

## GMP Inspection report - Community format

<b>Inspected site(s):</b>	<i>Name and full address of the Inspected site</i>	
<b>Activities Carried out</b>	<i>Manufacture of Active Substance</i>	<input type="checkbox"/>
	<i>Manufacture of Finished Medicinal Product</i>	<input type="checkbox"/>
	<i>Packaging</i>	<input type="checkbox"/>
	<i>Importing</i>	<input type="checkbox"/>
	<i>Laboratory Testing</i>	<input type="checkbox"/>
	<i>Batch Control and Batch Release</i>	<input type="checkbox"/>
<b>Inspection date(s):</b>	<i>Date(s), month, year</i>	
<b>Inspector(s):</b>	<i>Name of the inspector(s),</i>	
	<i>Name of expert / assessor (if applicable)</i>	
	<i>Name of the Competent Authority(ies).</i>	
<b>References:</b>	<i>Number of Marketing and / or Manufacturing Authorisations</i>	
	<i>EMA reference number(s). ( If the inspection is an EMA inspection)</i>	
<b>Introduction:</b>	<i>Short description of the company and the activities of the company.</i>	
	<i>It should be noted if a site master file was available before the inspection.</i>	
	<i>Date of the site master file.</i>	
	<i><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.</i>	
	<i>Date of previous inspection</i>	
	<i>Names of Inspectors involved in previous inspection</i>	
	<i>Major changes since the previous inspections should be detailed.</i>	

<b>Brief report of the inspection activities undertaken:</b>	
Scope of Inspection:	<i>Short description of the inspection (Product related inspection and/or General GMP inspection). The reason for the inspection should be specified.</i>
Inspected area(s):	<i>Each inspected area should be specified.</i>
Personnel met during the inspection:	<i>The names and titles of key personnel met, should be specified,( listed in annex)</i>
<b>Inspectors Team's findings and observations:</b>	<i>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.</i>
<i>Headings to be used ( Choose those headings relevant to the scope of the Inspection):</i>	<ul style="list-style-type: none"> <li>Quality Management</li> <li>Personnel</li> <li>Premises and Equipment</li> <li>Documentation</li> <li>Production</li> <li>Quality Control</li> <li>Contract Manufacture and Analysis</li> <li>Complaints and Product Recall</li> <li>Self Inspection</li> <li>Questions from the Assessment of the Application ( Pre- authorisation Inspections)</li> <li>Investigation of Product Recall or Product Defect</li> </ul>
<b>Miscellaneous:</b>	
Samples taken	
Distribution	
Assessment of the Site Master File	
<b>Annexes attached:</b>	<i>List of any annexes attached</i>

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

## **Definition 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