



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>01003</u>	<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>01012</u>	<u>43217</u>
13	Fundamentals of an Environmental Monitoring Program	Revised 2014 <i>(Published 1990)</i>	<u>01013</u>	<u>43513</u>
14	Validation of Column-Based Chromatography Processes for the Purification of Proteins	Revised 2008 <i>(Published 1992)</i>	<u>01014</u>	<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>01028</u>	<u>43232</u>
29	Points to Consider for Cleaning Validation	Revised 2012 <i>(Published 1998)</i>	<u>01029</u>	<u>43501</u>
30	Parametric Release of Pharmaceuticals and Medical Device Products Terminally Sterilized by Moist Heat	Revised 2012 <i>(Published 1999)</i>	<u>01030</u>	<u>43234</u>
31	Validation and Qualification of Computerized Laboratory Data Acquisition Systems	1999	<u>01031</u>	<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>01033</u>	<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	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
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71	Emerging Methods for Virus Detection	2015	01071 43523
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73	Prefilled Syringe User Requirements for Biotechnology Applications	2015	01073 43525
74	Reprocessing of Biopharmaceuticals	2016	01074 43526
75	Consensus Method for Rating 0.1µm 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



