19 February 2019

EMA/167084/2018 – Rev. 1

Committees and Inspections

Joint Audit Programme for EEA GMP inspectorates

Confidentiality agreement for audits template

Scope

A confidentiality agreement shall be signed by all JAP auditors and observers if requested by the audited GMP inspectorate or prior to the observed inspection if requested by the inspected company.

Confidentiality agreement for JAP audits

I, <insert name>, designated Joint Audit Programme auditor of the GMP inspectorate:

Name: <name audited GMP inspectorate>

Address: <address audited GMP inspectorate>

Date of audit: <date of JAP audit>

agree to comply with the following conditions:

**Article 1**

I pledge, subject to the provisions of article 2, to respect the confidentiality of all the information (written and oral) received in relation to the above-mentioned audit and/or observed inspection(s) during the audit as part of the Joint Audit Programme.

I shall use the information only within the framework of the Joint Audit Programme.

**Article 2**

The commitments resulting from Article 1 are permanent, but will not apply:

* to information available to the public at the time it is supplied;
* to information that a third party has communicated to me lawfully without a confidentiality agreement.

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Date Name Signature