support Services addresses design issues for imaging facilities support shops hazardous waste facilities and laboratory storerooms. Part IV HVAC Systems explains how to heat cool and ventilate labs with an eye towards energy conservation. Part V Administrative Procedures deals with bidding procedures final acceptance inspections and sustainability. The final part of the book features five appendices filled with commonly needed data and reference materials. This Fourth Edition is indispensable for all laboratory design teams whether constructing a new laboratory or renovating an old facility to meet new objectives.

Quality assurance of pharmaceuticals: a compendium of guidelines and related materials. Volume 2. Good manufacturing practices and inspection World Health Organization, 2024-01-31. The GMP Compendium for Medical Products is a valuable resource for manufacturers regulators and other stakeholders involved in producing and distributing medical products. It covers various topics from quality management systems to personnel hygiene equipment validation and complaint handling. The guidance provided is based on the latest scientific and technical knowledge and considers the evolving regulatory landscape and the challenges faced by the industry.

Trends On The Role Of Pet In Drug Development Philip H Elsinga, Aren Van Waarde, Rudi A J O Dierckx, Anne M J Paans, 2012-02-29. Drug development is very expensive and a fight against time. PET offers possibilities to speed up this process by adding unique in vivo information on pharmacokinetics dynamics of a drug at an early stage. This information can help decision makers to move the drug in the drug development process or to decide to stop further developments. This unique and complete book highlights the different ways PET can be used and describes the latest trends in the various disciplines within nuclear medicine to further improve methodologies and increase the number of tools to accelerate drug development. Various topics within tracer development instrumentation data analysis and many clinical and preclinical topics are described by leading scientists from industry and academia.

Practical Guide to Single-use Technology Adriana G Lopes, 2016-08-31. Single use technology SUT is now available for all processing operations within the biopharmaceutical industry. It has the potential to reduce capital costs improve plant throughput and reduce the risk of cross contamination. However there are no clear guidelines to aid the end user on implementation of these technologies into a validated good manufacturing practice GMP environment. This book is

the first comprehensive publication of practical considerations for each stage of the implementation process of SUT and covers the selection specification design and qualification of systems to meet end user requirements Serving as an introduction and practical reference to this growing area of application within the biopharmaceutical industry this handbook presents An approach for SUT implementation within an end users facility with examples for bioreactors tangential flow filtration and fill finish systems SUT within the context of regulatory guidance such as ICH Q8 Q9 Q10 and GMP Strategy for standardisation of single use bag systems and assessment of extractables and leachables Specifications of user requirements and design of specific SUT alongside process descriptions and flow diagrams Strategies and tools to evaluate risk with examples of risk assessments applicable to design processing and product quality and Qualification approach for different SUT types With the information presented in this book engineers researchers and professionals involved in biopharmaceuticals will be better prepared to plan and make effective decisions to design and implement SUT

Practical Pharmaceutics Yvonne Bouwman-Boer, V'Iain Fenton-May, Paul Le Brun, 2015-08-24 This book contains essential knowledge on the preparation control logistics dispensing and use of medicines It features chapters written by experienced pharmacists working in hospitals and academia throughout Europe complete with practical examples as well as information on current EU legislation From prescription to production from usage instructions to procurement and the impact of medicines on the environment the book provides step by step coverage that will help a wide range of readers It offers product knowledge for all pharmacists working directly with patients and it will enable them to make the appropriate medicine available to store medicines properly to adapt medicines if necessary and to dispense medicines with the appropriate information to inform patients and caregivers about product care and how to maintain their quality This basic knowledge will also be of help to industrial pharmacists to remind and focus them on the application of the medicines manufactured The basic and practical knowledge on the design preparation and quality management of medicines can directly be applied by the pharmacists whose main duty is production in community and hospital pharmacies and industries Undergraduate as well as graduate pharmacy students will find knowledge and backgrounds in a fully coherent way and fully supported with examples

WHO standards for quality, safety and efficacy of health products World Health Organization, 2023-08-11 To better understand Member State needs for WHO standards and guidelines for the quality safety and efficacy of health products a stakeholder feedback survey was conducted on 8 WHO guidelines This report presents the approach results and results analysis regarding the levels of adoption and factors that impede or support adoption of the selected WHO guidelines for health products The report is useful for those using WHO guidelines and those issuing guidelines

International IT Regulations and Compliance Siri H. Segalstad, 2008-11-20 Standards technologies and requirements for computer validation have changed dramatically in recent years and so have the interpretation of the standards and the understanding of the processes involved International IT Regulations and Compliance brings together current thinking on the implementation of

standards and regulations in relation to IT for a wide variety of industries The book provides professionals in pharmaceutical and semiconductor industries with an updated overview of requirements for handling IT systems according to various Quality Standards and how to translate these requirements in the regulations

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