



**PHARMACEUTICAL INSPECTION CONVENTION  
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME**

## PIC/S PUBLICATIONS

**The following list indicates the category and the section following which each PIC/S publication has been classified and published on the PIC/S website**

<b>Document</b>	<b>Reference</b>	<b>Category</b>	<b>Section</b>
PIC/S GMP Guide	PE 009-9	Documents for Industry	GMP Guide
Explanatory Notes for Pharmaceutical Manufacturers on the Preparation of a Site Master File	PE 008-4	Documents for Industry	Site Master Files
Site Master File for Source Plasma Establishments	PI 019-3	Documents for Industry	Site Master Files
Site Master File for Plasma Warehouses	PI 020-3	Documents for Industry	Site Master Files
PIC/S Scheme	PICS 1/95 (Rev. 5)	Document for Inspectorates	Inspectorates
Participating Authorities & Partners	PS/INF 21/2002 (Rev. 13)	Document for Inspectorates	Inspectorates
PIC Convention	---	Document for Inspectorates	Inspectorates
Quality System Requirements for Pharmaceutical Inspectorates	PI 002-3	Document for Inspectorates	Inspectorates
Procedure for Handling Rapid Alerts and Recalls Arising from Quality Defects	PI 010-4	Document for Inspectorates	Inspectorates
Standard Operating Procedure PIC/S Inspection Report Format	PI 013-3	Document for Inspectorates	Inspectorates
Standard Operating Procedure Team Inspections	PI 031-1	Document for Inspectorates	Inspectorates
Aide-Memoire Inspection of Utilities	PI 009-3	Documents for Inspectors	Aide-Memoires
Aide Memoire on GMP Particularities for Clinical Trial Products	PI 021-2	Documents for Inspectors	Aide-Memoires
Aide Memoire on Inspection of Quality Control Laboratories	PI 023-2	Documents for Inspectors	Aide-Memoires
Aide Memoire on Inspection of Biotech	PI 024-2	Documents for Inspectors	Aide-Memoires
Aide-Memoire on Medicinal Gases	PI 025-2	Documents for Inspectors	Aide-Memoires
Aide-Memoire on Packaging	PI 028-1	Documents for Inspectors	Aide-Memoires
Aide-Memoire on The Inspection of APIS	PI 030-1	Documents for Inspectors	Aide-Memoires
Questions & Answers document regarding Distribution Activities for Active Pharmaceutical Ingredients (APIs)	PS/INF 20/2011	Documents for Inspectors	Q&A Documents
PIC/S GMP Guide for Blood Establishments	PE 005-3	Documents for Inspectors	Guidance documents
PIC/S Guide to Inspections of Source Plasma Establishments and Plasma Warehouses (Inspection Guide)	PI 008-3	Documents for Inspectors	Guidance documents
PIC/S Guide to Good Practices for the Preparation of Medicinal Products in Healthcare Establishments	PE 010-3	Documents for Inspectors	Guidance documents
Guidance on Parametric Release	PI 005-3	Documents for Inspectors	Guidance documents
Validation Master Plan Installation and Operational Qualification Non-Sterile Process Validation Cleaning Validation	PI 006-3	Documents for Inspectors	Guidance documents
Validation of Aseptic Processes	PI 007-6	Documents for Inspectors	Guidance documents
Good Practices for Computerised Systems in Regulated "GxP" Environments	PI 011-3	Documents for Inspectors	Guidance documents
Recommendation on Sterility Testing	PI 012-3	Documents for Inspectors	Guidance documents

Document	Reference	Category	Section
Isolators Used for Aseptic Processing and Sterility Testing	PI 014-3	Documents for Inspectors	Guidance documents
Technical Interpretation of Revised Annex 1 To PIC/S GMP Guide	PI 032-1	Documents for Inspectors	Guidance documents
A Recommended Model for Risk-Based Inspection Planning in the GMP Environment	PI 037-1	Documents for Inspectors	Guidance documents
PIC/S Brochure	---	Documents for the Public	Information documents
PIC/S Blueprint	PS/W 8/2005	Documents for the Public	Information documents
Press Release November 2011	PR Nov 2011	Documents for the Public	Press Releases
Press Release no 2 June 2011	PR 02 June 2011	Documents for the Public	Press Releases
Press Release no 1 June 2011	PR 01 June 2011	Documents for the Public	Press Releases
Press Release November 2010	PR Nov 2010	Documents for the Public	Press Releases
Press Release May 2010	PR May 2010	Documents for the Public	Press Releases
Press Release November 2009	PR Nov 2009	Documents for the Public	Press Releases
Press Release May 2009	PR May 2009	Documents for the Public	Press Releases
Press Release November 2008	PR Nov 2008	Documents for the Public	Press Releases
Press Release May 2008	PR May 2008	Documents for the Public	Press Releases
Press Release November 2007	PR Nov 2007	Documents for the Public	Press Releases
Press Release May 2007	PR May 2007	Documents for the Public	Press Releases
Press Release December 2006	PR Dec 2006	Documents for the Public	Press Releases
Press Release June 2006	PR Jun 2006	Documents for the Public	Press Releases
Press Release February 2005	PR Feb 2005	Documents for the Public	Press Releases
Press Release June 2004	PR Jun 2004	Documents for the Public	Press Releases
Press Release November 2003	PR Nov 2003	Documents for the Public	Press Releases
Press Release June 2003	PR Jun 2003	Documents for the Public	Press Releases
Press Release May 2002	PR May 2002	Documents for the Public	Press Releases
Annual Report 1999	AR 1999	Documents for the Public	Annual Reports
Annual Report 2000	AR 2000	Documents for the Public	Annual Reports
Annual Report 2001	AR 2001	Documents for the Public	Annual Reports
Annual Report 2002	AR 2002	Documents for the Public	Annual Reports
Annual Report 2003	AR 2003	Documents for the Public	Annual Reports
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Annual Report 2005	AR 2005	Documents for the Public	Annual Reports
Annual Report 2006	AR 2006	Documents for the Public	Annual Reports
Annual Report 2007	AR 2007	Documents for the Public	Annual Reports
Annual Report 2008	AR 2008	Documents for the Public	Annual Reports
Annual Report 2009	AR 2009	Documents for the Public	Annual Reports
Annual Report 2010	AR 2010	Documents for the Public	Annual Reports
2002 Seminar: The Interface Between Good Clinical Practices and Manufacturing Practices	SB 028	Documents for the Public	PIC/S Seminars
2003 Seminar: The Inspection of Quality Control Laboratories	SB 029	Documents for the Public	PIC/S Seminars
2004 Seminar: The Inspection of API Manufacturers	SB 030	Documents for the Public	PIC/S Seminars

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2005 Seminar: Primary Packaging Material, Labelling & Prevention of Mix-Ups	SB 031	Documents for the Public	PIC/S Seminars
2006 Seminar: Quality Risk Management and Related ICH Topics	SB 032	Documents for the Public	PIC/S Seminars
2007 Seminar: Inspection Of Manufacturers of Solid Dosage Forms	SB 033	Documents for the Public	PIC/S Seminars
2008 Seminar: Good Distribution Practices	SB 034	Documents for the Public	PIC/S Seminars
2009 Seminar: Inspection of aseptic & sterile manufacturing	SB 035	Documents for the Public	PIC/S Seminars
2010 Seminar: GMP Inspection of Manufacturers of Traditional / Herbal Medicinal Products	SB 036	Documents for the Public	PIC/S Seminars
2011 Seminar: Good Pharmaceutical Inspection Practices	SB 037	Documents for the Public	PIC/S Seminars
PIC/S-PDA & ISPE Joint Workshop	---	Documents for the Public	Miscellaneous
Example of Quality Risk Management Implementation	PS/INF 01/2010	Documents for the Public	Miscellaneous