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PDA Technical Reports

PDA Technical Reports are global consensus documents, prepared by member-driven Teams (listed on inside front cover) comprised of content experts, including scientists and engineers working in the pharmaceutical/biopharmaceutical industry, regulatory authorities and academia. PDA Technical Reports are subjected to a global review of PDA members and other topic-specific experts, often including regulatory officials. The level of expertise of the Team and those participating in the global review ensure a broad perspective reflecting best thinking and practices currently available. Access the current Technical Report Library Online or via the PDA Bookstore

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Technical Report No. 1: Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control (Revised 2007)

TR 1 presents the principles of steam sterilization with a focus on the microbiology and engineering of moist heat sterilization to provide an understanding of the science of moist heat sterilization with sufficient technical detail to assist in developing a sterilization policy. The information is organized in a logical progression from the essential elements of sterilization science and technology through sterilization cycle development and qualification.

| PDA Bookstore Item Number 43381

Technical Report No. 3: Validation of Dry Heat Processes Used for Depyrogenation and Sterilization (Revised 2013)

TR 3 presents a modern, scientific approach to dry-heat depyrogenation and sterilization processes and includes recommendations for use by industry and regulators. The information provided can be used by manufacturers of pharmaceutical products for validating dry-heat depyrogenation and sterilization processes.

| PDA Bookstore Item Number 43506

Technical Report No. 12: Siliconization of Parenteral Drug Packaging Components (1988)

TR 12 reviews common lubricants, the reasons for their use, methods of application, and analytical measurement.

| PDA Bookstore Item Number 43217

Technical Report No. 13: Fundamentals of an Environmental Monitoring Program Revised (2022)

TR 13 aligns with current industry trends and regulatory expectations and provides additional guidance and focuses on increased expectations concerning data management and data integrity, qualification and maintenance of controlled environments, and rapid microbiological methods (RMM) and will aid in the establishment of an environmental monitoring program that is robust, meaningful, and practical whilst embracing innovation and the principles of quality risk management. This TR also includes updates related to microbiological and total airborne particulate control concepts and principles as they relate to facilities involved in the manufacture of sterile pharmaceutical products and other designated cleanroom environments. While the TR may serve as a resource applicable for controlled environments in general, its primary focus is environmental monitoring for sterile product manufacturing.

| PDA Bookstore Item Number 43558

Technical Report No. 13-2: Fundamentals of an Environmental Monitoring Program Annex 1: Environmental Monitoring of Facilities Manufacturing Low Bioburden Products (2020)

This addendum complements the existing TR 13 by providing elements to consider when designing a risk-based EM program to support the manufacture of low bioburden products using low bioburden processes and provides a means of determining the critical aspects, assessing the associated risks, and designing the appropriate environmental monitoring program for areas where bioburden control of manufacturing processes is required. TR 13-2 provides recommendations for the development of an environmental control and monitoring program for classified areas and the associated GMP processes used for manufacturing operations requiring bioburden control in the biotechnology and pharmaceutical industries. A review of regulatory requirements and the development of risk assessments based on the criticality and complexity of processes is included, along with industry examples of these risk-based approaches.

| PDA Bookstore Item Number 43549

Technical Report No. 14: Validation of Column-Based Chromatography Processes for the Purification of Proteins (Revised 2008)

TR 14 provides current industry perspective and scientific guidance on the validation of column-based separation processes for the purification of biopharmaceutical proteins and follows the lifecycle of the validation process. The intent is to provide guidelines with supporting rationale on developing a chromatography process, rather than a step-by-step guide on how to perform validation. Chromatography processes commonly used in the industry are the focus of this report. Other unique processes like expanded bed adsorption (EBA), simulated moving bed (SMB), and membrane chromatography are not addressed.

| PDA Bookstore Item Number 43220

Technical Report No. 15: Validation of Tangential Flow Filtration in Biopharmaceutical Applications Revised (Revised 2009)

TR 15 focuses on the validation of tangential flow filtration processes used to manufacture therapeutic proteins and polypeptides produced from recombinant or non-recombinant expression systems that can be characterized with appropriate analytical methods. Some principles may also apply to other product types, such as proteins and polypeptides isolated from tissues and body fluids. The document includes a detailed discussion of the activities associated with all steps needed to successfully complete validation of tangential flow filtration unit operations for protein purification and include: tangential flow filtration principles, process development and laboratory studies with scale-down models, manufacturing-scale validation batches, and finally, post- validation tasks, such as process monitoring.

| PDA Bookstore Item Number 43221

Technical Report No. 22: Process Simulation for Aseptically Filled Products Revised (2024)

TR 22 addresses process capability assessment for aseptic processing and the consideration of risk to product sterility and patient safety as criteria for the design of APS studies. Aseptic operations required in the preparation of sterile bulk materials and biotechnology inoculums and feed materials are not a part of this document. While the focus of this document is on aseptic processing in the pharmaceutical and biopharmaceutical industry, application of the concepts and principles to the preparation of sterile medical devices and diagnostics may be appropriate.

| PDA Bookstore Item Number 43226

Technical Report No. 26: Sterilizing Filtration of Liquids (Revised 2008)

TR 26 describes the use and validation of sterilizing filtration as implemented by pharmaceutical scientists and engineers. The report addresses enhancements in filtration technologies and regulatory requirements within the pharmaceutical industry. References to scientific publications and international regulatory documents are provided where more detail and supportive data may be found.

| PDA Bookstore Item Number 43230

Technical Report No. 27: Pharmaceutical Package Integrity (1998)

TR 27 reviews issues of pharmaceutical product package integrity and provides guidance for evaluating the barrier qualities of a pharmaceutical package. Although it is written to reflect the complexity of all pharmaceutical products and packages, the emphasis throughout the document is on packaging intended for sterile products. The information provided in this guideline is intended to assist users in developing integrity assessment strategies for use during the phases of product life.

| PDA Bookstore Item Number 43231

Technical Report No. 28: Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals (Revised 2006)

TR 28 provides guidance relative to the validation of aseptic processing activities utilized for the production of sterile bulk pharmaceutical chemicals. The document addresses acceptance criteria limitations and evolving regulatory expectations.

| PDA Bookstore Item Number 43232

Technical Report No. 29: Points to Consider for Cleaning Validation Revised (Revised 2012)

TR-29 covers all facets of cleaning validation for pharmaceutical manufacturers, including those of active pharmaceutical ingredients, clinical supplies, and finished drug products for human and veterinary consumption, as well as biologics, nutraceuticals, and personal care products. The report promotes a lifecycle cleaning-validation approach that follows the three stages underlying the risk-management approach, as that found in ICH Q9, which focuses efforts on the protection of the patient and on product quality: Stage 1–Process development; Stage 2–Qualification and verification; and Stage 3–Periodic assessment and monitoring.

| PDA Bookstore Item Number 43501

Technical Report No. 30: Parametric Release of Pharmaceuticals and Medical Device Products Terminally Sterilized by Moist Heat Revised (Revised 2012)

TR 30 provides current, demonstrated best practices of terminal sterilization by moist heat as a product release method with an emphasis on use of science-based approaches during the development of a parametric release program for pharmaceutical and medical device products. The document outlines a sterility assurance release program that is founded upon effective control, monitoring, and documentation of a validated sterile product manufacturing process where sterility release is dependent upon demonstrated achievement of critical operational parameters in lieu of end product sterility testing.

| PDA Bookstore Item Number 43234

Technical Report No. 33: Evaluation, Validation, and Implementation of Alternative and Rapid Microbiological Methods Revised (Revised 2013)

TR 33 is intended to provide guidance for the successful evaluation, validation, and implementation of alternative and rapid microbiological methods needed by the pharmaceutical, biotechnology and medical device industries to assure product quality. This technical report was written to establish industry-wide criteria on what constitutes an acceptable alternative or rapid microbiology test to the compendial or classical method and how to prove it to the satisfaction of quality organizations and regulatory agencies.

| PDA Bookstore Item Number 43510

Technical Report No. 34: Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products (2001)

TR 34 addresses essential user requirements for the application of isolator technology to a broad range of manufacturing, development and testing applications in the health care product manufacturing industry. It covers not only product sterility assurance, but also the use of isolators for the containment of hazardous materials.

| PDA Bookstore Item Number 43239

Technical Report No. 38: Manufacturing Chromatography Systems Postapproval Changes (ChromPAC): Chemistry, Manufacturing, and Controls Documentation (2006)

TR 38 addresses post-approval changes to drug substance manufacturing processes for chromatography systems and outlines the recommended test documentation in support of the changes. The document provides manufacturers with clarity on the appropriate test documentation when reporting changes to chromatographic operations in an approved manufacturing process, while ensuring patient safety, drug efficacy, and quality. This document provides recommendations for post-approval changes to manufacturing process chromatography systems in the production of drug substance that is used for both chemically synthesized drug products and human-specified biological products (with the exception of therapeutic DNA plasmid products).

| PDA Bookstore Item Number 43315

Technical Report No. 39: Guidance for Temperature-Controlled Medicinal Products — Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment (Revised 2021)

TR 39 provides guidance for establishing a quality management system for distribution of all types of temperature-sensitive medicinal and pharmaceutical products. This guidance covers the shipping site, where the product is prepared for transportation, and the shipment of the product from the shipping site until its arrival at the receiving site where it will be stored or distributed to patient (end user).

| PDA Bookstore Item Number 43556

Technical Report No. 40: Sterilization Filtration of Gases (2005)

TR 40 provides guidance in the selection, qualification and validation of a filter that is appropriate for sterilizing filtration of a process gas stream, defined as the complete removal of all microbiological contaminants, excluding viruses. The document also provides some discussion regarding certain circumstances wherein other contaminants such as viruses and plasmids can also be removed by filtration. The focus is limited to hydrophobic membrane filter elements.

| PDA Bookstore Item Number 43314

Technical Report No. 41: Virus Filtration (Revised 2022)

TR 41 presents what virus filters are and where they can be used in current and emerging bioprocesses. Recommendations for selection of a suitable virus filter are presented that include information on their physical and biological/safety characterization and guidance on how to incorporate quality by design (QbD) principles into virus filtration applications. Strategies for evaluating and validating virus retention by virus filtration, including defining the worst-case test parameters, are also discussed. Finally, considerations which reflect best practices and current thinking for implementing virus filtration into novel manufacturing technologies, such as barrier filters, continuous bioprocessing modes for filtration, or production of ATMPs are also included.

| PDA Bookstore Item Number 43561

Technical Report No. 43: Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing: Covering Ampoules, Bottles, Cartridges, Syringes and Vials Revised (Revised 2023)

TR 43 provides an approach to a quality decision-making process and represents best practices for the identification and classification of visual nonconformities for glass containers. The standardized quality criteria in TR 43 are intended as guidance for container manufacturers and for incoming container acceptance inspection at pharmaceutical companies. Five detailed lexicons have been updated which visually illustrate glass nonconformities—one for Moulded glass bottles and vials, and four for tubular glass vials, ampoules, cartridges, and syringes. Additionally, defects specific to ready-to-use containers and their categorization are included for use as applicable. TR 43 applies solely to empty glass containers.

| PDA Bookstore Item Number 43566

Technical Report No. 44: Quality Risk Management for Aseptic Processes (2008)

TR 44 presents methods used to assess risk which are appropriate for the organization and the process being assessed. The purpose of this technical report is to provide an overview of a quality risk management program and to present a model to facilitate the risk assessment of aseptic processing of sterile products. It provides a tool to assess and evaluate activities, conditions and controls that impact establishing and maintaining aseptic conditions and endotoxin control.

| PDA Bookstore Item Number 43410

Technical Report No. 45: Filtration of Liquids Using Cellulose-Based Depth Filters (2008)

TR 45 provides guidelines for the selection, validation and use of cellulose-based depth filters in pharmaceutical and biopharmaceutical applications. The report also provides information on physical and performance characteristics of cellulose-based depth filter products in sheet, lenticular cartridge (modules) and capsule configurations to assist the filter user in defining a consistent, standardized approach for choosing, implementing and using depth filters in the pharmaceutical and biopharmaceutical manufacturing processes.

| PDA Bookstore Item Number 43422

Technical Report No. 46: Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to the End User (Revised 2024)

TR 46 addresses issues specifically encountered within the last mile of the distribution of medicinal products and devices and accounts for expanded regulations, the development and implementation of newer, more advanced technologies, and supply chains that have become more extensive and complex. For the purposes of this technical report, last mile is defined as the final transfer of a drug from the manufacturer or wholesaler to the end user which could be either the patient or the entity (e.g., pharmacy, hospital) that provides the drug to the patient. The TR provides recommendations and tools based on current best practices to ensure that product quality is maintained in the last mile, including guidance on temperature control, monitoring and security, and data management, with a focus on supply chain management and covers supply chains in Europe, Africa, Brazil, U.S., Canada and China.

| PDA Bookstore Item Number 43573

Technical Report No. 47: Preparation of Virus Spikes Used for Virus Clearance Studies (2010)

TR 47 presents the quality attributes that may be applied to virus and bacteriophage spike preparations, as well as to cell lines used for virus propagation and sample testing and provides case studies for the same. This Technical Report is not intended to establish standards for the production of virus spike preparations or to represent standards for quality attributes for particular viruses; rather it presents principles important in selecting and defining appropriate quality attributes for selected model viruses, with an emphasis on minimizing the impact of the virus spike itself on the results of validation studies (viral clearance) conducted on scale down models of the process unit operation.

| PDA Bookstore Item Number 43486

Technical Report No. 48: Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance (2010)

TR 48 presents information regarding moist heat sterilizers used in the pharmaceutical, medical device and biotechnology industries. This technical report focuses on design and operation aspects from the development of User Requirements Specifications (URS) through equipment qualification (Installation Qualification (IQ) / Operational Qualification (OQ)) and culminating with ongoing maintenance requirements. The focus of this report does not include Performance Qualification (PQ).

| PDA Bookstore Item Number 43487

Technical Report No. 49: Points to Consider for Biotechnology Cleaning Validation (2010)

TR 49 aligns cleaning validation practices with the life cycle approaches to validation, as enabled by the International Conference on Harmonisation guidelines on pharmaceutical development (Q8), quality risk management (Q9) and quality systems (Q10). The document addresses reducing the possibility of product contamination from biopharmaceutical manufacturing equipment by demonstrating that the cleaning process adequately and consistently removes product residues, process residues, and environmental contaminants from the cleaned equipment/system, so that this equipment/system can be safely used for the manufacture of defined subsequent products (which may be the same or a different product).

| PDA Bookstore Item Number 43488

Technical Report No. 50: Alternative Methods for Mycoplasma Testing (2010)

TR 50 provides guidance regarding the use of alternative methods in an analytical lab setting. The report focuses on non-culture testing methodology, including Nucleic Acid Amplification Technique (NAT) assays and enzyme activity-based assays.

| PDA Bookstore Item Number 43489

Technical Report No. 51: Biological Indicators for Gas and Vapor-Phase Decontamination Processes: Specification, Manufacture, Control and Use (2010)

TR 51 provides a comprehensive review of recommended specifications for biological indicators (BIs) to be used with sporicidal gas and vapor-phase decontamination cycles including guidance regarding BI manufacture, quality control, and use. The principles described in this report are based upon the manufacture and use of BIs prepared from spore suspensions; however, they can be equally applied to the preparation of BIs from other sources. Recommendations for quality assurance and quality control in the manufacture and use of BIs are also included. Ethylene oxide is not discussed in this document.

| PDA Bookstore Item Number 43490

Technical Report No. 52: Guidance for Good Distribution Practices (GDPs) For the Pharmaceutical Supply Chain (2011)

TR 52 describes the overall quality system for distribution of pharmaceutical products and is meant to assist manufacturers in assuring that quality, integrity, and efficacy of the product are not compromised in the distribution channels, including handling, storage, transportation and distribution. It applies to all parties involved, including, but not limited to, the manufacturer, the holder of the marketing authorization, third party Logistics Service Providers (termed 3PLs), wholesale distributors, and transportation carriers.

| PDA Bookstore Item Number 43491

Technical Report No. 53: Guidance for Industry: Stability Testing to Support Distribution of New Drug Products (2011)

TR 53 describes the use and justification of studies using scientific data and rationale necessary to determine an appropriate stability budget for a drug product. The document focuses on four situations that should be considered during stability testing: product storage, manufacturing and distribution operations (road, sea, and/or air), product use under a variety of circumstances (e.g., following reconstitution from powder), and excursions.

| PDA Bookstore Item Number 43492

Technical Report No. 54: Implementation of Quality Risk Management For Pharmaceutical and Biotechnology Manufacturing Operations (2012)

TR 54 provides detailed guidance for the application and implementation of quality risk management (QRM) principles throughout the product lifecycle. Intended to align with ICH Q9 and present information that can be helpful to the reader on how to implement QRM, the report emphasizes QRM application during commercial manufacturing and integrating QRM into the pharmaceutical quality system.

| PDA Bookstore Item Number 43493

Technical Report No. 54-2: Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations Annex 1: Case Study Examples for Quality Risk Management in Packaging and Labeling (2013)

TR 54-2 provides specific case studies on how to apply quality risk management (QRM) to pharmaceutical manufacturing, specifically packaging and labelling operations. This report is intended to align with ICH Q9 and is one in a series of similar documents that provide additional examples of how to apply risk management tools across the product supply chain.

| PDA Bookstore Item Number 43504

Technical Report No. 54-3: Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations Annex 2: Case Studies in the Manufacturing of Pharmaceutical Drug Products (2013)

TR 54-3 provides specific case study examples of how to apply quality risk management to the manufacturing of pharmaceutical drug products. These case studies were chosen to illustrate the adaptability of quality risk management tools to help solve various problems, implement corrective actions, and keep processes in a state of control.

| PDA Bookstore Item Number 43511

Technical Report No. 54-4: Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations Annex 3: Case Studies in the Manufacturing of Biotechnological Bulk Drug Substances (2014)

TR 54-4 provides detailed examples of characteristic operations and case studies that demonstrate the value of implementing QRM to effectively manage risks during manufacturing of biotechnological bulk drug substances. Each section of this technical report begins with an overview of a stage of the biopharmaceutical manufacturing process and the typical risks associated with that stage, followed by a case study demonstrating how to apply a QRM tool to control, mitigate, and/or eliminate risks during that stage of production. This report also includes a section on the application of QRM to additional factors that can affect biopharmaceutical manufacturing, such as primary contact surface for drug substance, extractables/leachables in the process stream, and environmental controls.

| PDA Bookstore Item Number 43518

Technical Report No. 54-5: Quality Risk Management for the Design, Qualification, and Operation of Manufacturing Systems (2017)

TR 54-5 provides practical guidance on how to manage quality risks throughout the manufacturing system lifecycle and illustrates concepts through two case studies. The information in this technical report is applicable to both new and existing manufacturing systems used in clinical, commercial manufacturing, drug substance (API), drug product, packaging and warehousing and critical utility systems. It focuses on manufacturing systems, which can potentially impact product quality.

| PDA Bookstore Item Number 43533

Technical Report No. 54-6: Formalized Risk Assessment for Excipients (2019)

TR 54-6 provides additional guidance on the excipient risk assessment process required by the European Commission Guidelines on the formalized risk assessment for ascertaining the appropriate GMP for excipients of medicinal products for human use and incorporated into the PIC/S publication of the same name. The information in TR 54-6 applies to all excipients used in drug products for human use at all stages of the product lifecycle.

| PDA Bookstore Item Number 43542

Technical Report No. 55: Detection and Mitigation of 2,4,6-Tribromoanisole and 2,4,6-Trichloroanisole Taints and Odors in the Pharmaceutical and Consumer Healthcare Industries (2012)

TR 55 provides guidance on how to detect and mitigate 2,4,6-Tribromoanisole (TBA) and 2,4,6-Trichloroanisole (TCA) odors and taints. This report provides background on issues with TBA and TCA taints including uses of 2,4,6-tribromophenol (TBP) and 2,4,6-trichlorophenol (TCP) in industry, the role of fungal halophenol methylation that generates TBA and TCA haloanisole taints, sensory and physiochemical properties of TBP, TCP, TBA, and TCA, case examples from food and beverage industries with root causes and remedial actions, and examples of TBA taint recalls from the pharmaceutical and consumer healthcare industries. Additionally, this report offers guidance on signal detection from adverse event and/or product quality complaints and resulting recalls, toxicology and safety, analytical method development and use, supply chain controls, risk analysis and mitigation.

| PDA Bookstore Item Number 43494

Technical Report No. 56: Application of Phase-Appropriate Quality System and cGMP to the Development of Therapeutic Protein Drug Substance (API or Biological Active Substance) (Revised 2016)

TR 56 provides an overview of the ideal state for broad good manufacturing practices (GMPs) throughout the product lifecycle and as they become more stringent from the discovery/R&D stage through Phase 3 clinical trials to commercial launch. This report also describes a basic framework for clinical trial manufacturing for sites where full commercial development and/or manufacturing may not be the organizational goal (e.g., university/grant-funded investigators, start-up biotech firms).

| PDA Bookstore Item Number 43530

Technical Report No. 57: Analytical Method Validation and Transfer for Biotechnology Products (2012)

TR 57 provides practical and strategic guidance to efficiently use historical data and knowledge to design suitable risk-based AMV studies and set appropriate protocol acceptance criteria. The information provided applies to all biotechnological manufacturers and all contract development and manufacturing organizations. This TR does not provide specific guidance for the timing of AMV study execution with respect to the parallel product development lifecycle stages or guidance for analytical instrument qualification.

| PDA Bookstore Item Number 43497

Technical Report No. 57-2: Analytical Method Development and Qualification for Biotechnology Products (2015)

TR 57-2 provides practical, risk-based guidance for the development and qualification portions of the analytical method life cycle for biotechnology products. This technical report describes the method development and qualification portions of the life cycle that lead to method validation, which is outlined in PDA *Technical Report No. 57: Analytical Method Validation and Transfer for Biotechnology Products.* TR 57-2 includes guidance for analytical method development and analytical method qualification studies such as risk-based strategies and priorities; analytical target profile and quality by design (QbD) concepts; target performance criteria; and modern quality expectations such as those presented in ICH Q8–10 guidelines.

| PDA Bookstore Item Number 43519

Technical Report No. 58: Risk Management for Temperature-Controlled Distribution (2012)

TR 58 is meant to complement ICH Q9: Quality Risk Management and is part of the series of good distribution technical reports produced by PDA. This document provides specific guidance on the identification, assessment, evaluation, control and review of risks in the distribution process, such as receipt, storage, handling and shipping of bulk, intermediate and finished pharmaceuticals, biological medicinal products and medical devices. It also provides guidance for handling incidents, like temperature excursions, that occur during the distribution process.

| PDA Bookstore Item Number 43499

Technical Report No. 59: Utilization of Statistical Methods for Production Monitoring (2012)

TR 59 presents relevant and easy to use Statistical Process Control Methods applicable to the pharmaceutical industry. The document presents strategies and guidance in identifying and properly using statistical methods to conform to predetermined quality characteristics with the goal of providing supporting objective evidence. The TR also discusses the fundamental importance of statistics behind the requisite process understanding for process improvement and development.

| PDA Bookstore Item Number 43500

Technical Report No. 60: Process Validation: A Lifecycle Approach (2013)

TR 60 presents real-world guidance for the application of a lifecycle approach to process validation. The lifecycle approach has been the focus of process validation guidance from major regulatory agencies and represents significant expectations in this area. This technical report reviews requirements for process validation studies across the three-stage approach defined by FDA and also discuss best practices for integration with supporting Quality Systems.

| PDA Bookstore Item Number 43502

Technical Report No. 60-2: Process Validation: A Lifecycle Approach Annex 1: Oral Solid Dosage/Semisolid Dosage Forms (2017)

TR 60-2 illustrates how concepts from TR 60 can be applied to oral solid and semisolid dosage drug products so the reader can gain a clear understanding of the application of the process validation lifecycle to these technologies. The scope of this document is limited to oral solid dosage forms such as tablets and capsules (excluding liquid-filled capsules) and semisolid dosage forms, which includes creams, ointments, and suppositories.

| PDA Bookstore Item Number 43532

Technical Report No. 60-3: Process Validation: A Lifecycle Approach Annex 2: Biopharmaceutical Drug Substances Manufacturing (2021)

TR 60-3 is intended to assist in the design and implementation of globally compliant validation programs to ensure process reproducibility and robustness as they relate to biotechnology-derived, purified protein drug substances (e.g., therapeutic proteins, polypeptides, and vaccine drug substances). These models are based on the material and practices established in PDA TR 60 and global regulatory guidances. Points to consider are provided to facilitate the collection of data in support of a regulatory filing for the approval of a biopharmaceutical drug substance intended to be used in a pharmaceutical product. The strategies discussed primarily focus on the validation of nonsterile, low-bioburden, well-characterized, protein-based drug substance processes. **NOTE:** This TR replaces *Technical Report No. 42 Process Validation of Protein Manufacturing.*

| PDA Bookstore Item Number 43551

Technical Report No. 61: Steam In Place (2013)

TR 61 presents information on SIP processes that provide moist heat sterilization and/or sanitization of equipment and systems supporting the manufacture of medicinal products. The principles discussed in this report may also be applied to those systems where portable equipment is steamed at a fixed station (steam out of place).

| PDA Bookstore Item Number 43503

Technical Report No. 62: Recommended Practices for Manual Aseptic Processes (2013)

TR 62 outlines methods and approaches for control and evaluation of aseptic processing operations for drug products/medicinal products which use all- or partially-manual procedures. This technical report has value for hospital and formulation pharmacies where manual aseptic processing may occur. The guidance provided in this report may be applicable to operations including: vaccine preparation, cell culture, gene therapy, Investigational New Drug/IMP manufacturing, clinical and commercial manufacturing, and pharmacy formulation and dispensing.

| PDA Bookstore Item Number 43505

Technical Report No. 63: Quality Requirements for the Extemporaneous Preparation of Clinical Trial Materials (2013)

TR 63 discusses extemporaneous preparation (EP) techniques used to prepare a variety of formulations for a variety of dosage forms for small-scale clinical studies where dosing is in-clinic. The document describes a quality system that will support the preparation of clinical trial materials in a nonmanufacturing environment in a manner that will ensure product quality and patient safety.

| PDA Bookstore Item Number 43507

Technical Report No. 64: Active Temperature-Controlled Systems: Qualification Guidance (2024)

TR 64 discusses the expectation that materials that are stored and shipped within a controlled environment are maintained within a defined temperature range. This document discusses the process of qualifying actively controlled spaces that are designed to maintain a stable and uniform temperature around the cargo for the duration of transportation or storage at any temperature range.

| PDA Bookstore Item Number 43509

Technical Report No. 65: Technology Transfer (2022)

TR 65 provides a standardized approach to the technology transfer process. It supplies a matrixed "Reference Guide to Technology Transfer Activities and Deliverables," which can be used to coordinate cross-functional technology transfer activities that help achieve operational readiness and culminate in regulatory approval. It is intended to provide a level of detail and approaches that can be applied across technology transfer types.

| PDA Bookstore Item Number 43560

Technical Report No. 66: Application of Single-Use Systems in Pharmaceutical Manufacturing (2014)

TR 66 provides the reader with critical concepts or points to consider when implementing an SUS strategy in a pharmaceutical manufacturing process. These concepts are intended to be valid both for chemically synthesized small molecules and for bioprocesses that produce large-molecule biopharmaceutical products. This document discusses SUSs that are in either direct or indirect contact with the raw materials, intermediates, and pharmaceutical drug substances or drug products. The document does not discuss disposable items related to laboratory activities, final delivery system to the patient, transfusion bags, packaging, or medical devices.

| PDA Bookstore Item Number 43515

Technical Report No. 67: Exclusion of Objectionable Microorganisms from Nonsterile Pharmaceuticals, Medical Devices, and Cosmetics (2014)

TR 67 provides guidance to the nonsterile product manufacturing industry on how to manage the microbial risks associated with manufacturing and storage as well as how to determine what isolates would be deemed an objectionable microorganism in nonsterile products. This document is intended to be globally applicable. When country-specific regulations are cited, they are meant to serve as examples of such and are not binding to the industry stakeholders outside the country's jurisdiction.

| PDA Bookstore Item Number 43516

Technical Report No. 68: Risk-Based Approach for Prevention and Management of Drug Shortages (2024)

TR 68 addresses the following aspects for proactive prevention of drug shortages and provides useful tools to assist in preparation:

- A holistic, risk-based framework at a product level for the prevention and management of drug shortages caused by manufacturing and quality issues
- A risk-triage model that can be used to assess drug-shortage risks and implement appropriate controls in the end-to-end value chain for the manufacturing and distribution of a product
- Templates for developing a Drug Shortage Risk Register and a Drug Shortage Prevention and Response Plan at a product level

The concepts and approach presented in this report may be adopted and applied by other stakeholders in the entire supply chain, such as wholesale distributors, as well as suppliers and vendors of materials used in processing, for example, filters, single-use bags, flow paths, resins, and solvents.

| PDA Bookstore Item Number 43572

Technical Report No. 69: Bioburden and Biofilm Management in Pharmaceutical Manufacturing Operations (2015)

TR 69 presents the current scientific understanding of the causes of, and control strategies for, bioburden in pharmaceutical production systems, with a special emphasis on biofilms in fluid-handling systems. The scope of the report encompasses pharmaceutical and biopharmaceutical manufacturing processes but does not include final aseptic and terminal sterilization fill-finish operations. The focus of the TR is to enable the development of a comprehensive program for bioburden management including strategies for preventing and controlling biofilms based on current scientific knowledge of microbial growth and adaptation.

| PDA Bookstore Item Number 43521

Technical Report No. 70: Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities (2015)

TR 70 identifies the systematic elements essential to assuring compliant cleaning and disinfection programs for aseptic and bioburden-controlled manufacturing facilities and classified environments. Focusing on controlled and non-controlled environments, microbial contamination control and corrective actions for loss of control for viable excursions contamination, this technical report provides comprehensive information and suggested best practices as well as appropriate references to support such guidance. This document is not intended to fully address product-contact surface cleaning from a clean in place or clean out of place system, which is specifically addressed in PDA Technical Report No. 29: Points to Consider for Cleaning Validation and PDA Technical Report No. 49: Points to Consider for Biotechnology Cleaning Validation.

| PDA Bookstore Item Number 43522

Technical Report No. 71: Emerging Methods for Virus Detection (2015)

TR 71 describes and critically assesses methods used for the detection of potential adventitious viruses in biomedicinal products and their production processes. It also details new methods that have emerged as a result of technological advances in molecular biology, mass spectrometry and genomics, all of which offer the potential for novel virus detection opportunities.

| PDA Bookstore Item Number 43523

Technical Report No. 72: Passive Thermal Protection Systems for Global Distribution: Qualification and Operational Guidance (2015)

TR 72 discusses the qualification and operational handling of passive thermal protection systems (TPS) for temperature-controlled distribution of pharmaceutical and biological products. The decision to use a passive system versus an active system is dictated by many factors and the intent of this report is to assist stakeholders in the supply chain to preserve the quality, safety, and efficacy of pharmaceutical and biological products during distribution. This report provides guidance on the types of passive systems, including the materials used in their manufacture, characteristics and capabilities of these systems, qualification approach, operational use and reuse, and options for recycling at the end of those systems' lives.

| PDA Bookstore Item Number 43524

Technical Report No. 73: Prefilled Syringe User Requirements for Biotechnology Applications (2015)

TR 73 discusses the requirements for the 1 mL long glass prefilled syringe (PFS) for biotechnology applications. This report provides guidance on material selection and evaluation for suitability, syringe preparation and handling (including human factors), and drug product compatibility (physical and chemical) with the syringe materials and mode of delivery. Plastic syringes and ancillary devices, such as autoinjectors, are not within scope.

| PDA Bookstore Item Number 43525

Technical Report No. 73-2: Application of Medical Device Regulations, Annex I Requirements (GSPRs) for Staked Needle Syringes (2024)

TR 73-2 represents the current state of knowledge as to the application of European Union Regulation (EU) 2017/745 on medical devices (MDR). As this is a new regulatory requirement, expectations of the Notified Body (NB) and competent authorities may diverge as the process evolves. As an addendum to PDA *Technical Report No. 73: Prefilled Syringe User Requirements for Biotechnology Applications*, this technical report provides recommendations on preparing the required documentation of the device part of the PFS to facilitate obtaining an NB opinion. It systematically recommends the amount and depth of information needed for each relevant GSPR to support pharmaceutical companies in assembling the submission file to the NBs and provides information on documents that provide guidance on completing the NB submission file. The device part, including its corresponding components and materials, are in scope as they will be evaluated by the NBs, but the medicinal product (drug) is not.

| PDA Bookstore Item Number 43570

Technical Report No. 74: Reprocessing of Biopharmaceuticals (2016)

TR 74 provides guidance in the design, development, controls, procedures, validation, regulatory submission, and implementation of reprocessing procedures for recombinant biopharmaceutical manufacturing. The information presented focuses on recombinant biopharmaceutical products including proteins and polypeptides produced via recombinant and non-recombinant cell-culture expression systems. The guidance is general in nature, and the two case studies provided illustrate how the general principles may be applied.

| PDA Bookstore Item Number 43526

Technical Report No. 75: Consensus Method for Rating 0.1µm Mycoplasma Reduction Filters (2016)

TR 75 describes a consensus filter challenge test for standardizing test parameters across laboratories. The express purpose of this technical report is to educate users and filter manufacturers about best practices for mycoplasma reduction filtration and suggest a consistent method which filter manufactures can use for testing and rating the effectiveness of mycoplasma reduction filters. It describes the implementation of a specific filtration testing method and positive controls for establishing a manufacturer's claims of mycoplasma reduction for their filters.

| PDA Bookstore Item Number 43528

Technical Report No. 76: Identification and Classification of Visible Nonconformities in Elastomeric Components and Aluminum Seals for Parenteral Packaging (2016)

TR 76 provides a building block for developing a comprehensive specification for elastomeric components and aluminum seals. It offers consistent and standardized quality criteria that can be used by pharmaceutical and medical device manufacturers for the visual inspection of incoming elastomeric components and aluminum seals, and by suppliers for outgoing inspection. This report is not intended to establish mandatory standards for the classification and identification of elastomeric component and aluminum seal nonconformities. It is intended to be a single-source overview that complements existing guidelines and standards or documents listed in the reference section of this technical report.

| PDA Bookstore Item Number 43529

Technical Report No. 77: The Manufacture of Sterile Pharmaceutical Products Using Blow-Fill-Seal Technology (2017)

TR 77 provides recommendations specific to the operation of blow-fill-seal (BFS) technology for the manufacture of sterile pharmaceuticals (e.g., ophthalmic, parenteral, and inhalation). The intent of this document is to provide supplemental information to assist the user with interpretation of international standards and regulatory guidance from the perspective of BFS operations. Consideration is given to specific aspects of BFS operations not covered in published information. This Technical Report addresses considerations for BFS technology related to the installation and operation of machinery and evaluation of related materials and final product containers. Support areas such as laboratory, solution compounding, gowning airlocks, etc. are not considered specific to blow-fill-seal and are not included within the scope of this document. This technical report is intended as a guide for the industry and is not meant to supplant or duplicate any existing regulatory guidance.

| PDA Bookstore Item Number 43531

Technical Report No. 78: Particulate Matter in Oral Dosage Forms (2017)

TR 78 documents the current practices used by manufacturers of drug products, active pharmaceutical ingredients, excipients, and packaging/primary containers to control, inspect, sample, and test intrinsic and extrinsic particulate matter in oral dosage forms. The scope of this Technical Report includes current practices of monitoring for particulates, as well as recent quality, clinical relevance, and regulatory experience in oral dosage forms.

| PDA Bookstore Item Number 43535

Technical Report No. 79: Particulate Matter Control in Difficult to Inspect Parenterals (2018)

TR 79 describes best practices for difficult to inspect parenteral (DIP) product lifecycle management, destructive testing, and trending to supplement portions of the guidance given in *USP General Chapter<1790>: Visible Particulates in Injection.* This Technical Report is intended to provide logical pathways to DIP product inspection and testing to support continual process improvement in the industry.

| PDA Bookstore Item Number 43536

Technical Report No. 80: Data Integrity Management System for Pharmaceutical Laboratories (2018)

TR 80 provides the framework and tools necessary to establish a robust data integrity management system to ensure data integrity for paper, hybrid, and computerized systems within the laboratory. It is intended to outline regulatory requirements and expectations, along with best industry practices, to ensure data integrity, to highlight common gaps in laboratory data management practices, and to recommend methods of remediation.

| PDA Bookstore Item Number 43537

Technical Report No. 81: Cell-Based Therapy Control Strategy (2019)

This TR focuses on the development of a risk-based control strategy adapted to cell-based therapy that can mitigate the risk of generating a product of poor quality. The content applies to autologous and allogeneic cell therapy applications, including cells with ex vivo genetic modification. Though some concepts may be applicable to their development, gene therapy vectors for in vivo dosing are not within the scope of this report.

| PDA Bookstore Item Number 43538

Technical Report No. 82: Low Endotoxin Recovery (2019)

TR 82 aims to describe the underlying mechanisms and contributing factors of Low Endotoxin Recovery (LER), summarize the potential clinical impact of the LER phenomenon, present guidelines for developing LER hold-time study design, and provide strategies for the mitigation of LER. Multiple case studies are provided to illustrate the complexity of the issue and highlight potential methods for remediation of LER.

| PDA Bookstore Item Number 43539

Technical Report No. 83: Virus Contamination in Biomanufacturing: Risk Mitigation, Preparedness, and Response (2019)

TR 83 describes proven, successful principles used and measures that can be taken to mitigate the risk of contamination by viruses and provides guidance in effective preparation and response should such an event occur in manufacturing processes which use in vitro mammalian or other eukaryotic cell cultures to produce biopharmaceutical products.

| PDA Bookstore Item Number 43541

Technical Report No. 84: Integrating Data Integrity Requirements into Manufacturing & Packing Operations (2020)

TR 84 addresses data integrity from the perspective of manufacturing operations. It discusses regulatory trends, risk management concepts, and recommendations for implementing appropriate data integrity controls in manufacturing operations applicable to paper-based, electronic-based, and hybrid systems. The case studies included in this technical report provide examples of how to assess current data integrity risks and implement the concepts presented in the report.

| PDA Bookstore Item Number 43547

Technical Report No. 85: Enhanced Test Methods for Visible Particle Detection and Enumeration on Elastomeric Closures and Glass Containers (2021)

TR 85 addresses test and inspection methods for visible particles in primary packaging components for injectable products, specifically glass vials and syringes, and the elastomeric closures used to seal them. This document is most relevant for ready-to-sterilize (RTS) and ready-to-use (RTU) components since these are not subjected to a further cleaning process immediately before use. These studies and methods were developed as part of a larger initiative to eliminate visible particles in injectable products. The test and inspection methods discussed within this report are the first step in a standard-setting process. Once test and inspection methods are available, accepted, and implemented, they can be used to assess process capability and establish meaningful process control limits.

| PDA Bookstore Item Number 43552

Technical Report No. 86: Industry Challenges and Current Technologies for Pharmaceutical Package Integrity Testing (2021)

TR 86 discusses the challenges encountered in using complex package systems for sterile drugs and biologics (e.g., syringes, syringe assemblies, bulk containers) and introduces important elements to consider in decision-making. It also presents information on some innovative methods for package integrity testing using existing technologies, including the potential impact of cryogenic conditions.

| PDA Bookstore Item Number 43553

Technical Report No. 87: Current Best Practices for Pharmaceutical Glass Vial Handling and Processing (2021)

TR 87 provides a technical understanding of glass, its strength, and its limitations, and to provide guidance in best handling practices for glass vials throughout the pharmaceutical process — receipt, storage, preparation, filling, stoppering, freeze-drying, and capping. This document focuses on glass vials, where surface damage may occur, and where excess stresses may be applied during processing and handling. Many of the principles discussed here can be applied to the handling of glass syringes, cartridges, ampoules, and other glass container types. This report also reviews typical pharmaceutical glass handling processes and identifies areas of concern. Points to consider are presented for line, material, and equipment enhancements as well as guidance and practical approaches for using procedural controls to better employ existing equipment.

| PDA Bookstore Item Number 43555

Technical Report No. 88: Microbial Data Deviation Investigations in the Pharmaceutical Industry (2022)

TR 88 presents a holistic approach for performing a microbiological investigation. It provides a framework to assist with focusing on the investigational areas that may contain or contribute to the root cause of data deviations, such as sampling, test methodology, and suitability of the test, as opposed to providing methods for analysis of batch acceptability. This technical report promotes a lifecycle approach, but greater emphasis is placed on laboratory and manufacturing investigations of marketed drug products. Microbial assays of antibiotics and vitamins and the detection and enumeration of protozoans, viruses, and prions are not included in the scope of this report. Additionally, batch disposition is separate from the outcome of a microbial investigation report.

| PDA Bookstore Item Number 43557

Technical Report No. 89: Strategies for Vaccine Development and Lifecycle Management (2023)

TR 89 describes different strategies that can be applied to manage the development and lifecycle of vaccine products. The concepts covered are intended to apply to different types of vaccines, and "real world" examples are provided for different types of vaccines. This report includes strategies that can be applied in early development to licensure and those that are focused on lifecycle management of marketed products (legacy products and novel pharmaceuticals). Specific aspects of control strategies that are particularly relevant to both prophylactic and therapeutic vaccines are covered in this report, including setting and managing specifications, managing process parameters with respect to classification and lifecycle management, and consideration of comparability requirements.

| PDA Bookstore Item Number 43563

Technical Report No. 90: Contamination Control Strategy Development in Pharmaceutical Manufacturing (2023)

TR 90 presents a holistic approach to contamination control principles, where the practices are designed to work together to achieve proactive contamination control and are evaluated for their collective effectiveness. The holistic approach also demands that contamination control measures be tailored to the specific risks around each individual process. This document focuses on contamination control practices against microbial and other adventitious agents, endotoxins, and foreign particulate matter in the manufacture of sterile drugs, low bioburden drug substances, and some nonsterile drugs that are vulnerable to contamination.

| PDA Bookstore Item Number 43564

Technical Report No. 91: Post-Approval Change Management and Implementation for Biologics and Pharmaceutical Drug Products — A User's Guide (2023)

TR 91 expands on the latest concepts and tools for improving PAC management, as published in ICH Q12. It provides a practical guide for the pharmaceutical industry on how to implement PACs within the framework of an effective PQS and in alignment with ICH quality guidelines. The information in this technical report focuses on chemistry, manufacturing, and controls (CMC) changes that can be applied to PACs for both small-molecule and large-molecule pharmaceutical products.

| PDA Bookstore Item Number 43567

PDA Points to Consider

PDA Points to Consider are consensus documents which reflect current industry best-practices and thinking regarding a particular topic. These documents are prepared by member-driven Teams comprised of content experts, including scientists and engineers working in the pharmaceutical/biopharmaceutical industry, regulatory authorities and academia. Access the current Points to Consider Library Online or via the PDA Bookstore

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Points to Consider No. 1: Aseptic Processing (2024)

This document provides points to consider on topics related to the physical environment in which aseptic processing is conducted, monitoring of that environment, cleanroom personnel, material transfer, aseptic-process simulation and validation, "modern" blow-fill-seal technology, cleaning, disinfection and sterilization, and critical utilities. It also includes points to consider on aspects of filter-integrity testing and water-for-injection (WFI) preparation.

| PDA Bookstore Item Number 43568

Points to Consider for Aging Facilities (2017)

This document takes into account the pharmaceutical industry's general thoughts and suggestions on how to identify and modernize aging facilities.

This document reviews:

- How to recognize that a facility is aging
- Impediments to modernization
- The business case for modernization
- Strategies for modernization
- The impact of changing standards
- How to slow the aging process
- The regulatory landscape

| PDA Bookstore Item Number 43534

Points to Consider for the Aseptic Processing of Sterile Pharmaceutical Products in Isolators (2020)

This document focuses on important regulatory and technical updates surrounding isolator design, validation, and operations for aseptic processing in terms of the two primary types of isolators - open and closed. It is organized by topics related to what to consider in designing and managing isolator systems, followed by relevant points to consider.

| PDA Bookstore Item Number 43543

Points to Consider for Sensitivity to Oxidation by Peroxide (2020)

This document addresses aspects related to the design, development, processing, instrumentation, materials, and equipment specific to issues with products sensitive to oxidation when exposed to H_2O_2. The material presented primarily applies to isolator systems, where vapor phase hydrogen peroxide (VPHP) or vaporized hydrogen peroxide (VHP) is used to decontaminate the system. General topics related to sterility assurance and development of the VHP decontamination process are not included, nor is cycle development from a sterility standpoint.

| PDA Bookstore Item Number 43544

Points to Consider for Risks Associated with Sterilizing Grade Filters and Sterilizing Filtration (2020)

This document describes the identification of the sterilizing filtration value stream throughout the process including the use of FTA and FMEA tools to identify, analyze, and evaluate risks, and the identification of risk controls intended to prevent sterilizing-grade filter failure. The overall risk to patient safety is discussed, focusing on the level of control over each identified risk.

| PDA Bookstore Item Number 43545

Points to Consider for Implementation of Pre-Use Post-Sterilization Integrity Testing (2020)

This document provides the reader with points to consider on how to best implement and execute a pre-use/post-sterilization integrity test (PUPSIT) of final, sterilizing grade liquid filters for products that are not terminally sterilized. The material addresses variations in filtration design, set-up, operation, process stream attributes, and manufacturing operational philosophies which have a significant impact on how PUPSIT is incorporated into a manufacturing process.

| PDA Bookstore Item Number 43546

Points to Consider in Remote and Hybrid GMP/GDP Inspections (2021)

This document examines advantages and best practices for planning and implementing all types of remote regulatory inspections, including desktop, virtual, and hybrid inspections. It describes best practices that will help all participants engage efficiently and avoid unnecessary or unexpected delays, stressors, or complications in the remote inspection process. The document also presents the complete results of a PDA global survey on biopharmaceutical manufacturing experiences related to remote inspections.

| PDA Bookstore Item Number 43554

Points to Consider for Microbial Control in ATMP Manufacturing (2022)

This Points-to-Consider document provides a summary of microbiological challenges for ATMP manufacturing and guidance on how to address these challenges based on the current state of technology, regulatory environment, and industry best practices. The PtC addresses ATMP process technologies from cell-free production of mRNA therapeutics to viral vector-induced in-vivo gene therapies to ex-vivo engineering of human cells for autologous or allogeneic cell therapies. The control aspects covered include facility design, equipment and instrumentation design and maintenance, analyst and operator gowning and qualification, and microbiological process monitoring.

| PDA Bookstore Item Number 43562

Points to Consider in Remote and Hybrid GMP/GDP Audits (2022)

This Points to Consider document describes steps that can be taken to ensure an effective and efficient remote assessment. It introduces standard nomenclature to describe the types of remote audits and discusses key considerations for their scheduling, duration, planning, conduct, closing, reporting, and follow up. The document is designed to assist both the auditor and auditee as they work through the challenges of remote and hybrid auditing and determine the changes in practices, standard operating procedures, and quality agreements that are necessary to facilitate effective and efficient remote audits.

| PDA Bookstore Item Number 43559

Points to Consider No. 9: Lessons Learned from the COVID-19 Pandemic (2023)

This document captures ideas and learnings that were considered important to the pharmaceutical manufacturing industry during the COVID-19 pandemic period when industry and regulators were looking for, and struggling with, how to move forward. In additions to addressing manufacturing, people, quality, regulatory considerations, and supply chain, this PtC captures a wide variety of topic areas and touches on points normally outside of PDA's normal purview, such as human resources, public policy, and employee transportation in order to provide a document that could be used to prepare for and respond to a similar pandemic if one was to occur in the future.

| PDA Bookstore Item Number 43569

PDA/ANSI Standards

PDA has been accredited as a standards developing organization by the American National Standards Institute (ANSI) since 2017. PDA's standards program focuses on documentary standards, building on the existing rigorous, volunteer expert-driven scientific process used to develop PDA's technical reports. PDA Standards are Intended to be Scientifically Derived Technical Standards. Examples Include:

- Material quality standards – this may describe tests, specifications, or data conversion on specified materials.
- Universal Process & procedure standards – This may be an agreed upon processes in the industry or agreed upon way of doing something.
- Format or Referencing standard – This could be an agreed upon list of definitions, nomenclature, or data formats to facilitate global harmonization in scientific language.
- Measurement/ Metrology standards – Supports harmonization in equipment use, statistical calculations, and formulas.

Access PDA Standards via the PDA Bookstore

ANSI/PDA Standard 001-2020: Enhanced Purchasing Controls to Support the Bio-Pharmaceutical, Pharmaceutical, Medical Devices and Combination Products Industries

A standard guidance for the selection and control of suppliers of purchased goods and services that can impact product quality and patient safety.

| PDA Bookstore Item Number 60000

ANSI/PDA Standard 02-2021: Cryopreservation of Cells for Use in Cell Therapies, Gene Therapies, and Regenerative Medicine Manufacturing

This standard provides guidance on how to establish suitable procedures for the cryopreservation and recovery of biological cells for use in cell and gene therapy products and regenerative medicine manufacturing either as an intermediate step or when cryopreservation is the final step. The guide emphasizes the effect cryopreservation and recovery may have on cell viability and cell function. It is not intended to provide information on the terms and procedures directly associated with regulatory requirements governing cell-based products. The best practices and guidance details outlined in the document provide general procedural support for cryopreservation of cell-based products during both early and late phases of product development.

| PDA Bookstore Item Number 60003

ANSI/PDA Standard 04-2021: Phage Retention Nomenclature Rating for Small- and Large-Virus Retentive Filters

This standard addresses the use of virus-removal filters that retain viruses by a size-exclusion mechanism. This document should be considered as a guide intended to provide filter suppliers with an approach to standardizing methodology and nomenclature for large- and small-virus retentive filters using bacteriophage as a model. The objective is to assist users/manufacturers in selecting the most appropriate filter for their specific application needs. This guidance is intended to:

- Provide detailed methods and acceptance criteria for testing bacteriophage (also referred to as phage) retention by large- and small-virus retentive filters,
- Provide methods for preparing and enumerating suitable sized bacteriophage (PP7 and PR772 as models for small and large viruses, respectively) as test items, and
- Guide selection of appropriately rated filters as defined by suppliers in a standardized manner using a risk-based approach.

This is not a substitute for process validation for viral clearance claims.

| PDA Bookstore Item Number 60001

ANSI/PDA Standard 05-2021: Consensus Method for Rating Filters for Mycoplasma Reduction

This standard describes a filter challenge test for standardizing test parameters across laboratories using 47 mm discs and using *A. laidlawii* as the test organism. While this standard is primarily to educate users and filter manufacturers about best practices for mycoplasma reduction filtration, this test is also to be used by the filter manufacturers to validate a mycoplasma-retentive filter within a manufacturing process and to qualify a filter for a mycoplasma retentive claim. The test gives mycoplasma retention a standard unit of measure so that different filters can be compared under the same conditions.

| PDA Bookstore Item Number 60002

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