# Standards Manager Web Standards List

## PDA-Parenteral Drug Association

| Id | Number | Title | Year | Organization | Page |
|---|---|---|---|---|---|
| 1 | TR 89 | Strategies for Vaccine Development and Lifecycle Management | 2023 | PDA | |
| 2 | TR 90 | Contamination Control Strategy Development in Pharmaceutical Manufacturing | 2023 | PDA | |
| 3 | TR 88 | Microbial Data Deviation Investigations in the Pharmaceutical Industry | 2022 | PDA | |
| 4 | TR 13 | Fundamentals of an Environmental Monitoring Program | 2022 | PDA | |
| 5 | TR 41 | Virus Filtration | 2022 | PDA | |
| 6 | TR 65 | Technology Transfer | 2022 | PDA | |
| 7 | TR 60-3 | Process Validation: A Lifecycle Approach Annex 2: Biopharmaceutical Drug Substances Manufacturing | 2021 | PDA | |
| 8 | TR 39 | Guidance for Temperature-Controlled Medicinal Products - Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment | 2021 | PDA | |
| 9 | TR 85 | Enhanced Test Methods for Visible Particle Detection and Enumeration on Elastomeric Closures and Glass Containers | 2021 | PDA | |
| 10 | TR 86 | Industry Challenges and Current Technologies for Pharmaceutical Package Integrity Testing | 2021 | PDA | |
| 11 | TR 87 | Current Best Practices for Pharmaceutical Glass Vial Handling and Processing | 2021 | PDA | |
| 12 | TR 84 | Integrating Data Integrity Requirements into Manufacturing & Packaging Operations | 2020 | PDA | |
| 13 | TR 13-2 | Fundamentals of an Environmental Monitoring Program Annex 1: Environmental Monitoring of Facilities Manufacturing Low Bioburden Products | 2020 | PDA | |
| 14 | TR 82 | Low Endotoxin Recovery | 2019 | PDA | |
| 15 | TR 80 | Data Integrity Management System for Pharmaceutical Laboratories | 2018 | PDA | |
| 16 | TR 81 | Cell-Based Therapy Control Strategy | 2018 | PDA | |
| 17 | TR 54-5 | Quality Risk Management for the Design, Qualification, and Operation of Manufacturing Systems | 2017 | PDA | |
| 18 | TR 77 | The Manufacture of Sterile Pharmaceutical Products Using Blow-Fill-Seal Technology | 2017 | PDA | |
| 19 | TR 74 | Reprocessing of Biopharmaceuticals | 2016 | PDA | |
| 20 | TR 76 | Identification and Classification of Visible Nonconformities in Elastomeric Components and Aluminum Seals for Parenteral Packaging | 2016 | PDA | |
| 21 | TR 56 | Application of Phase-Appropriate Quality System and cGMP to the Development of Therapeutic Protein Drug Substance (API or Biological Active Substance) | 2016 | PDA | |
| 22 | TR 57-2 | Analytical Method Development and Qualification for Biotechnology Products | 2015 | PDA | |
| 23 | TR 69 | Bioburden and Biofilm Management in Pharmaceutical Manufacturing Operations | 2015 | PDA | |
| 24 | TR 70 | Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities | 2015 | PDA | |
| 25 | TR 71 | Emerging Methods for Virus Detection | 2015 | PDA | |
| 26 | TR 72 | Passive Thermal Protection Systems for Global Distribution: Qualification and Operational Guidance | 2015 | PDA | |
| 27 | TR 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 | PDA | |
| 28 | TR 65 | Technology Transfer | 2014 | PDA | |
| 29 | TR 66 | Application of Single-Use Systems in Pharmaceutical Manufacturing | 2014 | PDA | |
| 30 | TR 67 | Exclusion of Objectionable Microorganisms from Nonsterile Pharmaceuticals, Medical Devices, and Cosmetics | 2014 | PDA | |
| 31 | TR 68 | Risk-Based Approach for Prevention and Management of Drug Shortages | 2014 | PDA | |
| 32 | TR 13 | Fundamentals of an Environmental Monitoring Program | 2014 | PDA | |
| 33 | TR 3 | Validation of Dry Heat Processes Used for Depyrogenation and Sterilization | 2013 | PDA | |

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| 34 | TR 43 | Identification and Classification of Nonconformities in Moulded and Tubular Glass Containers for Pharmaceutical Manufacturing | 2013 | PDA | |
| 35 | TR 33 | Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods | 2013 | PDA | |
| 36 | TR 60 | Process Validation: A Lifecycle Approach | 2013 | PDA | |
| 37 | TR 62 | Recommended Practices for Manual Aseptic Processes | 2013 | PDA | |
| 38 | TR 63 | Quality Requirements for the Extemporaneous Preparation of Clinical Trial Materials | 2013 | PDA | |
| 39 | TR 64 | Active Temperature-Controlled Systems: Qualification Guidance | 2013 | PDA | |
| 40 | TR 54-2 | Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operation: Annex 1: Case Study Examples for Quality Risk Management in Packaging and Labeling | 2013 | PDA | |
| 41 | TR 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 | PDA | |
| 42 | TR 57 | Analytical Method Validation and Transfer for Biotechnology Products | 2012 | PDA | |
| 43 | TR 59 | Utilization of Statistical Methods for Production Monitoring | 2012 | PDA | |
| 44 | TR 54 | Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations | 2012 | PDA | |
| 45 | TR 29 | Points to Consider for Cleaning Validation | 2012 | PDA | |
| 46 | TR 22 | Process Simulation for Aseptically Filled Products | 2011 | PDA | |
| 47 | TR 52 | Guidance for Good Distribution Practices (GDPs) For the Pharmaceutical Supply Chain | 2011 | PDA | |
| 48 | TR 53 | Guidance for Industry: Stability Testing to Support Distribution of New Drug Products | 2011 | PDA | |
| 49 | TR 47 | Preparation of Virus Spikes Used for Virus Clearance Studies | 2010 | PDA | |
| 50 | TR 48 | Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance | 2010 | PDA | |
| 51 | TR 49 | Points to Consider for Biotechnology Cleaning Validation | 2010 | PDA | |
| 52 | TR 50 | Alternative Methods for Mycoplasma Testing | 2010 | PDA | |
| 53 | TR 51 | Biological Indicators for Gas and Vapor-Phase Decontamination Processes: Specification, Manufacture, Control and Use | 2010 | PDA | |
| 54 | TR 15 | Validation of Tangential Flow Filtration in Biopharmaceutical Applications | 2009 | PDA | |
| 55 | TR 46 | Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to the End User | 2009 | PDA | |
| 56 | TR 44 | Quality Risk Management for Aseptic Processes | 2008 | PDA | |
| 57 | TR 26 | Sterilizing Filtration of Liquids | 2008 | PDA | |
| 58 | TR 14 | Validation of Column-Based Chromatography Processes for the Purification of Proteins | 2008 | PDA | |
| 59 | TR 1 | Validation of Moist Heat Sterilization Processes: Cycle Design, Development | 2007 | PDA | |
| 60 | TR 39 | Guidance for Temperature-Controlled Medicinal Products - Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment | 2007 | PDA | |
| 61 | TR 38 | Manufacturing Chromatography Systems Postapproval Changes (ChromPAC): Chemistry, Manufacturing and Controls Documentation | 2006 | PDA | |
| 62 | TR 40 | Sterilizing Filtration of Gases | 2005 | PDA | |
| 63 | TR 41 | Virus Filtration | 2005 | PDA | |
| 64 | TR 42 | Process validation of protein manufacturing. Parenteral drug Association | 2005 | PDA | |
| 65 | TR 3 | Validation of Dry Heat Processes Used for Depyrogenation and Sterilization | 2005 | PDA | |
| 66 | TR 32 | Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations | 2004 | PDA | |
| 67 | TR 36 | Current Practices in the Validation of Aseptic Processing | 2002 | PDA | |
| 68 | TR 34 | Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products | 2001 | PDA | |
| 69 | TR 33 | Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods | 2000 | PDA | |
| 70 | TR 27 | Pharmaceutical Package Integrity | 1998 | PDA | |
| 71 | TR 25 | Uniformity Analysis: Validation and In-Process Testing | 1998 | PDA | |

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| 72 | TR 24 | Current Practices in the Validation of Aseptic Processing | 1997 | PDA | |
| 73 | TR 17 | Current Practices in the Validation of Aseptic Processing | 1992 | PDA | |
| 74 | TR 9 | Review of Commercially Available Particulate Measurement Systems | 1988 | PDA | |
| 75 | TR 12 | Siliconization of Parenteral Drug Packaging Components | 1988 | PDA | |
| 76 | TR 7 | Depyrogenation | 1985 | PDA | |
| 77 | TR 3 | Validation of Dry Heat Processes Used for Depyrogenation and Sterilization | 1981 | PDA | |