EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 April 2025
EMA/129980/2025
European Medicines Agency

Questions and answers on how should third party audit(s) be reflected in part C of the QP declaration?

How should third party audit(s) be reflected in part C of the QP declaration?

In part C of the QP declaration, information on audits as basis of QP Declaration of GMP Compliance should be given. Audit(s) of the active substance manufactured at the site(s) listed in PART A should be reported.

According to GMP part I, 5.29, the MIAH shall verify compliance with GMP either by himself or through an entity acting on his behalf under a contract.[1]

If the audit is undertaken by the MIAH, the auditing body column should be left empty.

If the audit is performed by a third-party body (*i.e.* contract acceptor on behalf of the MIAH contract giver), this should be detailed as reflected in the contract.

In case the audit is performed on behalf of the MIAH by different entity/entities belonging to the same overall company, this should also be detailed in the auditing body column.

It is emphasised that in case the MIAH site does not perform the audit itself, the MIAH should be the contract giver. Consequently, the contract giver should always correspond to the MIAH site and the contract acceptor is expected to be the auditing body that actually performed the audit. Other contracted entities not directly involved in performing the audit should not be detailed in the table since the MIAH site has the ultimate responsibility.[2]

[1] For the veterinary products, the reference to GMP Eudralex Volume 4 will eventually be superseded by respective Implementing Acts, when they come into force.

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MIAH Site (or contract giver)	Auditing body (contract acceptor)
<MIAH>	**<Name and address of auditing body> unless the audit is performed by the MIAH himself**

The same principles also apply in the case of sharing of audit reports between different MIAHs using the same active substance supplier.

[2] Regarding contracts, see Q&A on EU GMP guide part I: Basic requirements for medicinal products: Chapter 7: Outsourced activities.