



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

PS/INF 18/2008 (Rev)  
22 December 2009

**PIC/S PLURIANNUAL TRAINING SCHEDULE  
(2009-2012)**

*Note by the Secretariat*

1. The training of GMP inspectors has been one of PIC/S' main purpose and asset since the beginning. In order to remain a leading reference in this field and to offer a high-level training programme for inspectors, PIC/S has to further develop an attractive and coherent training programme covering the whole range of inspectors' needs, from basic training seminars for new inspectors to expert circles dedicated to experienced inspectors.

2. The present document aims at presenting the panel of existing and future training tools within PIC/S as well as respective objectives and priorities for the 3-4 years to come.

**I. ANNUAL SEMINARS**

3. The annual seminar has always been and should remain PIC/S' showcase for inspectors from PIC/S Participating Authorities (PAs) but also from Applicant and non-member Competent Authorities. Generally organised by new PAs, it is also a good opportunity for them to present their country and Competent Authority to other PAs.

**OBJECTIVES:**

4. In the PIC/S Blueprint (PS/W 8/2005) the following objectives are defined regarding annual seminars:

- Provide high-quality training seminars;
- Improve presentations given at seminars;
- Include where necessary a region-specific training module (ASEAN, EU);
- Possibly organise joint training courses with professional organisations (see section VI. below);
- Possibly elaborate training modules (see section II. below).

5. The following additional objectives should also be considered:
- 2009: Organise a seminar on “Aseptic & Sterile manufacturing from APIs to finished dosage forms” (Uppsala, Sweden);
  - 2010: Organise a seminar on the “Inspection of Herbal Medicines” (Malaysia);
  - 2011: Organise a seminar on “Good Inspection Practices” (South Africa);
  - Continue organising one seminar per year on an attractive and current topic;
  - Authorities in charge of organising annual seminars should use the expertise of the PIC/S Working Group on Training to guarantee the high level of presentations and workshops;
  - Envisage additional sessions on region-specific regulations in conjunction with 2010 and 2011 annual seminars.

## **II. BASIC SEMINAR FOR NEW INSPECTORS**

6. The PIC/S Working Group on Training suggested introducing a basic training module (4 days) for new inspectors. The seminar would be open to inexperienced inspectors from PIC/S PAs and Applicants (e.g. one inspector per Authority).

### **OBJECTIVES:**

- Organise the first edition in 2010 or 2011;
- If successful, repeat the seminar (e.g. one per year).

## **III. EXPERT CIRCLES AND WORKING GROUPS**

7. Expert Circles are set-up by the PIC/S Committee with a view to facilitate discussions and to exchange information on specific areas of interest. Expert Circles' main goal is to develop guidance documents and to provide training to inspectors in their field of specialisation<sup>1</sup>. Meetings of Expert Circles are open to inspectors from PIC/S PAs and Applicants. If the topic of the meeting is of general interest (i.e. if training sessions are scheduled), non-PIC/S Competent Authorities can also be invited. Currently, the following four Expert Circles are active:

- Expert Circle on APIs;
- Expert Circle on Computerised Systems;
- Expert Circle on Human Blood and Tissue;
- Expert Circle on Quality Risk Management.

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<sup>1</sup> With the exception of the Expert Circle on Computerised Systems (which has sought a specific mandate for inspectors' training), Expert Circles and Working Groups are currently mainly developing guidance documents or training modules for the future. The training aspect of Expert Circles and Working Groups is therefore, very limited, for the time being.

8. PIC/S has also set-up a Working Group in charge of drafting a guideline on Good Distribution Practices (GDP). Once the guideline will be finalised, the Working Group could envisage turning into an Expert Circle on GDP providing dedicated training to GDP inspectors. Other Expert Circles could be created, if needed.

9. After the completion of its mandate (i.e. drafting a PIC/S guide on good preparation practices in healthcare establishments), the Expert Circle on Hospital Pharmacies suggested PIC/S to set-up a Working Group in charge of drafting an Annex 3 on radiopharmaceuticals to the new guide. The mandate of the Working Group also proposes the development of a training programme for inspectors to enable them to inspect radiopharmacies in a harmonised manner.

#### OBJECTIVES:

10. The PIC/S Blueprint lists the following objectives regarding Expert Circles:

- Provide high-quality Expert Circle meetings with the aim of further harmonizing standards and providing training;
- Increase the number of Expert Circles and Working Groups (from 5 to 8);
- Improve the quality of presentations;
- Include region-specific training sessions (if needed);
- Establish Special Interest Groups;
- Review Terms of References of existing Expert Circles.

11. The following additional objectives should also be considered:

- Guarantee that Expert Circles organise meetings on a regular basis (ideally one per year);
- Encourage new PAs to organise Expert Circle meetings;
- Expert Circles should encourage the creation of Scientific Committees to help Organising Authorities to develop high-quality meeting programmes and to avoid repetitiveness of training.

#### IV. JOINT VISITS PROGRAMME (JVP)

12. There are currently 27 joint visits groups (11 created in 2008), representing over 90 inspectors. In 2006, PIC/S decided to extend the scope of the JVP to Good Clinical Practices (GCP) on a trial basis (4 groups). In 2008, PIC/S decided to open-up the JVP to inspectors from Applicant Authorities and from ASEAN countries (on a trial basis).

#### OBJECTIVES:

13. The PIC/S Blueprint lists the following objectives regarding the JVP:

- Ensure that the JVP remains both an effective training tool and an efficient means to harmonise GMP standards.
- Encourage participation by all Participating Authorities;
- Monitor the implementation of the Programme's Guidelines;

- Introduce coached visits for training purposes (see Section V. below)
14. The following additional objectives should also be considered:
- In order to avoid the more and more frequent turn-over in JVP groups, PIC/S should introduce a process of replacement of inspectors who intend to leave the programme before the end of the joint visit cycle (e.g. propose a deputy to bridge the vacancy).
  - Evaluate the efficiency of opening-up JVP to GCP by 2011;
  - Evaluate the efficiency of opening-up JVP to ASEAN by 2012.

## **V. COACHED INSPECTIONS**

15. In conformity with the PIC/S Blueprint, a programme for coached inspections (an experimented inspector training a junior inspector) was introduced in 2009. The programme is open to inspectors from PAs and Applicants.

### **OBJECTIVES:**

- Set-up 3-5 groups in 2009-2010;
- Evaluate the efficiency of the programme by 2012.

## **VI. PIC/S-INDUSTRY WORKSHOPS**

16. In November 2007, PIC/S organised a first joint training workshop with ISPE on “Quality Risk Management” in conjunction with the annual seminar in Singapore. In November 2008 a second workshop was organised on the “Manufacture of Sterile Medicinal Products EU/PIC/S revised GMP Annex 1” jointly with PDA and ISPE.

### **OBJECTIVES:**

- Joint workshops with ISPE and PDA could be organised on a regular basis, in the future and extended to other international professional or industry associations;
- Professional and/or industry associations could also run short training courses (for industry and inspectors from Competent Authorities) on specific technical topics prior to or after PIC/S seminars. Committee meetings or Expert Circle meetings);
- PIC/S could ask professional and/or industry associations to organise web-based training modules (webinars) for inspectors.