

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

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

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



