Inspection of company audit reports

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Approval

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1. Purpose and scope

In order to assure a harmonized conduct of inspections of establishment licence holders this document summarizes the conditions under which an inspector of the competent Regulatory Authority does have a look into audit reports of a company. It should be distinguished between internal audit reports of a company (including audit reports of different sites within the same group/company) as well as reports from audits of suppliers.

2. Basics

- Therapeutic Products Act (TPA/HMG/LPTh; SR 812.21)
- Medicinal Products Licensing Ordinance (MPLO/AMBV/OAMéd; SR 812.212.1)
- Guides to GMP: Eudralex Vol 4, PIC/S PE 009 part I and II
- EU Guidelines on Good Distribution Practice of medicinal products for human use

3. Definitions and abbreviations

Internal audit	A systematic independent and documented process performed by internal staff or by subcontracted third party auditors for obtaining evidence and evaluating it objectively, to determine the effectiveness and applicability of the required quality assurance system within the company (required by GMP part I, Ch. 1.1, ix and 9 respectively GMP part II, Ch. 2.4)
Supplier audit	Audit of external suppliers or contractors performed by company auditors (or by subcontracted third party auditors) in order to assess the compliance of suppliers of key services, critical raw materials or contractors used for outsourced manufacturing or distribution activities (performed in the context of the requirement in the GMP part I, Ch. 7 respectively GMP part II, Ch. 16.13 as well by GDP, Ch. 5.2 and Ch. 7)

4. Interpretation

The inspector does by law have access to all documents in a company related to medicinal products (art. 62, MPLO). In principle, this does include also internal and supplier audit reports. Inspectors are by law forced to maintain professional confidentiality.

4.1 Internal audits

The systems of Quality Assurance appropriate for manufacture and distribution of medicinal products should ensure that - within the company - there is a procedure for internal audit (self-inspection) in place which regularly appraises the effectiveness and applicability of the quality assurance system. It is part of the inspection by the competent Regulatory Authority to make sure that a company complies with this requirement.

The inspector therefore has to assess, if the company is planning and performing internal audits and that appropriate follow-up actions are taken and that these activities are documented. However, internal audit reports (this does include reports internal of a group, e.g. by auditors from the Headquarter, other from affiliates) are generally not read by inspectors of the competent authority as part of a routine inspection. This shall help that companies include all findings in the reports.

4.2 Supplier audit reports

According to GMP starting materials for manufacturing medicinal products should only be purchased from approved suppliers named in the relevant specifications. Furthermore, any activity covered by the GMP Guide or GDP guidelines that are outsourced should be appropriately defined, agreed and controlled in order to avoid misunderstandings which could result in a product or operation of unsatisfactory quality. There must be a written Contract between the Contract Giver and the Contract Acceptor which clearly establishes the duties of each party. Supplier audits may need to be performed as an element to check and verify the compliance of the suppliers.

The inspector therefore has to assess, if the company is fulfilling the GMP/GDP requirements. In contrast to internal audit reports, the inspector may at any time review supplier audit reports as part of a routine GMP/GDP inspection or of a product related inspection.
Supplier audit reports may also be used as an element for providing supporting evidence for the GMP status of a foreign manufacturing site from a country which GMP control system is not accepted by Switzerland.

4.3 Confidentiality

4.3.1 Inspectors

The inspector should be made aware of and maintain confidentiality whenever he/she gains access to confidential information as a result of inspections. According to the Therapeutic Products Act (TPA/HMG/LPTh) maintaining secrecy is a mandatory requirement.

4.3.2 Company

If necessary companies should include in their contracts with 3rd parties (suppliers including contractors) a paragraph allowing a breach of confidentiality towards regulatory authorities, related to technical information such as audit reports, since according MPLO, the competent authority is allowed to review any related technical document.

5. Changes to the previous version

- Whole document: Adaptation to MPLO of 14th Nov. 2018: art. 43 was replaced by art. 62

6. Appendixes

- None