PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

WHAT IS PIC/S ?

The Pharmaceutical Inspection Co-operation Scheme (PIC/S) was established in 1995 as an extension to the Pharmaceutical Inspection Convention (PIC) of 1970.

PIC/S is a non-binding co-operative arrangement between Regulatory Authorities in the field of Good Manufacturing Practice (GMP) of medicinal products for human or veterinary use. It is open to any Authority having a comparable GMP inspection system. PIC/S comprises more than 50 Participating Authorities coming from all over the world (Europe, Africa, America, Asia and Australasia). The exact list of PIC/S Participating Authorities is available on the PIC/S web site (www.picscheme.org).

PIC/S will strive to improve public health by leading development and implementation of inspection frameworks for human and veterinary medicines through harmonisation of standards and offering world class training to regulatory inspectors around the globe.

As the Scheme is an arrangement between Regulatory Authorities, it is very flexible, dynamic and proactive. A Committee of the Participating Authorities' representatives (PIC/S Committee) supervises the operation of the Scheme. All decisions are taken unanimously. The Committee is assisted in its task by 7 Sub-Committees (e.g. on the training of inspectors, on GMDP harmonisation, etc.), by an Executive Bureau, which steers the Organisation in-between meetings, and by a small Secretariat, which mainly assists the Committee, the Sub-Committees, the Bureau and Participating Authorities in their duties.

WHAT IS GMP ...?

GMP is defined as follows in the PIC/S GMP Guide: "Good Manufacturing Practice is that part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorisation or product specification."

Put in other words: GMP ensures that the production of medicines meets the required quality standards.

WHAT ARE THE MAIN ACTIVITIES ?

TRAINING

The training of GMP inspectors has been at the heart of PIC/S since the beginning. However, PIC/S has also opened some of its training tools to inspectors active in other areas such as Good Distribution (GDP), Good Clinical Practices (GCP) and Good Pharmacovigilance Practices (GVP). All PIC/S training activities are regrouped under the PIC/S Inspectorates' Academy (PIA) at **www.picscheme.org/en/pia-home**

SEMINARS

PIC/S arranges an annual Training Seminar for inspectors, with each Seminar dealing with a specific topic. The Seminars are hosted by a different PIC/S Participating Authority each year, as shown in the table below.

The annual PIC/S Seminar usually results in the setting-up of a Drafting Group, which develops new or amends existing GMP guidance documents. For example, the 2004 PIC/S Seminar on the Inspection of Active Pharmaceutical Ingredients (APIs) resulted in a PIC/S guidance document for inspectors (Aide-Memoire on the Inspection of APIs).

Year	Seminar Topic	Country / Authority
2024	Revised Annex 1 (Sterile Manufacturing)	Brazil / ANVISA
2023	Soft Skills that Make a Good GMP/GDP Inspector in 2023	Thailand / Thai FDA
2022	Inspection of the Pharmaceutical Quality System (PQS)	Ireland / HPRA
2021	GMP Assessment Approaches in Post Covid-19 Era	Korea (Republic of) / MFDS
2020	Distant Assessment of GMP Compliance	Finland / FIMEA

JOINT VISITS PROGRAMME AND COACHED INSPECTIONS

Another avenue for the training for inspectors is the PIC/S Joint Visits Programme. Under this programme three inspectors from three different countries are teamed up to observe GMP inspections in each country with a view to comparing inspection procedures and techniques and to harmonise GMP interpretation. Any differences are reported to the PIC/S Sub-Committee on Training for appropriate action. PIC/S equally offers a programme of Coached Inspections, which allows junior inspectors to be trained by more experienced inspectors.

TRAINING COURSES FOR NEW INSPECTORS

PIC/S regularly provides training courses for new GMP inspectors organised by Ireland / HPRA.

EXPERT CIRCLES

PIC/S has formed several "Expert Circle" groups with the aim to enable inspectors:
(i) to discuss and exchange information on specific technical areas of GMP;
(ii) to develop draft guidance documents (incl. new Annexes to the GMP Guide); and
(iii) to provide for training opportunities in their field of expertise.
Expert Circles on Human Blood, Tissues, Cells and Advanced Therapy Medicinal Products (ATMPs), Active Pharmaceutical Ingredients (APIs), Good Distribution Practices (GDP), Quality Risk Management (QRM), Controlling Cross-Contamination in Shared Facilities, Good Clinical Practices (GCP) and Good Pharmacovigilance Practices (GVP) are currently active and meet regularly.

STANDARDS & GUIDANCE DOCUMENTS

Since its creation, PIC/S has been active in the development and promotion of harmonised GMP standards and guidance documents.

The main instrument for harmonisation has been the PIC/S GMP Guide. Originally, the latter derives from the WHO GMP Guide and has been further developed in order to comply with stringent manufacturing and health requirements, to cover new areas (e.g. biologicals) and to adapt to scientific and industrial technology (e.g. biotech).

In 1989, the EU adopted its own GMP Guide, which – in terms of GMP requirements – is equivalent to the PIC/S GMP Guide. Since that time, the EU and the PIC/S GMP Guides have been developed in parallel (both Guides are practically identical).

In addition to the GMP Guide, PIC/S has also been a pioneer in developing a number of guidelines and guidance documents such as the Site Master File, the Recommendation on Quality System Requirements for Pharmaceutical Inspectorates and the first Guideline for the Manufacture of Active Pharmaceutical Ingredients. As a matter of fact, PIC/S has been instrumental in elaborating a first draft for the ICH Q7A Guide on APIs, which was finalised by ICH in 2000 and then adopted by PIC/S.

Other guidance documents are developed by ad-hoc Working Groups.
Current Working Groups are listed on:
www.picscheme.org/en/activities

EXCHANGE OF INFORMATION

The sharing of information between PIC/S Participating Authorities has become increasingly important at a time when resources – whether in terms of staff or finance – are scarce.

The Scheme relies on the exchange of information on GMP inspections on a purely voluntary basis. There is no obligation whatsoever to accept inspection results. There are also important limitations to the exchange of information under PIC/S, notably the fact that it does not apply to the exchange of information between the Participating Authorities of countries party to the European Economic Area (EEA) and their MRA Partners. For these Authorities, the EU legislation or the MRA is applicable – not PIC/S rules. However, the exchange of information within PICS should become increasingly important to its Participating Authorities, notably in connection with foreign inspections. A guidance on GMP inspection reliance was adopted in 2018 with an aim to maximise inspection resources for GMP compliance of overseas facilities.

The sharing of information between PIC/S Participating Authorities also applies to quality defects of batches of medicinal products, which have been distributed on the market. Through the PIC/S Rapid Alert and Recall System, such critical information is circulated among PIC/S Participating Authorities, which are in a better position to oversee the withdrawal of the defective batches from their markets.

HOW TO JOIN PIC/S ?

Before an Authority is accepted by PIC/S, a detailed assessment is undertaken to determine whether the Authority is able to apply an inspection system comparable to that of current PIC/S Authorities. This assessment involves an examination of the Authority's GMP inspection and licensing system (or equivalent), quality system, legislative requirements, inspector training, etc. It is followed by a visit by a PIC/S delegation to observe in particular inspectors carrying out routine GMP inspections.

Membership may take several years to achieve, during which time various changes and improvements may be recommended by the PIC/S Committee; if necessary, follow-up visits are undertaken to verify the suitability of corrective actions.

PIC/S introduced in 2014 a pre-accession procedure to better prepare potentially interested Authorities for PIC/S accession. The pre-accession procedure offers the advantage of allowing a Competent Authority to identify the gaps between PIC/S requirements and its GMP Regulatory Compliance Programme.

In line with the Joint Reassessment Programme, existing PIC/S Participating Authorities are also reassessed for equivalence on a regular basis. This ensures that both new applicants and older members fulfil the same requirements.

FOR MORE INFORMATION...

Pharmaceutical Inspection Co-operation Scheme (PIC/S)
14, rue du Roveray - 1207 GENEVA - Switzerland

Phone: +41 22 738 92 16
e-mail: info@picscheme.org
web site: **www.picscheme.org**