# PDA Technical Documents

PDA BOOKSTORE

| No. | TITLE | | Paper Version | Digital Version |
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| | **PDA Technical Reports** | | | |
| 1 | Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control | Revised 2007 *(Published 1980)* | 01001 | 43381 |
| 3 | Validation of Dry Heat Processes Used for Depyrogenation and Sterilization | Revised 2013 *(Published 1981)* | 01003 | 43506 |
| 4 | Design Concepts For the Validation of a Water for Injection System **(Retired)** | 1983 | | 43209 |
| 5 | Sterile Pharmaceutical Packaging: Compatibility and Stability **(Retired)** | 1984 | | 43210 |
| 7 | Depyrogenation **(Retired)** | 1985 | | 43212 |
| 9 | Review of Commercially Available Particulate Measurement Systems **(Retired)** | 1988 | | 43214 |
| 10 | Parenteral Formulations of Proteins and Peptides: Stability and Stabilizers **(Retired)** | 1988 | | 43215 |
| 11 | Sterilization of Parenterals by Gamma Radiation **(Retired)** | 1988 | | 43216 |
| 12 | Siliconization of Parenteral Drug Packaging Components | 1988 | 01012 | 43217 |
| 13 | Fundamentals of an Environmental Monitoring Program | Revised 2014 *(Published 1990)* | 01013 | 43513 |
| 14 | Validation of Column-Based Chromatography Processes for the Purification of Proteins | Revised 2008 *(Published 1992)* | 01014 | 43220 |
| 15 | Validation of Tangential Flow Filtration in Biopharmaceutical Applications | Revised 2009 *(Published 1992)* | 01015 | 43221 |
| 16 | Effects of Gamma Irradiation on Elastomeric Closures **(Retired)** | 1992 | | 43222 |
| 17 | Current Practices in the Validation of Aseptic Processing -- 1992 **(Retired)** | 1993 | | 43223 |
| 18 | Validation of Computer-Related Systems **(Retired)** | 1995 | | 43224 |
| 19 | Rapid/Automated ID Methods Survey **(Retired)** | 1990 | | 43225 |
| 20 | Report on Survey of Current Industry Gowning Practices **(Retired)** | 1990 | | 41239 |
| 21 | Bioburden Recovery Validation **(Retired)** | 1990 | | 41258 |
| 22 | Process Simulation for Aseptically Filled Products | Revised 2011 *(Published 1996)* | | 43226 |
| 23 | Industry Survey on Current Sterile Filtration Practices **(Retired)** | 1997 | | 43227 |
| 24 | Current Practices in the Validation of Aseptic Processing **(Retired)** | 1997 | | 43228 |
| 25 | Blend Uniformity Analysis: Validation and In-Process Testing **(Retired)** | 1997 | | 43229 |
| 26 | Sterilizing Filtration of Liquids | Revised 2008 *(Published 1998)* | | 43230 |
| 27 | Pharmaceutical Package Integrity | 1998 | | 43231 |
| 28 | Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals | Revised 2006 *(Published 1998)* | 01028 | 43232 |
| 29 | Points to Consider for Cleaning Validation | Revised 2012 *(Published 1998)* | 01029 | 43501 |
| 30 | Parametric Release of Pharmaceuticals and Medical Device Products Terminally Sterilized by Moist Heat | Revised 2012 *(Published 1999)* | 01030 | 43234 |
| 31 | Validation and Qualification of Computerized Laboratory Data Acquisition Systems | 1999 | 01031 | 43235 |
| 32 | Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations **(Retired)** | Revised 2004 *(Published 1999)* | | 43236 |
| 33 | Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods | Revised 2013 *(Published 2000)* | 01033 | 43510 |
| 34 | Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products | 2001 | 01034 | 43239 |
| 35 | A Proposed Training Model for the Microbiological Function in the Pharmaceutical Industry **(Retired)** | 2001 | | 43240 |

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| 36 | Current Practices in the Validation of Aseptic Processing – 2001 **(Retired)** | 2002 | | 43241 |
| 38 | Manufacturing Chromatography Systems Postapproval Changes (ChromPAC): Chemistry, Manufacturing, and Controls Documentation | 2006 | 01038 | 43315 |
| 39 | Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment | 2007 | 01039 | 43312 |
| 40 | Sterilization Filtration of Gases | 2005 | 01040 | 43314 |
| 41 | Virus Filtration | 2008 | 01041 | 43313 |
| 42 | Process Validation of Protein Manufacturing | 2005 | 01042 | 43311 |
| 43 | Identification and Classification of Nonconformities in Molded and Tubular Glass Containers for Pharmaceutical Manufacturing: Covering Ampoules, Bottles, Cartridges, Syringes and Vials | Revised 2013 (Published 2007) | 01043 | 43508 |
| 44 | Quality Risk Management for Aseptic Processes | 2008 | 01044 | 43410 |
| 45 | Filtration of Liquids Using Cellulose-Based Depth Filters | 2008 | 01045 | 43422 |
| 46 | Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to the End User | 2009 | 01046 | 43485 |
| 47 | Preparation of Virus Spikes Used for Virus Clearance Studies | 2010 | 01047 | 43486 |
| 48 | Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance | 2010 | 01048 | 43487 |
| 49 | Points to Consider for Biotechnology Cleaning Validation | 2010 | 01049 | 43488 |
| 50 | Alternative Methods for Mycoplasma Testing | 2010 | 01050 | 43489 |
| 51 | Biological Indicators for Gas and Vapor-Phase Decontamination Processes: Specification, Manufacture, Control and Use | 2010 | 01051 | 43490 |
| 52 | Guidance for Good Distribution Practices (GDPs) For the Pharmaceutical Supply Chain | 2011 | 01052 | 43491 |
| 53 | Guidance for Industry: Stability Testing to Support Distribution of New Drug Products | 2011 | 01053 | 43492 |
| 54 | Implementation of Quality Risk Management For Pharmaceutical and Biotechnology Manufacturing Operations | 2012 | 01054 | 43493 |
| 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 | 01054-2 | 43504 |
| 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 | 01054-3 | 43511 |
| 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 | 01054-4 | 43518 |
| 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 | 01055 | 43494 |
| 56 | Application of Phase-Appropriate Quality System and cGMP to the Development of Therapeutic Protein Drug Substance (API or Biological Active Substance) | Revised 2016 (Published 2012) | 01056 | 43530 |
| 57 | Analytical Method Validation and Transfer for Biotechnology Products | 2012 | 01057 | 43497 |
| 57-2 | Analytical Method Development and Qualification for Biotechnology Products | 2015 | 01057-2 | 43519 |
| 58 | Risk Management for Temperature-Controlled Distribution | 2012 | 01058 | 43499 |
| 59 | Utilization of Statistical Methods for Production Monitoring | 2012 | 01059 | 43500 |
| 60 | Process Validation: A Lifecycle Approach | 2013 | 01060 | 43502 |
| 60-2 | Process Validation: A Lifecycle Approach Annex 1: Oral Solid Dosage/Semisolid Dosage Forms | 2017 | 01060-2 | 43532 |

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| 61 | Steam In Place | 2013 | 01061 | 43503 |
| 62 | Recommended Practices for Manual Aseptic Processes | 2013 | 01062 | 43505 |
| 63 | Quality Requirements for the Extemporaneous Preparation of Clinical Trial Materials | 2013 | 01063 | 43507 |
| 64 | Active Temperature-Controlled Systems: Qualification Guidance | 2013 | 01064 | 43509 |
| 65 | Technology Transfer | 2014 | 01065 | 43514 |
| 66 | Application of Single-Use Systems in Pharmaceutical Manufacturing | 2014 | 01066 | 43515 |
| 67 | Exclusion of Objectionable Microorganisms from Nonsterile Pharmaceuticals, Medical Devices, and Cosmetics | 2014 | 01067 | 43516 |
| 68 | Risk-Based Approach for Prevention and Management of Drug Shortages | 2014 | | 43517 |
| 69 | Bioburden and Biofilm Management in Pharmaceutical Manufacturing Operations | 2015 | 01069 | 43521 |
| 70 | Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities | 2015 | 01070 | 43522 |
| 71 | Emerging Methods for Virus Detection | 2015 | 01071 | 43523 |
| 72 | Passive Thermal Protection Systems for Global Distribution: Qualification and Operational Guidance | 2015 | 01072 | 43524 |
| 73 | Prefilled Syringe User Requirements for Biotechnology Applications | 2015 | 01073 | 43525 |
| 74 | Reprocessing of Biopharmaceuticals | 2016 | 01074 | 43526 |
| 75 | Consensus Method for Rating 0.1$\mu$m Mycoplasma Reduction Filters | 2016 | 01075 | 43528 |
| 76 | Identification and Classification of Visible Nonconformities in Elastomeric Components and Aluminum Seals for Parenteral Packaging | 2016 | 01076 | 43529 |
| 77 | The Manufacture of Sterile Pharmaceutical Products Using Blow-Fill-Seal Technology | 2017 | 01077 | 43531 |
| 54-5 | Quality Risk Management for the Design, Qualification, and Operation of Manufacturing Systems | 2017 | 01054-5 | 43533 |
| 78 | Particulate Matter in Oral Dosage Forms | 2017 | 01078 | 43535 |
| 79 | Particulate Matter Control in Difficult to Inspect Parenterals | 2018 | 01079 | 43536 |
| 80 | Data Integrity Management System for Pharmaceutical Laboratories | 2018 | 01080 | 43537 |
| 81 | Cell-Based Therapy Control Strategy | 2019 | 01081 | 43538 |

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| **PDA Points to Consider Paper** | | | |
| Points to Consider for Aseptic Processing - PDA Journal of Pharmaceutical Science and Technology: 2003 Supplement Volume 57 Issue 2 | **2003** | 03004 | 42148 |
| Points to Consider for Aseptic Processing: Part 1, January 2015 | **2015** | 03005 | 43520 |
| Points to Consider for Aseptic Processing: Part 2, May 2016 | **2016** | 03007 | 43527 |
| Points to Consider for Aging Facilities | **2017** | 03008 | 43534 |



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| **PDA Surveys** | | | |
| Risk Mitigation of Tribromoanisole (TBA)/Trichloroanisole (TCA) Taints and Odors: A Pharmaceutical Industry Benchmarking Survey | **2011** | | 45000 |
| Business Case for Pharmaceutical Quality | **2012** | | 45001 |
| Glass Quality: 2011 and 2012 Results and Comparison | **2013** | | 45002 |
| 2013 PDA Objectionable Microorganisms for Nonsterile Pharmaceutical, Consumer Health, Medical Devices, Dietary Supplement and Cosmetic Products | **2014** | | 45003 |
| 2014 PDA Process Validation Survey | **2014** | | 45004 |
| 2014 Quality Culture Metrics | **2015** | | 45005 |
| 2014 Visual Inspection | **2015** | | 45006 |
| 2015 Particulate Matter in Oral Dosage Forms | **2016** | | 45007 |
| 2015 Particulate Matter in Difficult to Inspect Parenterals | **2016** | | 45008 |
| 2015 Aging Facilities | **2016** | | 45009 |
| 2017 PDA Aseptic Processing Survey | **2017** | | 45010 |
| 2017 PDA PUPSIT Survey | **2017** | | 45011 |
| 2017 PDA Glass Quality Survey | **2018** | | 45012 |