

Table B.2 — Examples for microelectronic cleanrooms

Air cleanliness class ^a (ISO Class) in operation	Airflow type ^b	Average, airflow velocity ^c m/s	Air changes per hour ^d m ³ /m ² · h	Examples of applications
2	U	0,3 to 0,5	na	Photolithography, semiconductor processing zone ^e
3	U	0,3 to 0,5	na	Work zones, semiconductor processing zone
4	U	0,3 to 0,5	na	Work zones, multilayer masks processing, fabrication of compact discs, semiconductor service zone, utility zones
5	U	0,2 to 0,5	na	Work zones, multilayer masks processing, fabrication of compact discs, semiconductor service zone, utility zones
6	N or M ^f	na	70 to 160	Utility zones, multilayer processing, semiconductor service zones
7	N or M	na	30 to 70	Service zones, surface treatment
8	N or M	na	10 to 20	Service zones

NOTE na = not applicable

^a Occupancy states associated with the ISO Class should be defined and agreed in advance of establishing optimum design conditions.

^b When airflow type is listed, it represents the airflow characteristics for cleanrooms of that class: U = unidirectional; N = non-unidirectional; M = mixed (combination of U and N).

^c Average airflow velocity is the way that unidirectional airflow in cleanrooms usually is specified. The requirement on unidirectional airflow velocity will depend on local parameters such as geometry and thermals. It is not necessarily the filter face velocity.

^d Air changes per hour is the way that non-unidirectional and mixed airflow is specified. The suggested air changes are related to a room height of 3,0 meter.

^e Impervious barrier techniques should be considered.

^f With effective separation between contamination source and zones to be protected. Could be a physical or airflow barrier.

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Brian Midcalf



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Handbook of Pharmaceutical Manufacturing Formulations, Third Edition Sarfaraz K. Niazi, 2019-12-09 The Handbook of Pharmaceutical Manufacturing Formulations Third Edition Volume Six Sterile 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 sixth 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

The ASQ Certified Pharmaceutical GMP Professional Handbook Mark Allen Durivage, 2024-09-30 The ASQ Certified Pharmaceutical GMP Professional Handbook assists candidates preparing for the Certified Pharmaceutical Good Manufacturing Practices Professional CPGP examination and serves as a handy reference guide for practitioners in the field This handbook covers compliance with good manufacturing practices GMPs as regulated and guided by national and international agencies for the pharmaceutical industry

Microbial Limit and Bioburden Tests Lucia Clontz, 2008-10-14 In recent years the field of pharmaceutical microbiology has experienced numerous technological advances accompanied by the publication of new and harmonized compendial methods It is therefore imperative for those who are responsible for monitoring the microbial quality of pharmaceutical biopharmaceutical products to keep abreast of the latest c

Handbook of Pharmaceutical Manufacturing Formulations Sarfaraz K. Niazi, 2016-04-19 No other area of regulatory compliance receives more attention and scrutiny by regulatory authorities than the regulation of sterile products for obvious reasons With the increasing number of potent products particularly the new line of small protein products joining the long list of proven sterile products the technology of manufacturing ster

Cleanrooms for Food Processing: Design, Operation, and Compliance for Safe and Efficient Production Charles Nehme, The global food industry stands at a critical juncture facing ever increasing demands for safety quality and efficiency all while navigating a complex landscape of stringent regulations and consumer expectations Contamination whether microbial particulate or chemical poses a persistent threat to product integrity shelf life and ultimately public health For decades the principles of cleanliness have been paramount in food production but the challenges

of modern processing environments necessitate a more advanced systemic approach. This is where the specialized world of cleanroom technology becomes not just beneficial but indispensable. Having dedicated over three decades to the intricate domain of HVAC and MEP systems across diverse industrial, commercial, and residential projects worldwide, I have witnessed firsthand the transformative power of meticulously designed and operated controlled environments. My journey has consistently reinforced the fundamental truth that optimal performance, safety, and energy efficiency in any built environment hinge on a profound understanding of its underlying systems, particularly those governing air quality and contamination control. While the concept of cleanrooms is well established in pharmaceuticals and microelectronics, its application in food processing presents unique complexities and critical nuances. Unlike manufacturing sterile drugs, food products are inherently biological, often perishable, and subject to different pathways of contamination. This book bridges that gap, translating the rigorous principles of cleanroom design and operation into the specific context of food production. It is born from a recognition that achieving superior food safety and quality in today's sophisticated facilities requires a holistic perspective, one that integrates architectural design, advanced HVAC strategies, stringent operational protocols, and robust validation methodologies. My aim with this book is to provide a comprehensive practical guide for engineers, facility managers, quality assurance professionals, consultants, and students involved in the design, construction, operation, and maintenance of food processing cleanrooms. We will explore everything from the fundamental principles of contamination control and cleanroom classification to the intricacies of HVAC system design, a cornerstone of any effective cleanroom, and the critical aspects of monitoring, validation, and compliance. Furthermore, we will delve into energy efficiency considerations and emerging technologies that are shaping the future of hygienic food production. This work is a synthesis of extensive international experience, best practices, and a deep-seated commitment to fostering environments where food can be processed safely, efficiently, and with the highest regard for quality. It is my sincere hope that *Cleanrooms for Food Processing* will serve as an invaluable resource, empowering professionals to design, build, and maintain facilities that not only meet but exceed the exacting demands of the modern food industry, ensuring optimal performance and safeguarding public trust worldwide. Charles Nehme, Global HVAC and MEP Consultant

Biocontamination Control for Pharmaceuticals and Healthcare Tim Sandle, 2024-01-28 *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. The first edition of the book covered many of the aspects of the strategy, but the new official guidance signals that a roadmap is required to fully comply with its requirements. Completely updated with the newest version of the EU GMP EN17141, the new edition expands the coverage of quality risk management and new complete examples to help professionals bridge the gap between regulation and implementation. *Biocontamination Control for Pharmaceuticals and Healthcare* offers professionals in pharma, quality control, and related areas guidance on building a complete biocontamination strategy. Includes the most

current regulations Contains three new chapters including Application of Quality Risk Management and its Application in Biocontamination Control Designing an Environmental Monitoring Programme and Synthesis An Anatomy of a Contamination Control Strategy Offers practical guidance on building a complete biocontamination strategy Aerosol Measurement Pramod Kulkarni,Paul A. Baron,Klaus Willeke,2011-07-12 Aerosol Measurement Principles Techniques and Applications Third Edition is the most detailed treatment available of the latest aerosol measurement methods Drawing on the know how of numerous expert contributors it provides a solid grasp of measurement fundamentals and practices a wide variety of aerosol applications This new edition is updated to address new and developing applications of aerosol measurement including applications in environmental health atmospheric science climate change air pollution public health nanotechnology particle and powder technology pharmaceutical research and development clean room technology integrated circuit manufacture and nuclear waste management **Quality** Kathleen E. McCormick,Janet H. Sanders,2022-07-14 Quality second edition provides comprehensive application of regulatory guidelines and quality concepts and methodologies related to pharmaceutical manufacturing It is an excellent resource for practitioners those pursuing pharmaceutical related certifications and for students trying to learn more about pharmaceutical manufacturing This book provides the background theory applied descriptions of the guidelines and concepts plus questions and problems at the end of the chapters that will help provide practice for the reader to apply the concepts In this book the authors share their combined 60 years of extensive practical experience in the industry and in process improvement combined with detailed understanding of the needs of the industry and education system This book provides real life examples from industry and guidelines for practical application of tools that can be referenced by operators engineers and management This book is fully revised updated and expanded with new content in areas such as QbD Lean Six Sigma basic data analysis and CAPA tools Fully revised updated and expanded new edition Features new topics such as QbD Lean Six Sigma basic data analysis and CAPA tools Includes end of chapter summaries and end of chapter question and or problems Provides detailed steps and examples for applying the guidelines and quality tools Written in an accessible style making the content easy to understand and apply *Process Validation & cGMP (Part - 1)* Mr. Rohit Manglik,2024-03-24 Covers fundamentals of process validation documentation regulatory guidelines and GMP principles in pharmaceutical manufacturing *Regenerative Medicine and Tissue Engineering* Daniel Eberli,2011-08-29 Tissue Engineering may offer new treatment alternatives for organ replacement or repair deteriorated organs Among the clinical applications of Tissue Engineering are the production of artificial skin for burn patients tissue engineered trachea cartilage for knee replacement procedures urinary bladder replacement urethra substitutes and cellular therapies for the treatment of urinary incontinence The Tissue Engineering approach has major advantages over traditional organ transplantation and circumvents the problem of organ shortage Tissues reconstructed from readily available biopsy material induce only minimal or no immunogenicity when reimplanted in the patient This book is aimed at anyone interested

in the application of Tissue Engineering in different organ systems It offers insights into a wide variety of strategies applying the principles of Tissue Engineering to tissue and organ regeneration

Guidelines for Safe Handling of Powders and Bulk Solids CCPS (Center for Chemical Process Safety),2010-08-13 Powders and bulk solids handled widely in the chemical pharmaceutical agriculture smelting and other industries present unique fire explosion and toxicity hazards Indeed substances which are practically inert in consolidated form may become quite hazardous when converted to powders and granules The U S Chemical Safety and Hazard Investigation Board is currently investigating dust explosions that occurred in 2003 at WestPharma CTA Acoustics and Hayes Lemmerz and is likely to recommend that companies that handle powders or whose operations produce dust pay more attention to understanding the hazards that may exist at their facility This new CCPS guidelines book will discuss the types of hazards that can occur in a wide range of process equipment and with a wide range of substances and will present measures to address these hazards

Sterilization of Medical Devices Anne Booth,2018-12-12 This book presents vital information on international sterilization standards and guidance on practical application of these standards in the manufacturing process It covers validation industrial sterilization methods emerging sterilization techniques laboratory testing manufacturing of sterile devices and device reuse Excerpted from *The Validator* edited by Anne F Booth more than fifty experts share their knowledge of current technologies in easy to understand articles that establish methods to ensure compliance Contents include reviews of ISO sterilization standards industrial sterilization methods and technologies and support testing methodologies

Metric Handbook Pamela Buxton,2015-03-05 Significantly updated in reference to the latest construction standards and evolving building types Many chapters revised including housing transport offices libraries and hotels New chapter on flood aware design Sustainable design integrated into chapters throughout Over 100 000 copies sold to successive generations of architects and designers this book belongs in every design studio and architecture school library The Metric Handbook is the major handbook of planning and design information for architects and architecture students Covering basic design data for all the major building types it is the ideal starting point for any project For each building type the book gives the basic design requirements and all the principal dimensional data and succinct guidance on how to use the information and what regulations the designer needs to be aware of As well as building types the Metric Handbook deals with broader aspects of design such as materials acoustics and lighting and general design data on human dimensions and space requirements The Metric Handbook provides an invaluable resource for solving everyday design and planning problems

CleanRooms ,2008-12 A central resource of technology and methods for environments where the control of contamination is critical

Environmental Monitoring for Cleanrooms and Controlled Environments Anne Marie Dixon,2016-04-19 A critical technology in the science of contamination control environmental monitoring is a technique that provides important data on the quality of a process processing environment and final product which can aid scientists in identifying and eliminating potential sources of contamination in cleanrooms and

controlled environments In response **Contamination and ESD Control in High-Technology Manufacturing** Roger W. Welker,R. Nagarajan,Carl E. Newberg,2006-08-04 A practical how to guide that effectively deals with the control of both contamination and ESD This book offers effective strategies and techniques for contamination and electrostatic discharge ESD control that can be implemented in a wide range of high technology industries including semiconductor disk drive aerospace pharmaceutical medical device automobile and food production manufacturing The authors set forth a new and innovative methodology that can manage both contamination and ESD often considered to be mutually exclusive challenges requiring distinct strategies Beginning with two general chapters on the fundamentals of contamination and ESD control the book presents a logical progression of topics that collectively build the necessary skills and knowledge Analysis methods for solving contamination and ESD problems Building the contamination and ESD control environment including design and construction of cleanrooms and ESD protected environments Cleaning processes and the equipment needed to support these processes Tooling design and certification Continuous monitoring Consumable supplies and packaging materials Controlling contamination and ESD originating from people Management of cleanrooms and ESD protected workplace environments Contamination and ESD Control in High Technology Manufacturing conveys a practical working knowledge of contamination and ESD control strategies and techniques and it is filled with case studies that illustrate key principles and the benefits of contamination and ESD control Moreover its straightforward style makes the material which integrates many disciplines of engineering and science clear and accessible Written by three leading industry experts this book is an essential guide for engineers and designers across the many industries where contamination and ESD control is a concern *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 **Microbial Contamination Control in Parenteral Manufacturing** Kevin Williams,2004-05-20 This reference surveys emerging trends concepts and procedures used in the characterization and control of contaminants the sterile production of traditional drugs and biologics the design construction and validation of new parenteral facilities and the monitoring of clean environments vividly illustrating the routes by which products proce

Pharmaceutical Isolators Brian Midcalf,2004 This work considers the basic concepts definitions and standards necessary in the design construction commissioning maintenance and use of pharmaceutical isolators

Handbook for Critical Cleaning: Applications, processes, and controls Barbara Kanegsberg,Ed Kanegsberg,Edward Kanegsberg,2011 Nearly all companies which manufacture or fabricate high value physical objects components parts assemblies perform critical cleaning at one or more stages These range from the giants of the semiconductor aerospace and biomedical world to a host of small to medium to large companies producing a dizzying array of components

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