

Standards Manager Web Standards List
ISPE-International Society for Pharmaceutical Engineering

Id	Number	Title	Year	Organization	Page
1		Baseline Guide - Pharma 4.0	2023	ISPE	0
2		Baseline Guide volume 6 - Biopharmaceutical Manufacturing Facilities	2023	ISPE	0
3		Drug Shortages Prevention Model	2023	ISPE	0
4		Good Practice Guide - Process Gases	2023	ISPE	0
5		Guide - 503B Compounding - Regulatory basis and industry good practices for outsourcing facilities	2023	ISPE	0
6		Report on ISPE work to support establishment of the EU Health Emergency Preparedness and Response Authority (HERA)	2023	ISPE	0
7		Good Practice Guide - Membrane-Based Water for Injection Systems	2022	ISPE	0
8		Good Practice Guide - Containment for Potent Compounds	2022	ISPE	0
9		Good Practice Guide - Continuous Manufacturing of Oral Solid Dosage Forms	2022	ISPE	0
10		GAMP 5 Guide - A Risk-Based Approach to Compliant GxP Computerized Systems	2022	ISPE	0
11		APQ Guide Series - Process Performance and Product Quality Monitoring System	2022	ISPE	0
12		APQ Guide - Change Management System	2022	ISPE	0
13		APQ Guide - Cultural Excellence	2022	ISPE	0
14		APQ Guide - Management responsibilities and management review	2021	ISPE	0
15		GAMP Good Practice Guide - Enabling Innovation	2021	ISPE	0
16		Good Practice Guide - Controlled Temperature Chambers	2021	ISPE	0
17		Good Practice Guide - Good Engineering Practice	2021	ISPE	0
18		Good Practice Guide - Investigational Medicinal Product Reverse Logistics	2021	ISPE	0
19		Good Practice Guide - Knowledge Management in the Pharmaceutical Industry	2021	ISPE	0
20		Good Practice Guide - Maintenance	2021	ISPE	0
21		Guide - Advanced Therapy Medicinal Products - Autologous Cell Therapy	2021	ISPE	0
22		Guide - Cleaning Validation Lifecycle - Applications, Methods, and Controls	2020	ISPE	0
23		Increasing Domestic Resiliency in the Supply of Essential Active Pharmaceutical Ingredients	2020	ISPE	0
24		Good Practice Guide - Equipment Reliability	2020	ISPE	0
25		Good Practice Guide - Critical Utilities GMP Compliance	2020	ISPE	0
26		GAMP RDI Good Practice Guide - Data Integrity by Design	2020	ISPE	0
27		APQ Guide Series - Corrective Action and Preventive Action (CAPA) System	2020	ISPE	0
28		Baseline Guide volume 4 - Water and Steam Systems	2019	ISPE	0
29		Baseline Guide volume 5 - Commissioning and Qualification	2019	ISPE	0
30		GAMP RDI Good Practice Guide - Data Integrity - Manufacturing Records	2019	ISPE	0
31		Good Practice Guide - Asset Management	2019	ISPE	0
32		Good Practice Guide - HVAC and Process Equipment Air Filters	2019	ISPE	0
33		Good Practice Guide - Practical Implementation of the Lifecycle Approach to Process Validation	2019	ISPE	0
34		Good Practice Guide - Single-Use Technology	2018	ISPE	0
35		Good Practice Guide - Technology Transfer	2018	ISPE	0
36		GAMP RDI Good Practice Guide - Data Integrity - Key Concepts	2018	ISPE	0

37		Baseline Guide volume 3 - Sterile Product Manufacturing Facilities	2018	ISPE	0
38		Cultural Excellence Report	2017	ISPE	0
39		GAMP Good Practice Guide - Global Information Systems Control and Compliance	2017	ISPE	0
40		GAMP Good Practice Guide - IT Infrastructure Control and Compliance	2017	ISPE	0
41		GAMP Good Practice Guide - Validation and Compliance of Computerized GCP Systems and Data	2017	ISPE	0
42		GAMP Guide - Records and Data Integrity	2017	ISPE	0
43		Baseline Guide volume 7 - Risk-Based Manufacture of Pharmaceutical Products	2017	ISPE	0
44		Good Practice Guide - Decommissioning of Pharmaceutical Equipment and Facilities	2017	ISPE	0
45		Good Practice Guide - Sampling for Pharmaceutical Water, Steam, and Process Gases	2016	ISPE	0
46		Good Practice Guide - Management of Engineering Standards	2016	ISPE	0
47		Good Practice Guide - Operations Management	2016	ISPE	0
48		Baseline Guide volume 2 - Oral Solid Dosage Forms	2016	ISPE	0
49		Handbook - Sustainability	2015	ISPE	0
50		GAMP Good Practice Guide - A Risk-Based Approach to Regulated Mobile Applications	2014	ISPE	0
51		Good Practice Guide - Approaches to Commissioning and Qualification of Pharmaceutical Water and Steam Systems	2014	ISPE	0
52		Good Practice Guide - Clinical Supply Systems	2014	ISPE	0
53		Good Practice Guide - Harmonizing the Definition and Use of Non-Investigational Medicinal Products (NIMPs)	2013	ISPE	0
54		Good Practice Guide - Booklet Labels	2013	ISPE	0
55		Guide - Biopharmaceutical Process Development and Manufacturing	2013	ISPE	0
56		Guide Series PQLI Part 3 - Change Management System as a Key Element of a Pharmaceutical Quality System	2012	ISPE	0
57		Guide Series PQLI Part 4 - Process Performance and Product Quality Monitoring System	2012	ISPE	0
58		Good Practice Guide - Assessing the particulate containment performance of pharmaceutical equipment	2012	ISPE	0
59		Good Practice Guide - Comparator Management	2012	ISPE	0
60		Good Practice Guide - Ozone Sanitization of Pharmaceutical Water Systems	2012	ISPE	0
61		Good Practice Guide - Packaging, Labeling, and Warehousing Facilities	2012	ISPE	0
62		Good Practice Guide - Quality Laboratory Facilities	2012	ISPE	0
63		GAMP Good Practice Guide - A Risk-Based Approach to Testing of GxP Systems	2012	ISPE	0
64		GAMP Good Practice Guide - A Risk-Based Approach to GxP Compliant Laboratory Computerized Systems	2012	ISPE	0
65		GAMP Good Practice Guide - A Risk-Based Approach to GxP Process Control Systems	2011	ISPE	0
66		Good Practice Guide - Applied Risk Management for Commissioning and Qualification	2011	ISPE	0
67		Good Practice Guide - Process Gases	2011	ISPE	0
68		Good Practice Guide - Project Management for the Pharmaceutical Industry	2011	ISPE	0
69		Good Practice Guide - Cold Chain Management	2011	ISPE	0
70		Good Practice Guide - Interactive Response Technology	2011	ISPE	0
71		Guide - Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment	2011	ISPE	0
72		Guide Series PQLI Part 1 - Product Realization using Quality by Design (QbD) - Concepts and Principles	2011	ISPE	0
73		Guide Series PQLI Part 2 - Product Realization using Quality by Design (QbD) - Illustrative Example	2011	ISPE	0
74		GAMP Good Practice Guide - Manufacturing Execution Systems - A Strategic and Program Management Approach	2010	ISPE	0
75		GAMP Good Practice Guide - A Risk-Based Approach to Calibration Management	2010	ISPE	0
76		GAMP Good Practice Guide - A Risk-Based Approach to Operation of GxP Computerized Systems	2009	ISPE	0
77		Good Practice Guide - Heating, Ventilation, and Air Conditioning	2009	ISPE	0

78		Good Practice Guide - Development of Investigational Therapeutic Biological Products	2007	ISPE	0
79		GAMP Good Practice Guide - Electronic Data Archiving	2007	ISPE	0
80		Baseline Guide volume 1 - Active Pharmaceutical Ingredients	2007	ISPE	0
81		Comprehensive Guide to Clinical Materials	2006	ISPE	0
82		GAMP Good Practice Guide - A Risk-Based Approach to Compliant Electronic Records and Signatures	2005	ISPE	0

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