

permitted. [NOTE—A description of terms used in this chapter can be found in the Appendix at the end of the chapter.]

The guidance provided in this chapter and the monitoring parameters given for microbiological evaluation should be applied only to clean rooms, restricted-access barrier systems (RABS), and isolators used for aseptic processing. ISO-classified environments used for other purposes are not required to meet the levels of contamination control required for aseptically produced sterile products. The environments used for nonsterile applications require different microbial control strategies.

A large proportion of products labeled as sterile are manufactured by aseptic processing rather than terminal sterilization. Because aseptic processing relies on the exclusion of microorganisms from the process stream and the prevention of microorganisms from entering open containers during processing, product bioburden as well as the bioburden of the manufacturing environment are important factors governing the risk of unacceptable microbial contamination. The terms *aseptic* and *sterile* are not synonymous. *Sterile* means having a complete absence of viable microorganisms or organisms that have the potential to reproduce. In the purest microbiological sense, an *aseptic* process is one that prevents contamination by the exclusion of microorganisms. In contemporary aseptic healthcare-product manufacturing, *aseptic* describes the process for handling sterilized materials in a controlled environment designed to maintain microbial contamination at levels known to present minimal risk.

In any environment where human operators are present, microbial contamination at some level is inevitable. Even the most cautious clean-room environment design and operation will not eliminate the shedding of microorganisms if human operators are present. Thus, an expectation of zero contamination at all locations during every aseptic processing operation is technically not possible and thus is unrealistic. There are no means to demonstrate that an aseptic processing environment and the product-contact surfaces within that environment are sterile. Monitoring locations should be determined based upon an assessment of risk. Although manufacturers should review environmental monitoring results frequently to ensure that the facility operates in a validated state of control, monitoring results can neither prove nor disprove sterility. Because of the limitations of monitoring, manufacturers cannot rely directly on monitoring, statistics, or periodic aseptic-processing simulations to ensure a sterility assurance level.

Environmental monitoring is usually performed by personnel and thus requires operator intervention. As a result, environmental monitoring can both increase the risk of contamination and also give false-positive results. Thus, intensive monitoring is unwarranted, particularly in the ISO 5 environments that are used in the most critical zones of aseptic processing.

A number of sampling methods can be used to assess and control the microbiological status of controlled environments for aseptic processing. At present, nearly all of these methods rely on the growth and recovery of microorganisms, many of which can be in a damaged state caused by environmental stress and therefore may be difficult to recover. The numerical values for air, surface, and personnel monitoring included in this chapter are not intended to represent limits or specifications but are strictly informational. Because of the variety of microbiological sampling equipment and methods, it is not scientifically reasonable to suggest that the attainment of these values guarantees microbial control or that excursions beyond values in this chapter indicate a loss of control. The assessment of risks associated with manufacturing environments must be made over a significant period; and in each case, the contamination recovery rate metric should be established on the basis of a review of actual findings within the facility. The objective of each user should be to use contamination recovery rates to track ongoing performance and to refine the microbiological control program to foster improvements. When optimum operational conditions are achieved within a facility, con-

tamination recovery rate levels typically become relatively stable within a normal range of variability.

There are no standard methods for air sampling, and available literature indicates that air-sampling methods are highly variable. It should not be assumed that similar sample volumes taken by different methods will produce similar rates of recovery. Many factors can affect microbial recovery and survival, and different air sampler suppliers may have designed their systems to meet different requirements. Also, sample-to-sample variation in microbial sampling can be extensive. Limited data are available regarding the accuracy, precision, sensitivity, and limits of detection of monitoring methods used in the aseptic processing of healthcare products.

Surface sampling methods are also not standardized. Different media are employed, and in the case of swabs, different results have been reported for wet and dry swab methods and contact plates. Replicate sample contact plates should be expected to give similar results under identical conditions, but rates of recovery have been reported to be both lower than expected and highly variable. In general, surface monitoring has been found to recover <50%, even when used with relatively high inoculum levels on standardized coupons. In actual production environments where organisms are stressed to varying degrees, recovery rates may be lower.

ADVANCED ASEPTIC TECHNOLOGIES

Advanced aseptic technologies can be defined as those that do not rely on the direct intervention of human operators during processing. At present, technologies such as isolators, blow/fill/seal, and closed RABS (designs that are never opened during setup or operation) may be considered advanced aseptic technologies, provided that direct intervention by gownned personnel is disallowed during processing. In recent years, isolator technology has found a broad acceptance in healthcare manufacturing. Isolators and closed RABS effectively separate the operator from the critical aseptic processing environment. Because these systems substantially reduce contamination risk, their microbiological control levels are higher than those of conventional clean rooms that have comparable particulate air classification level, for example, ISO 5.

CLEAN ROOM CLASSIFICATION FOR ASEPTIC PROCESSING ENVIRONMENTS

The design and construction of clean rooms and controlled environments are covered in ISO 14644 series. This standard defines the performance of a clean environment with respect to the concentration of total particulates per unit volume. ISO 14644-1 stipulates the total particulate counts allowed for a clean environment to meet the defined air quality classifications. The reader is referred to this standard regarding the design characteristics and certification of clean environments.

Pharmaceutical manufacturers are concerned with nonviable particulate contamination in injectable products (see *Particulate Matter in Injections* (788)). Unlike microbial contamination in which experimental data suggest that humans are the only significant source, nonviable particulates can arise both from humans and from processing equipment. Studies indicate that gownned humans slough particulate and microbial contamination at a rather consistent rate. However, the relationship between microbial (viable) and nonviable contamination does not hold for particulates shed by processing equipment. Where equipment is the primary source of particulate matter, the resulting particulates are essentially all nonviable.

The argument that if fewer total particulates are present in a clean room, it is less likely that airborne microorganisms will be present is true only if human operators are the

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Katrin Zwirgmaier



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Pharmaceutical Microbiological Quality Assurance and Control David Roesti, Marcel Goverde, 2020-01-02 Relying on practical examples from the authors experience this book provides a thorough and modern approach to controlling and monitoring microbial contaminations during the manufacturing of non sterile pharmaceuticals Offers a comprehensive guidance for non sterile pharmaceuticals microbiological QA QC Presents the latest developments in both regulatory expectations and technical advancements Provides guidance on statistical tools for risk assessment and trending of microbiological data Describes strategy and practical examples from the authors experience in globalized pharmaceutical companies and expert networks

Emerging Non-Clinical Biostatistics in Biopharmaceutical Development and Manufacturing Harry Yang, 2016-11-30 The premise of Quality by Design QbD is that the quality of the pharmaceutical product should be based upon a thorough understanding of both the product and the manufacturing process This state of the art book provides a single source of information on emerging statistical approaches to QbD and risk based pharmaceutical development A comprehensive resource it combines in depth explanations of advanced statistical methods with real life case studies that illustrate practical applications of these methods in QbD implementation

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 changes Microbial Limit and Bioburden Tests Validation Approaches and Global Requirements guides readers through the various microbiological methods listed in the compendia with easy to follow diagrams and approaches to validations of such test methodologies Includes New and Updated Material Now in its second edition this work is the culmination of research and discussions with technical experts as well as USP and FDA representatives on various topics of interest to the pharmaceutical microbiologist and those responsible for the microbial quality of products materials equipment and manufacturing facilities New in this edition is an entire chapter dedicated to the topic of biofilms and their impact on pharmaceutical and biopharmaceutical operations The subject of rapid methods in microbiology has been expanded and includes a discussion on the validation of alternative microbiological methods and a case study on microbial identification in support of a product contamination investigation Substantially updated and revised this book assists readers in understanding the fundamental issues associated with pharmaceutical microbiology and provides them with tools to create effective microbial contamination control and microbial testing programs for the areas under their responsibility

Principles of Pharmacy Henry V. Army, 1926

Cell-Based Therapy for Degenerative Retinal Disease Marco A. Zarbin, Mandeep S. Singh, Ricardo P. Casaroli-Marano, 2019-03-01 This book discusses why specific diseases are being targeted for cell based retinal therapy what evidence exists that justifies optimism for this approach and what challenges

must be managed in order to bring this technology from the laboratory into routine clinical practice There are a number of unanswered questions e g surgical approach to cell delivery management of immune response optimum cell type to transplant that very likely are not going to be answered until human trials are undertaken but there is a certain amount of de risking that can be done with preclinical experimentation This book is essential reading for scientists clinicians and advanced students in stem cell research cell biology and ophthalmology 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 The Chapter 795 Answer Book Patricia Kienle, 2023-04-28 The Chapter Answer Book 2nd Edition provides a comprehensive overview and explanation of the requirements and recommendations of USP Chapter as well as practical advice and consideration in complying with the chapter This book outlines quality of practice standards for nonsterile compounding by following a nonsterile product from receipt to preparation in a healthcare facility addressing core elements of the revised USP Chapter

Integrated Pharmaceutics Antoine Al-Achi, Mali Ram Gupta, William Craig Stagner, 2022-09-07 This work is an examination of all aspects of the science in developing effective dosage form for drug delivery Pharmaceutics refers to the subfield of pharmaceutical sciences that develops drug delivery products or devices to optimize the drug s performance once administered This multidisciplinary field draws on physical chemistry organic chemistry and biophysics to generate and refine these crucial elements of medical care Moreover incorporating such disparate dimensions of drug product design as material properties and legal regulation bridges the gap between effective chemicals and viable medical treatments Integrated Pharmaceutics provides a comprehensive introduction to the creation and manufacture of effective dosage forms for drug delivery It presents its subject following the principles of physical pharmacy product design and drug regulations This tripartite structure allows readers to move from theory to practice beginning from a firm foundation of physical

pharmacy principles including drug solubility and stability estimation rheology and interfacial properties From there it proceeds to discussions of drug product design and of harmonizing pharmaceutical design with the regulatory regimens and technological standards of the United States European Union and Japan Readers of the second edition of Integrated Pharmaceutics will also find A glossary defining key terms extensive informative appendices and a list of references leading to the primary literature in the field for each chapter Earlier chapters are expanded with additional new chapters including one entitled Biotechnology Products Supplementary instructor guide with questions and solutions available online for registered professors Updated regulatory guidelines including quality by design design space analysis process analytical technology polymorphism characterization blend sample uniformity and stability protocols Integrated Pharmaceutics is a useful textbook for graduate students in pharmaceutical sciences drug formulation and design and biomedical engineering In addition professionals in the pharmaceutical industry including regulatory bodies will find it a helpful reference guide

Pharmaceutical Manufacturing Handbook Shayne Cox Gad,2008-03-17 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 *United States Exports of Domestic and Foreign Merchandise* ,1948 *Practical Druggist and Pharmaceutical Review of Reviews* Benjamin Lillard,1919 United States Court of International Trade Reports United States. Court of International Trade,1993 *Practical Druggist and Pharmaceutical Review of Reviews* ,1915

Illuminating Engineering ,1965-07 *Bibliography of Medical Reviews* ,1976 *Applied Pharmaceutics in Contemporary Compounding* Robert P. Shrewsbury,2015-01-01 Applied Pharmaceutics in Contemporary Compounding Third Edition is designed to convey a fundamental understanding of the principles and practices involved in both the development and the production of compounded dosage forms by applying pharmaceutical principles *Products for Life Science Research, 2000-2001* ,2000 **N.A.R.D. Notes** National Association of Retail Druggists (U.S.),1909 *Poorly Soluble Drugs* Gregory K. Webster,Robert G. Bell,J. Derek Jackson,2017-01-06 This book is the first text to provide a comprehensive assessment of the application of fundamental principles of dissolution and drug release testing to poorly soluble compounds and formulations Such drug products are vis vis their physical and chemical properties inherently incompatible with aqueous dissolution However dissolution methods are required for product development and selection as well as for the fulfillment of regulatory obligations with respect to biopharmaceutical assessment and product quality understanding The percentage of poorly soluble drugs defined in classes 2 and 4 of the Biopharmaceutics Classification System BCS has significantly increased in the modern pharmaceutical development pipeline This book provides a thorough exposition of general method

development strategies for such drugs including instrumentation and media selection the use of compendial and non compendial techniques in product development and phase appropriate approaches to dissolution development Emerging topics in the field of dissolution are also discussed including biorelevant and biphasic dissolution the use of enzymes in dissolution testing dissolution of suspensions and drug release of non oral products Of particular interest to the industrial pharmaceutical professional a brief overview of the formulation and solubilization techniques employed in the development of BCS class 2 and 4 drugs to overcome solubility challenges is provided and is complemented by a collection of chapters that survey the approaches and considerations in developing dissolution methodologies for enabling drug delivery technologies including nanosuspensions lipid based formulations and stabilized amorphous drug formulations **The Pacific Campaign in World War II** William Bruce Johnson, 2006-05-02 This is a fascinating new account of how diplomacy and politics gave way to military strategy and warfare in the Pacific Presenting previously unpublished documents this book freshly examines the key events in the fight for the Pacific

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