

Reference of the document

X Annexes

Date

**Report on the audit of** *(audited National Competent Authority)*  
**done on :** *(date of the audit)*

*By .... rapporteur*

## **1. Introduction**

- *Country information*
- *Pharmaceutical industry information*
- *Regulatory authority information*
- *Laboratory information*
- *Pre-MRA audit and PIC/S*
- *Description of the regulatory authority*
- *List of the applicable legislations*
- *Organizational charts*

Summary of the context of the audit, overall description of the GMP/ licensing/ handling of quality defects, systems. Cross references to submitted documents by the audited National Competent Authority (NCA) are possible.

Composition of the audit team.

## **2. Participants of the audited NCA**

(Please include only a list of key personnel in NCA and not all participants).

## **3. Scope of the assessment**

(Please include a general list of products regulated by the NCA and covered by the audit.)

Including the schedule of the audit.

#### **4. Assessing documentation including on site evaluations at the Inspectorate and Laboratories**

(The completed audit check-list should be provided as an annex.)

- 4.1 Component 1: legislative and regulatory: requirements and scope**
- 4.2 Component 2: regulatory directives and policies**
- 4.3 Component 3: GMP standards**
- 4.4 Component 4: inspection resources**
- 4.5 Component 5: inspection procedures**
- 4.6 Component 6: Inspection performance standards**
- 4.7 Component 7: enforcement powers and procedures**
- 4.8 Component 8: alert and crisis systems**
- 4.9 Component 9: analytical capability**
- 4.10 Component 10: surveillance programme**
- 4.11 Component 11: quality management system**

For each of the components, it is necessary to quote indicators which are partially or not matched and the level of evaluated risk (Critical, Very Important and Important) for the equivalence of the assessed NCA.

#### **5 Reports on the observed inspection**

*(This section should only be used to summarize the observed inspections and their outcome)*

*Where applicable, the Observed Inspection Evaluation Reports (OIER) are to be attached as an annex for future reference.*

#### **6. Summary and conclusion**

### 6.1 Outstanding issues and identification of areas of improvement:

Concerns sorted by indicators number	Proposed Corrective Actions	Objective evidence	Conclusion of the audit team
Indicator :			

### 6.2 Conclusion:

A clear statement on the conclusion of the assessment/evaluation: equivalent or not equivalent and the next steps to be taken should be added here.

**Date**

**Name(s) and Signature(s)**

## ANNEX

Summary of the Audit Checklist			
Component	Sub-component	Importance	Evaluation method
1 - Legislative and Regulatory Requirements and Scope	1A - Empowering legislation	Critical	Documentation review
	1B - Conflict of interest	Very important	Documentation review On-site evaluation at Inspectorate
2 - Regulatory directives and policies	2A - Procedures for designating inspectors	Very important	Documentation review
	2B - Enforcement Policies	-	Evaluated as part of sub-component 7B
	2C - Code of conduct/ Code of ethics	Very important	Documentation review
	2D - Training certification policies/guidelines	-	Evaluated as part of sub-component 4C
	2E - Alert/crisis management policies/procedures/guidelines	-	Evaluated as part of sub-component 8A
	2F - Organisational structure	-	Evaluated as part of sub-component 11A
3 - GMP Standards	3A - Details/ scope of GMP	Critical	Documentation review
	3B - Process validation	-	Evaluated as part of sub-component 3A
4 - Inspection resources	4A - Staffing: Initial qualification	Very important	Documentation review On-site evaluation at Inspectorate
	4B - Number of inspectors	Very important	Documentation review On-site evaluation at Inspectorate
	4C - Training programme	Very important	Documentation review On-site evaluation at Inspectorate
	4D - QA mechanism to assure effectiveness of training programme	-	Evaluated as part of sub-component 4C
5 - Inspection procedures	5A - Inspection strategy	Very important	Documentation review On-site evaluation at Inspectorate
	5B - Pre-inspection preparation	Very important	Documentation review On-site evaluation at Inspectorate Observed inspections
	5C - Format and content of inspection reports	Very important	Documentation review Observed inspections
	5D - Inspection methodology	-	Evaluated as part of sub-components 5E
	5E - SOP for conducting inspections	Critical	Documentation review Observed inspections
	5F - Inspection procedures - Post-inspection activities	Very important	Documentation review On-site evaluation at Inspectorate Observed inspections
	5G - Inspection procedures – Storage of inspection data	Important	Documentation review Observed inspections
6 - Inspection performance standard	6A - Performance standards	Very important	Documentation review On-site evaluation at Inspectorate
7 - Enforcement powers and procedures	7A - Provision for written notice of violations	-	Evaluated as part of sub-component 7B
	7B - Non-compliance management	Critical	Documentation review On-site evaluation at Inspectorate
	7C - Appeal mechanism	Important	Documentation review On-site evaluation at Inspectorate
	7D - Other measures	-	Evaluated as part of sub-components 7B

Component	Sub-component	Importance	Evaluation method
8 - Alert and crisis systems	8A - Alert mechanisms	Critical	Documentation review On-site evaluation at Inspectorate
	8B - Crisis management mechanisms	-	Evaluated as part of sub-component 8A
	8C - Alert performance standards	Important	Documentation review
9 - Analytical capability	9A - Access to laboratories	Critical	Documentation review On-site evaluation at Laboratory
	9B - SOPs for analytical support	Very important	Documentation review On-site evaluation at Laboratory On-site evaluation at Inspectorate
	9C - Validation of analytical methods	Very important	Documentation review On-site evaluation at Laboratory
10 - Surveillance programme	10A - Sampling and audit procedure	Very important	Documentation review On-site evaluation at Laboratory On-site evaluation at Inspectorate
	10B - Recall monitoring	-	Evaluated as part of sub-component 7B
	10C - Consumer complaint system	Very important	Documentation review On-site evaluation at Inspectorate
	10D - Adverse reaction reporting system/ procedures	-	Not evaluated - not considered within the scope of a GMP regulatory compliance programme.
	10E - Medicinal product defect reporting system/ procedures	-	Evaluated as part of sub-component 10C
11 - Quality management system	11A - Quality management system	Critical	Documentation review On-site evaluation at Inspectorate On-site evaluation at Laboratory