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	0
2	TR 90	Contamination Control Strategy Development in Pharmaceutical Manufacturing	2023	PDA	0
3	TR 91	Post-Approval Change Management and Implementation for Biologics and Pharmaceutical Drug Products ù A Users̊ Guide	2023	PDA	
4	TR 88	Microbial Data Deviation Investigations in the Pharmaceutical Industry	2022	PDA	0
5	TR 13	Fundamentals of an Environmental Monitoring Program	2022	PDA	0
6	TR 41	Virus Filtration	2022	PDA	0
7	TR 65	Technology Transfer	2022	PDA	0
8	TR 60-3	Process Validation: A Lifecycle Approach Annex 2: Biopharmaceutical Drug Substances Manufacturing	2021	PDA	0
9	TR 39	Guidance for Temperature-Controlled Medicinal Products - Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment	2021	PDA	0
10	TR 85	Enhanced Test Methods for Visible Particle Detection and Enumeration on Elastomeric Closures and Glass Containers	2021	PDA	0
11	TR 86	Industry Challenges and Current Technologies for Pharmaceutical Package Integrity Testing	2021	PDA	0
12	TR 87	Current Best Practices for Pharmaceutical Glass Vial Handling and Processing	2021	PDA	0
13	TR 84	Integrating Data Integrity Requirements into Manufacturing & Packaging Operations	2020	PDA	0
14	TR 13-2	Fundamentals of an Environmental Monitoring Program Annex 1: Environmental Monitoring of Facilities Manufacturing Low Bioburden Products	2020	PDA	0
15	TR 82	Low Endotoxin Recovery	2019	PDA	0
16	TR 79		2018	PDA	
17	TR 80	Data Integrity Management System for Pharmaceutical Laboratories	2018	PDA	0
18	TR 81	Cell-Based Therapy Control Strategy	2018	PDA	0
19	TR 54-5	Quality Risk Management for the Design, Qualification, and Operation of Manufacturing Systems	2017	PDA	0
20	TR 77	The Manufacture of Sterile Pharmaceutical Products Using Blow-Fill-Seal Technology	2017	PDA	0
21	TR 60-2	Process Validation: A Lifecycle Approach	2017	PDA	
22	TR 75	Consensus Method for Rating 0.1 ?m Mycoplasma Reduction Filters	2016	PDA	
23	TR 74	Reprocessing of Biopharmaceuticals	2016	PDA	0
24	TR 76	Identification and Classification of Visible Nonconformities in Elastomeric Components and Aluminum Seals for Parenteral Packaging	2016	PDA	0
25	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	0
26	TR 57-2	Analytical Method Development and Qualification for Biotechnology Products	2015	PDA	0
27	TR 69	Bioburden and Biofilm Management in Pharmaceutical Manufacturing Operations	2015	PDA	0
28	TR 70	Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities	2015	PDA	0
29	TR 71	Emerging Methods for Virus Detection	2015	PDA	0
30	TR 72	Passive Thermal Protection Systems for Global Distribution: Qualification and Operational Guidance	2015	PDA	0
31	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	0
32	TR 65	Technology Transfer	2014	PDA	0
33	TR 66	Application of Single-Use Systems in Pharmaceutical Manufacturing	2014	PDA	0

34	TR 67	Exclusion of Objectionable Microorganisms from Nonsterile Pharmaceuticals, Medical Devices, and Cosmetics	2014	PDA	0
35	TR 68	Risk-Based Approach for Prevention and Management of Drug Shortages	2014	PDA	0
36	TR 13	Fundamentals of an Environmental Monitoring Program	2014	PDA	0
37	TR 3	Validation of Dry Heat Processes Used for Depyrogenation and Sterilization	2013	PDA	0
38	TR 43	Identification and Classification of Nonconformities in Moulded and Tubular Glass Containers for Pharmaceutical Manufacturing	2013	PDA	0
39	TR 33	Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods	2013	PDA	0
40	TR 60	Process Validation: A Lifecycle Approach	2013	PDA	0
41	TR 62	Recommended Practices for Manual Aseptic Processes	2013	PDA	0
42	TR 63	Quality Requirements for the Extemporaneous Preparation of Clinical Trial Materials	2013	PDA	0
43	TR 64	Active Temperature-Controlled Systems: Qualification Guidance	2013	PDA	0
44	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	0
45	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	0
46	TR 61	Steam In Place	2013	PDA	
47	TR 57	Analytical Method Validation and Transfer for Biotechnology Products	2012	PDA	0
48	TR 59	Utilization of Statistical Methods for Production Monitoring	2012	PDA	0
49	TR 54	Implementation of Quality Risk Management for Pharmaceutical and Biotechnology Manufacturing Operations	2012	PDA	0
50	TR 29	Points to Consider for Cleaning Validation	2012	PDA	0
51	TR 22	Process Simulation for Aseptically Filled Products	2011	PDA	0
52	TR 52	Guidance for Good Distribution Practices (GDPs) For the Pharmaceutical Supply Chain	2011	PDA	0
53	TR 53	Guidance for Industry: Stability Testing to Support Distribution of New Drug Products	2011	PDA	0
54	TR 47	Preparation of Virus Spikes Used for Virus Clearance Studies	2010	PDA	0
55	TR 48	Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance	2010	PDA	0
56	TR 49	Points to Consider for Biotechnology Cleaning Validation	2010	PDA	0
57	TR 50	Alternative Methods for Mycoplasma Testing	2010	PDA	0
58	TR 51	Biological Indicators for Gas and Vapor-Phase Decontamination Processes: Specification, Manufacture, Control and Use	2010	PDA	0
59	TR 15	Validation of Tangential Flow Filtration in Biopharmaceutical Applications	2009	PDA	0
60	TR 46	Last Mile: Guidance for Good Distribution Practices for Pharmaceutical Products to the End User	2009	PDA	0
61	TR 44	Quality Risk Management for Aseptic Processes	2008	PDA	0
62	TR 26	Sterilizing Filtration of Liquids	2008	PDA	0
63	TR 14	Validation of Column-Based Chromatography Processes for the Purification of Proteins	2008	PDA	0
64	TR 1	Validation of Moist Heat Sterilization Processes: Cycle Design, Development	2007	PDA	0
65	TR 39	Guidance for Temperature-Controlled Medicinal Products - Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment	2007	PDA	0
66	TR 38	Manufacturing Chromatography Systems Postapproval Changes (ChromPAC): Chemistry, Manufacturing and Controls Documentation	2006	PDA	0
67	TR 40	Sterilizing Filtration of Gases	2005	PDA	0
68	TR 41	Virus Filtration	2005	PDA	0
69	TR 42	Process validation of protein manufacturing. Parenteral drug Association	2005	PDA	0
70	TR 3	Validation of Dry Heat Processes Used for Depyrogenation and Sterilization	2005	PDA	0
71	TR 32	Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations	2004	PDA	0

72	TR 36	Current Practices in the Validation of Aseptic Processing	2002	PDA	0
73	TR 34	Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products	2001	PDA	0
74	TR 33	Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods	2000	PDA	0
75	TR 27	Pharmaceutical Package Integrity	1998	PDA	0
76	TR 25	Uniformity Analysis: Validation and In-Process Testing	1998	PDA	0
77	TR 24	Current Practices in the Validation of Aseptic Processing	1997	PDA	0
78	TR 17	Current Practices in the Validation of Aseptic Processing	1992	PDA	0
79	TR 9	Review of Commercially Available Particulate Measurement Systems	1988	PDA	0
80	TR 12	Siliconization of Parenteral Drug Packaging Components	1988	PDA	0
81	TR 7	Depyrogenation	1985	PDA	0
82	TR 3	Validation of Dry Heat Processes Used for Depyrogenation and Sterilization	1981	PDA	0