GMP Inspection report - Community format

Inspected site(s):	*Name and full address of the Inspected site*	
Activities Carried out	*Manufacture of Active Substance* *Manufacture of Finished Medicinal Product* *Packaging* *Importing* *Laboratory Testing* *Batch Control and Batch Release*	☐ ☐ ☐ ☐ ☐ ☐
Inspection date(s):	*Date(s), month, year*	
Inspector(s):	*Name of the inspector(s),* *Name of expert / assessor (if applicable)* *Name of the Competent Authority(ies).*	
References:	*Number of Marketing and / or Manufacturing Authorisations* *EMEA reference number(s).(If the inspection is an EMEA inspection)*	
Introduction:	*Short description of the company and the activities of the company.* *It should be noted if a site master file was available before the inspection.* *Date of the site master file.* *<u>For inspections in non-EC/EEA countries</u> it should be stated whether the Competent Authority of the country, where the inspection took place, was informed of the inspection and whether the Competent Authority took part in the inspection.* *Date of previous inspection* *Names of Inspectors involved in previous inspection* *Major changes since the previous inspections should be detailed.*	

Brief report of the inspection activities undertaken:	
Scope of Inspection:	*Short description of the inspection (Product related inspection and/or General GMP inspection). The reason for the inspection should be specified.*
Inspected area(s):	*Each inspected area should be specified.*
Personnel met during the inspection:	*The names and titles of key personnel met, should be specified,(listed in annex)*
Inspectors Team's findings and observations:	*Relevant headings from The Rules Governing Medicinal Products in the European Community, Good Manufacturing Practice for Medicinal Products Vol. IV.* *New headings may be introduced when relevant.*
Headings to be used (Choose those headings relevant to the scope of the Inspection):	Quality Management Personnel Premises and Equipment Documentation Production Quality Control Contract Manufacture and Analysis Complaints and Product Recall Self Inspection Questions from the Assessment of the Application (Pre- authorisation Inspections) Investigation of Product Recall or Product Defect
Miscellaneous: Samples taken Distribution Assessment of the Site Master File	
Annexes attached:	*List of any annexes attached*

Summary of Deficiencies:	*The deficiencies should be listed and the relevant reference to the EU GMP Guide and other relevant EU Guidelines should be mentioned.* *If the deficiencies are related more to the assessment of the application it should be clearly stated.* *The company should be asked to inform the Inspectorate about the progress of the corrected actions and a proposed time schedule for corrections.*
Recommendations	*To the Committee requesting the Inspection or to the Management / Enforcement Authority for the site inspected*
Summary and conclusions:	*The Inspection Team should state if the Company operates in accordance with the EU GMP Rules.*
Name(s) **Signatures(s)** **Organisation(s)** **Date:**	*The Inspection Report should be signed and dated by the Inspector(s)/Assessors having participated in the Inspection.*

<u>Definition</u> of Significant Deficiencies

1. CRITICAL DEFICIENCY: A deficiency which has produced, or leads to a significant risk of producing either a product which is harmful to the human or veterinary patient or a product which could result in a harmful residue in a food producing animal.

2. OTHER SIGNIFICANT DEFICIENCY: A non-critical deficiency, which has produced or may produce a product, which does not comply with its marketing authorisation.

or which indicates a significant deviation from EU Good Manufacturing Practice.

or (within EU) which indicates a significant deviation from the terms of the manufacturing authorisation.

or which indicates a failure to carry out satisfactory procedures for release of batches or (within EU)
a failure of the Qualified Person to fulfil his legal duties.

Note: Several smaller related deficiencies, none of which on their own may be significant, may together represent a significant deficiency and should be reported as such