



FREQUENTLY ASKED QUESTIONS

Good Manufacturing Practice (GMP) audit

What is a GMP audit?

A GMP audit is an audit that has as objective to verify whether a pharmaceutical manufacturer complies with the WHO GMP standards.¹

How many suppliers can be included in a GMP audit?

One supplier per GMP audit. The audit can include more than one supplier's site (manufacturing site or product line).

What is in a GMP audit report?

We produce a report for each audit. This report contains:

- An overview and analysis of the supplier's quality assurance system, detailing the compliance with WHO GMP guidelines
- Critical, major and minor observations
- A Corrective Action and Preventative Action (CAPA) plan
- The results of an internal rating system that QUAMED has developed, over standardized GMP activities.

How long does a GMP audit take?

Our GMP audits usually takes 6 days: 1.0 days preparation, 3.0 days on-site visit and 2.0 days analysis and reporting. The audit may be longer or shorter depending on the complexity of the manufacturing sites, the scope of work and the type of products. However, these days are not consecutive. The process of a GMP audit includes preparation, in-country visit and analysis/reporting. Once the in-country visit has started, the process is usually finalised within 3 months.

What are the costs of a GMP audit?

That depends on the specifics of the audit: which country, the size of the supplier and the number of sites to be included.

What resources are required for a GMP audit?

¹<https://www.who.int/teams/health-product-and-policy-standards/standards-and-specifications/norms-and-standards-for-pharmaceuticals/guidelines/production>



Typically, a GMP audit takes 6 days (1.0 day of preparation, 3.0 days for the site visit, and 2.0 days of analysis and reporting). QUAMED GMP audits are only carried out by qualified auditor(s) validated by QUAMED according to the internal Quality Management System. The report is verified and approved by QUAMED Technical Coordinator (0.5 days).

Who pays for the GMP audit?

This depends on who requests the audit. It can be one organisation, a group of organisations, or even the supplier itself.

Is a GMP audit report sufficient to validate a supplier?

Yes, a GMP audit is a full audit. The audit report can be used to validate a supplier depending on the outcomes and findings of the audit.

How is a GMP audit organised?

In the organisation of a GMP audit, there are four main phases: A. Preparation, B. In-country visit, C. Analysis and writing of draft report, D. Integrating CAPA plan and writing of final report.

These phases include the following steps and responsibilities. In particular cases the process may be slightly different.

A. Preparation

1. A request for a GMP audit is received by one or more organisations (NGOs or others). A pharmaceutical wholesaler / distributor may also request a GMP audit.
2. If there are more organisations involved, one lead organisation is designated by them to facilitate the communication.
3. The communication lines are:

QUAMED – lead organisation – other participating organisations.

4. Using information received from the lead organisation about the country and supplier(s), QUAMED develops draft terms of reference and a draft budget.
5. QUAMED shares the draft TOR and budget with the lead organisation
6. If required an introductory meeting is organised between the lead organisation, QUAMED and other participating organisations.
7. When the TOR and the budget are confirmed, QUAMED will send service agreements to the participating organisations for signature.
8. In some cases we will ask the selected supplier to fill in a questionnaire prior to an in-country visit.
9. Our auditor will contact the auditee to plan dates for a site visit, to propose a draft audit agenda for the days of the site visit and to request specific documents to prepare the site visit.

B. In-country visit.



10. The lead organization or QUAMED arranges or facilitates the transport of the QUAMED expert.
 11. The lead organization or QUAMED arranges an interpreter, if necessary.
 12. The QUAMED auditor conducts the GMP audit by visiting the supplier's premises and by assessing the GMP compliance, as per the QUAMED Quality Management System.
 13. The expert uses the standardized GMP audit report template to record findings.
- C. Analysis and writing of draft report
14. The auditor uses the QUAMED GMP audit methodology and format to record findings and produce a draft audit report within 30 days of the country visit.
 15. The draft report is verified by QUAMED Technical Coordinator for quality assurance purpose.
 16. QUAMED sends the draft report to the supplier for comments and with the request to produce a Corrective Action and Preventative Action (CAPA) plan.
 17. The supplier is requested to provide a response within 30 days.
- D. Integrating CAPA plan and writing of final report
18. The supplier's response and CAPA plan are verified and integrated in the draft report
 19. The final report is shared with the supplier and the organisation(s) that has commissioned the audit.