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 around 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 aims at harmonising inspection procedures worldwide by developing common standards in the field of GMP and by providing training opportunities to inspectors. It also aims at facilitating co-operation and networking between competent authorities, regional and international organisations, thus increasing mutual confidence.

This is reflected in PIC/S’ mission which reads as follows: “To lead the international development, implementation and maintenance of harmonised GMP standards and quality systems of inspectorates in the field of medicinal products.”

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) and Good Clinical Practices (GCP).

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).

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<thead>
<tr>
<th>Year</th>
<th>Seminar Topic</th>
<th>Country / Authority</th>
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<tr>
<td>2016</td>
<td>Inspectorates of the Future</td>
<td>UK / MHRA</td>
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<td>2015</td>
<td>Biopharmaceuticals (Biotechnology and Biologicals): How To Inspect</td>
<td>Indonesia / NADFC</td>
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<td>2014</td>
<td>Dedicated Facilities: yes or no?</td>
<td>France / ANSM</td>
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<td>2012</td>
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All PIC/S activities are listed on www.picscheme.org/training

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 has started with providing a training course for new GMP inspectors: the first such courses were 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), Computerised Systems, Active Pharmaceutical Ingredients (APIs), Good Distribution Practices (GDP) and Quality Risk Management (QRM) are currently active and meet regularly.
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: Annex 1 (jointly with the European Medicines Agency); Classification of Deficiencies; Advanced Therapy Medicinal Products; Good Clinical Practices and Good Pharmacovigilance Practices; Data Integrity; Controlling Cross-Contamination in Shared Facilities; and Veterinary Medicinal Products.

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 PIC/S should become increasingly important to its Participating Authorities due to the expected implementation of new requirements on quality risk management, which will impact on their inspection frequency.

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.
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 recently introduced a pre-accession procedure to better prepare potentially interested Authorities for PIC/S accession. PIC/S undertakes to carry out a gap analysis of such interested Authorities and identify areas of non-compliance with PIC/S requirements.

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.