PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PS/W 1/2011 (Rev. 1)
2 Annexes
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ASSESSMENT AND JOINT REASSESSMENT PROGRAMME

QUESTIONNAIRE FOR COMPETENT AUTHORITIES TO BE USED FOR ASSESSMENT, REASSESSMENT AND SELF-EVALUATION

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QUESTIONNAIRE FOR COMPETENT AUTHORITIES TO BE USED FOR ASSESSMENT, REASSESSMENT AND SELF-EVALUATION

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1. Introduction

1.1 This document should be used by:

(i) Competent Authorities wishing to accede to PIC/S and going through a pre-accession process (see Pre-Accession Guidelines);

(ii) Competent Authorities applying for PIC/S membership and going through an accession process (see Accession Guidelines);

(iii) PIC/S Participating Authorities being reassessed under the Joint Reassessment programme;

(iv) Competent Authorities for their own self-assessment.

2. Purpose

2.1 The purpose of this document is to provide guidance on the information and documentation to be submitted in order to ensure (i) equivalency in the way Authorities are assessed to determine the level of their GMP regulatory compliance programme (GRCP) and (ii) consistency in the way the information and documentation is presented and evaluated.

3. Scope

3.1 This document is applicable in the framework of (i) pre-accession of interested Competent Authorities (ii) assessment of Applicants (iii) re-assessment of Participating Authorities; and (iv) self-assessment of Competent Authorities.

4. Questionnaire / Self-Assessment

4.1 The Questionnaire (Annex 1) must be properly filled in and completed in English.

4.2 Whenever possible, clear and detailed cross-references (e.g. to SOPs or national legislation) must be indicated thus facilitating the work of the assessor(s) / auditor(s).

4.3 Competent Authorities applying for PIC/S membership should attach an official, signed letter with the Questionnaire expressing the will of the Competent Authority to join PIC/S and to go through the accession procedure. In the case where multiple authorities are responsible for covering various elements of the GMP regulatory compliance programme, they must all together as one fill in the Questionnaire and Audit Checklist, identifying for each item, “who” is responsible for “what”. They have to be signed by all parties involved.

4.4 The filled-in Questionnaire should be returned together with the PIC/S Audit Checklist (PS/W 1/2005), which is used as a self-evaluation tool and which allows the Competent Authority to verify whether its GRCP is equivalent to PIC/S requirements.

5. List of Documents

5.1 Applicants and Authorities under (re-)assessment should provide the supporting documents listed at Annex 2 together with the Questionnaire in order to support it.

5.2 For Competent Authorities going through a pre-accession, this questionnaire and supporting documents are part of their own self-assessment. .

6. References

PIC/S 1/95 Pharmaceutical Inspection Co-operation Scheme
PS/W 14/2011 Guidelines for the Accession to the PIC Scheme
PS/W 1/2005 Audit Checklist

7. Revision History

Version Number	Reason(s) for Revision
PS 2/99	Original version
PS 2/99-1	Change of the PIC/S Secretariat's e-mail address
PS 2/99-2	Change of the PIC/S Secretariat's co-ordinates
PS 2/99-3	Change of the PIC/S Secretariat's postal address
PS/W 1/2011	Merger of application form and questionnaire; harmonisation with the Joint Reassessment Programme and the Audit Checklist; introduction of the notion of "self-evaluation".
PS/W 1/2011 (Rev. 1)	Introduction of Pre-Accession Procedure

Questionnaire

Complete the questionnaire and return to:

Pharmaceutical Inspection Co-operation Scheme (PIC/S)
14, rue du Roveray
CH-1207 Geneva (Switzerland)
E-mail: info@picscheme.org

1. Applicant *(name of authority)*
In the case where multiple authorities are responsible for covering various elements of the GMP regulatory compliance programme, they must all together as one fill in the Questionnaire and Audit Checklist, identifying for each item, "who" is responsible for "what". They have to be signed by all parties involved.

2. Address

3. Country

4. Phone	**5. Fax**

6. E-mail

7. Web Site

8. Contact person *(name and title)*

9. Purpose: This questionnaire is submitted as a self-evaluation for:

a) PIC/S pre-accession
b) PIC/S membership application
c) PIC/S reassessment

10. Scope: The Applicant is competent for the inspection of Active Pharmaceutical Ingredient (API), finished medicinal product, investigational medicinal products, or any intermediate:

a) for human use
b) for veterinary use
c) for both human and veterinary use

11. Date

The following questions should be completed in parallel with the Audit Checklist (PS/W 1/2005)

1 - Legislative and Regulatory Requirements and Scope

1A - Empowering legislation

a) Is there a licensing system in force for (in liaison with indicator 14):
a1) Manufacturers of medicinal products for Human use and API in the country?
a2) Manufacturers of medicinal products and API abroad?
a3) Other sites abroad? (describe which)
a4) Wholesale distribution of medicinal products (including APIs)?
a5) Importers of dosage forms and API?
a6) Blood, cells, tissues banks?
a7) Contract laboratories?
a9) Manufacturers of investigational medicinal products?
a10) Manufacturers of medicinal gases?
a11) Manufacturers of medicinal products for veterinary use?
a12) Manufacturers of traditional medicines?
a13) Hospitals which manufacture?
a14) Pharmacies which manufacture?
a15) State organisations?
a16) Other - describe?

b) Is the Competent Authority fully or partially responsible for licensing and inspecting the products listed above? If not, please explain.

c) List the groups of products which are subject to legal provisions governing medicinal products.

1B - Conflict of interest

2 - Regulatory directives and policies

2A - Procedures for designating inspectors

a) In case of multiple agencies involved in the GRCP, by which authority are the inspectors employed?

b) What is the position of this authority within the public health service?

c) In case of multiple agencies involved in the GRCP, what are their positions within the public health service?

2B - Enforcement Policies

2C - Code of conduct/ Code of ethics

2D - Training certification policies/guidelines

2E - Alert/crisis management policies/procedures/guidelines

2F - Organisational structure

a) What connection has the Inspectorate with the licensing (drug registration) system?
b) What connection has the Inspectorate with the structure in charge of assessing the suspected quality defects?
c) What connection has the Inspectorate with the structure in charge of official quality control?

3 - GMP Standards

4 - Inspection resources

4A - Staffing: Initial qualification

4B - Number of inspectors

b) How many inspectors are employed by the applicant in the field of products in the scope of the application ?
b1) on a full-time basis:
b2) on a part-time basis:

in respect of

b3) Manufacturers and importers for APIs?
b4) Manufacturers, importers and exporters for medicinal products?
b5) Wholesalers and distributors for medicinal products (incl. APIs)?
b6) Pharmacies?
b7) Others (describe)?

c) Are inspectors belonging to another local competent authority involved in the GRCP? If yes:
c1) Identify the concerned competent authority?
c2) Define the regulatory framework for and the relationship with the applicant?
c3) Identify the scope of activities inside the GRCP
c4) How many inspectors are employed in this scope?
c4.1) on a full-time basis?
c4.2) on a part time basis?
c5) Describe the reporting system

d) Are inspectors sub-contracted by the applicant? If yes:
d1) Define the regulatory framework for and the reporting system?
d2) Are they subject to the same rules as the inspectors (i.e. conflicts of interests, training ….)
d1) How many inspectors are sub-contracted?

4C - Training programme (in liaison with indicators 32 and 33)

a) Is there a training programme for inspectors on recruitment?
a1) Is training formal?
a2) Is training carried out alongside an experienced inspector?
a3) Are new inspectors formally qualified to inspect in new areas?
b) Is there a training programme for inspectors during service?
b1) What means of training are used?
b2) What are the main topics in which training is given?
b3) How many days of training a year?

4D - QA mechanism to assure effectiveness of training programme

5 - Inspection procedures

5A - Inspection strategy

a) Are inspections of APIs manufacturers product-oriented? If not, please explain

b) Does the inspection of manufacturers of medicinal products cover:
b1) All activities from the purchase of materials and components to the shipment of products for sale?
b2) Part only of these activities? (state which)
b3) Laboratory examination of materials, packaging components, and products?
b4) Manufacturing documentation?
b5) Records of activities?
b6) Buildings and equipment - layout and sanitation?
b7) Personnel recruitment and training?
b8) Quality Management System?

c) Are inspectors:
c1) Allowed a free hand to conduct inspections as seems best to them?
c2) Given an Aide-Memoire to guide them through the inspection?
c3) Required to work through a check list of matters to be examined?

5B - Pre-inspection preparation (in liaison with indicator 36)

a) Must the manufacturer submit a Site Master Plan (equivalent to PIC/S) to inspectors prior to the inspection?

5C - Format and content of inspection reports (in liaison with indicators 38, 42 and 49)

a) Is there a classification system for deficiencies (e. g. critical, major, others)?

b) Are the reports of the inspectors:
b1) Usually in writing?
b2) General or detailed?
b3) Signed by the inspectors?

b4) Communicated to manufacturer?
b5) Confidential?
b6) PIC/S format?
b7) Reviewed by supervisors or quality control procedure?
b8) Are Site Master Files assessed as part of the reports?
b9) Is there a time limit for issuing the list of deficiencies?
b10) Is there a time limit for issuing the report?

5D - Inspection methodology

a) What is inspected and how many sites in each case?

a1) Manufacturers of medicinal products for Human use and API in the country?
a2) Manufacturers of medicinal products and API abroad?
a3) Other sites abroad? (describe which)
a4) Wholesale distribution of medicinal products (including APIs)?
a5) Importers of dosage forms and API?
a6) Blood, cells, tissues banks?
a7) Contract laboratories?
a9) Manufacturers of investigational medicinal products?
a10) Manufacturers of medicinal gases?
a11) Manufacturers of medicinal products for veterinary use?
a12) Manufacturers of traditional medicines?
a13) Hospitals which manufacture?
a14) Pharmacies which manufacture?
a15) State organisations?
a16) Other - describe?

b) How frequently are inspections made? If inspections are planned according to quality risk management principles, please explain the approach (in liaison with indicator 35).

c) How are inspections normally performed?
c1) System-based (i.e. global compliance to GMP)?
c2) Product oriented?
c3) Problem oriented?

d) Is assistance of experts used? (when appropriate)? If yes, in which fields?

5E - SOP for conducting inspections (in liaison with indicator 43)

a) How are inspectors instructed in the purpose and conduct of inspections?

b) Are some or all of these instructions in writing?

5F - Inspection procedures - Post-inspection activities (in liaison with indicator 48)

a) Are the findings of the inspectors as contained in their report conclusive or subject to confirmation (if yes, how and by whom?)?

b) Who defines the period within which the deficiencies found by inspectors are to be rectified?

c) How do the inspectors check if corrective actions have been taken within the given time frame?

d) In which cases are follow-up inspections carried out?

e) Are actions on the findings taken by the inspector, or the Inspectorate and/or some other body? If the latter, which body?

5G - Inspection procedures – Storage of inspection data

6 - Inspection performance standard

6A - Performance standards

a) How is the performance of the inspectors assessed?

7 - Enforcement powers and procedures

7A - Provision for written notice of violations

7B - Non-compliance management (in liaison with indicators 52, 53, 54, 55 and 56)

a) Which courses of actions are available?

a1) Informal pressure to alter buildings, equipment, manufacturing and analytical procedures? (state which)

a2) Formal action to:
(i) Change a registration or authorisation?
  (i.a) For the concerned product(s)?
  (i.b) For the manufacturer/ importer of the concerned product(s)
(ii) Suspend a registration or authorisation?
  (ii.a) For the concerned product(s)?
  (ii.b) For the manufacturer/ importer of the concerned product(s)
(iii) Revoke a registration or authorisation?
  (iii.a) For the concerned product(s)?
  (iii.b) For the manufacturer/ importer of the concerned product(s)
(iv) Suspend the sale of a product or products?
(v) Recall a product from the market?
(vi) Bring the matter before the courts for a legal remedy? If so, what remedy/remedies?
(vii) Other? - (describe)

c) Formal actions with respect to distributors of medicinal products / API

d) Can actions listed above be taken on the basis of inspection findings alone or is it necessary to first demonstrate that a product is deficient?

e) What is required to demonstrate that a product is deficient?
(i) Results from a laboratory examination of the product?
(ii) Evidence of plant or process failure derived from the manufacturer's records?
(iii) Evidence of failure of the product in use?

f) If a product is shown to be deficient:
(i) Is action limited to the manufacturing batch from which the deficient sample was taken?
(ii) Or can action be taken against other batches of the same product?
(iii) Or can action be taken against other/all products whose manufacture employs the same process(es)?
(iv) Or can action be taken against all activities of the manufacturer, for example, by suspension of his manufacturing authorisation?

7C - Appeal mechanism (in liaison with indicator 57)

a) Does the manufacturer have right of appeal against the actions described in Sub-Component 7B, letter d, e and f?

b) What action may be taken following an appeal?

c) Do you have similar actions concerning API (including manufacturers, importers and wholesalers)?

7D - Other measures

8 - Alert and crisis systems

8A - Alert mechanisms

a) When an allegedly defective medicinal product is discovered, must the company notify the Competent Authority and is the Inspectorate involved in any subsequent action?

b) Notifications of an allegedly defective product are commonly received from where?

8B - Crisis management mechanisms

a) Which of the following courses of action are used for suspected product quality defects:
a1) Warn users to examine stocks for possible defects?
a2) Suspend sales?
a3) Suspend use?
a4) Recall?
a5) Other? (describe or see 7Ba2)

b) If a recall is decided upon, does the Competent Authority (or other body) have a legal power to order it to be carried out? If not, what power does it have?

c) If a recall is decided upon, does the Competent Authority (or other body):
c1) Advise the manufacturer as to his best course of action, leaving that action for him to carry out?
c2) Carry out the recall itself?

8C - Alert performance standards

9 - Analytical capability

9A - Access to laboratories

9B - SOPs for analytical support

9C - Validation of analytical methods

10 - Surveillance programme

10A - Sampling and audit procedure

10B - Recall monitoring

10C - Consumer complaint system

10D - Adverse reaction reporting system/ procedures

10E - Drug product defect reporting system/ procedures

11 - Quality management system

11A - Quality management system

a) Has the Competent Authority / the Inspectorate a quality management system?

b) Is it a formal system and if so which guidelines/standards have been followed?

c) When was the quality management system implemented?

d) Is the Competent Authority/ the Inspectorate accredited/certified (by whom)?

PIC/S-specific components

a) What languages are the inspectors able to speak? Knowledge in English?

b) Availability of funds and ability to attend PIC/S Committee meetings (twice a year), seminars (1x / year), other training events (Expert Circles, Joint Visits Programme, etc) as well as to participate in the (re-)assessment of authorities?

c) Ability to pay the PIC/S annual fee?

List of Supporting Documents

to be submitted in English

I **National legislation enabling inspections, licensing, sampling and testing and recalls**

II **Information requested from companies prior to undertaking GMP Inspections e.g. Site Master File**

III **GMP standard if different from PIC/S, EU or WHO GMP Guides (the document should be submitted)**

IV **The number of manufacturers/wholesalers currently inspected and licensed/ registered showing type of medicinal products (incl. APIs) manufactured** NB: A list (or access to the relevant database) should be given during the on-site assessment

V **Copy of Quality Manual**

VI **List of SOPs**

VII **Programme for introduction and ongoing training for inspectors**

VIII **Names of inspectors carrying out GMP inspections on full-time or part-time bases including any specialist inspectors**

IX **Main professional requirements for inspectors, senior/principal inspectors, chief inspector** (The CVs of inspectors should be made available during the on-site assessment)

X **SOP for how to carry out inspections**

XI **Report format if different from PIC/S format**

XII **Statistical information on numbers of inspections carried out**