



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

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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	43315
39	Guidance for Temperature-Controlled Medicinal Products — Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment	2021	43556
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)	43508
44	Quality Risk Management for Aseptic Processes	2008	01044 43410
45	Filtration of Liquids Using Cellulose-Based Depth Filters	2008	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	43486
48	Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance	2010	43487
49	Points to Consider for Biotechnology Cleaning Validation	2010	43488
50	Alternative Methods for Mycoplasma Testing	2010	43489
51	Biological Indicators for Gas and Vapor-Phase Decontamination Processes: Specification, Manufacture, Control and Use	2010	43490
52	Guidance for Good Distribution Practices (GDPs) For the Pharmaceutical Supply Chain	2011	43491
53	Guidance for Industry: Stability Testing to Support Distribution of New Drug Products	2011	43492
54	Implementation of Quality Risk Management For Pharmaceutical and Biotechnology Manufacturing Operations	2012	43493
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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	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	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	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)	43530
57	Analytical Method Validation and Transfer for Biotechnology Products	2012	43497
57-2	Analytical Method Development and Qualification for Biotechnology Products	2015	43519
58	Risk Management for Temperature-Controlled Distribution	2012	43499
59	Utilization of Statistical Methods for Production Monitoring	2012	43500
60	Process Validation: A Lifecycle Approach	2013	43502
60-2	Process Validation: A Lifecycle Approach Annex 1: Oral Solid Dosage/Semisolid Dosage Forms	2017	43532

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61	Steam In Place	2013	43503
62	Recommended Practices for Manual Aseptic Processes	2013	43505
63	Quality Requirements for the Extemporaneous Preparation of Clinical Trial Materials	2013	43507
64	Active Temperature-Controlled Systems: Qualification Guidance	2013	43509
65	Technology Transfer	2014	43514
66	Application of Single-Use Systems in Pharmaceutical Manufacturing	2014	43515
67	Exclusion of Objectionable Microorganisms from Nonsterile Pharmaceuticals, Medical Devices, and Cosmetics	2014	43516
68	Risk-Based Approach for Prevention and Management of Drug Shortages	2014	43517
69	Bioburden and Biofilm Management in Pharmaceutical Manufacturing Operations	2015	43521
70	Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities	2015	43522
71	Emerging Methods for Virus Detection	2015	43523
72	Passive Thermal Protection Systems for Global Distribution: Qualification and Operational Guidance	2015	43524
73	Prefilled Syringe User Requirements for Biotechnology Applications	2015	43525
74	Reprocessing of Biopharmaceuticals	2016	43526
75	Consensus Method for Rating 0.1µm Mycoplasma Reduction Filters	2016	43528
76	Identification and Classification of Visible Nonconformities in Elastomeric Components and Aluminum Seals for Parenteral Packaging	2016	43529
77	The Manufacture of Sterile Pharmaceutical Products Using Blow-Fill-Seal Technology	2017	43531
54-5	Quality Risk Management for the Design, Qualification, and Operation of Manufacturing Systems	2017	43533
78	Particulate Matter in Oral Dosage Forms	2017	43535
79	Particulate Matter Control in Difficult to Inspect Parenterals	2018	43536
80	Data Integrity Management System for Pharmaceutical Laboratories	2018	43537
81	Cell-Based Therapy Control Strategy	2019	43538
82	Low Endotoxin Recovery	2019	43539
83	Virus Contamination in Biomanufacturing: Risk Mitigation, Preparedness, and Response	2019	43541
54-6	Formalized Risk Assessment for Excipients	2019	43542
84	Integrating Data Integrity Requirements into Manufacturing & Packing Operations	2020	43547
13-2	Fundamentals of an Environmental Monitoring Program Annex 1	2020	43549
60-3	Process Validation: A Lifecycle Approach Annex 2: Biopharmaceutical Drug Substances Manufacturing	2021	43551
85	Enhanced Test Methods for Visible Particle Detection and Enumeration on Elastomeric Closures and Glass Containers	2021	43552
86	Industry Challenges and Current Technologies for Pharmaceutical Package Integrity Testing	2021	43553
87	Current Best Practices for Pharmaceutical Glass Vial Handling and Processing	2021	43555
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