PDA Technical Documents

PDA BOOKSTORE

No.	TITLE		Paper Version	Digital Version
	PDA Technical Reports/Points To Consider			
1	Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control	Revised 2007 *(Published 1980)*	01001	43381
3	Validation of Dry Heat Processes Used for Depyrogenation and Sterilization	Revised 2013 *(Published 1981)*	01003	43506
4	Design Concepts For the Validation of a Water for Injection System (discontinued)	1983		
5	Sterile Pharmaceutical Packaging: Compatibility and Stability	1984	01005	43210
7	Depyrogenation (discontinued)	1985		
9	Review of Commercially Available Particulate Measurement Systems (discontinued)	1988		
10	Parenteral Formulations of Proteins and Peptides: Stability and Stabilizers	1988	01010	43215
11	Sterilization of Parenterals by Gamma Radiation	1988	01011	43216
12	Siliconization of Parenteral Drug Packaging Components	1988	01012	43217
13	Fundamentals of an Environmental Monitoring Program	Revised 2014 *(Published 1990)*	01013	43513
14	Validation of Column-Based Chromatography Processes for the Purification of Proteins	Revised 2008 *(Published 1992)*	01014	43220
15	Validation of Tangential Flow Filtration in Biopharmaceutical Applications	Revised 2009 *(Published 1992)*	01015	43221
16	Effects of Gamma Irradiation on Elastomeric Closures	1992	01016	43222
17	Current Practices in the Validation of Aseptic Processing -- 1992 (discontinued)	1993		
18	Validation of Computer-Related Systems (discontinued)	1995		
19	Rapid/Automated ID Methods Survey	1990	01019	43225
20	Report on Survey of Current Industry Gowning Practices	1990	01020	41239
21	Bioburden Recovery Validation (discontinued)	1990		
22	Process Simulation for Aseptically Filled Products	Revised 2011 *(Published 1996)*		43226
23	Industry Survey on Current Sterile Filtration Practices (discontinued)	1997		
24	Current Practices in the Validation of Aseptic Processing (discontinued)	1997		
25	Blend Uniformity Analysis: Validation and In-Process Testing (discontinued)	1997		
26	Sterilizing Filtration of Liquids	Revised 2008 *(Published 1998)*		43230
27	Pharmaceutical Package Integrity	1998		43231
28	Process Simulation Testing for Sterile Bulk Pharmaceutical Chemicals	Revised 2006 *(Published 1998)*	01028	43232
29	Points to Consider for Cleaning Validation	Revised 2012 *(Published 1998)*	01029	43501
30	Parametric Release of Pharmaceuticals and Medical Device Products Terminally Sterilized by Moist Heat	Revised 2012 *(Published 1999)*	01030	43234
31	Validation and Qualification of Computerized Laboratory Data Acquisition Systems	1999	01031	43235
32	Auditing of Suppliers Providing Computer Products and Services for Regulated Pharmaceutical Operations (discontinued)	Revised 2004 *(Published 1999)*		
33	Evaluation, Validation and Implementation of Alternative and Rapid Microbiological Methods	Revised 2013 *(Published 2000)*	01033	43510
34	Design and Validation of Isolator Systems for the Manufacturing and Testing of Health Care Products	2001	01034	43239
35	A Proposed Training Model for the Microbiological Function in the Pharmaceutical Industry	2001	01035	43240

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36	Current Practices in the Validation of Aseptic Processing – 2001 (discontinued)	2002		
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
	Points to Consider for Aseptic Processing: Part 1, January 2015	2015	03005	43520
69	Bioburden and Biofilm Management in Pharmaceutical Manufacturing Operations	2015	01069	43521
70	Fundamentals of Cleaning and Disinfection Programs for Aseptic Manufacturing Facilities	2015	01070	43522
71	Emerging Methods for Virus Detection	2015	01071	43523
72	Passive Thermal Protection Systems for Global Distribution: Qualification and Operational Guidance	2015	01072	43524
73	Prefilled Syringe User Requirements for Biotechnology Applications	2015	01073	43525
	Points to Consider for Aseptic Processing: Part 2, May 2016	2016	03007	43527
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

TITLE		Paper Version	Digital Version
PDA Surveys			
Risk Mitigation of Tribromoanisole (TBA)/Trichloroanisole (TCA) Taints and Odors: A Pharmaceutical Industry Benchmarking Survey	**2011**		45000
Business Case for Pharmaceutical Quality	**2012**		45001
Glass Quality: 2011 and 2012 Results and Comparison	**2013**		45002
2013 PDA Objectionable Microorganisms for Nonsterile Pharmaceutical, Consumer Health, Medical Devices, Dietary Supplement and Cosmetic Products	**2014**		45003
2014 PDA Process Validation Survey	**2014**		45004
2014 Quality Culture Metrics	**2015**		45005
2014 Visual Inspection	**2015**		45006
2015 Particulate Matter in Oral Dosage Forms	**2016**		45007
2015 Particulate Matter in Difficult to Inspect Parenterals	**2016**		45008
2015 Aging Facilities	**2016**		45009