



FREQUENTLY ASKED QUESTIONS

QUAMED Good Storage and Distribution Practices (GSDP) audit

What is a GSDP audit?

A GSDP audit is an audit that has as objective to verify whether a pharmaceutical supplier (wholesaler or distributor) complies with WHO GSDP standards.¹

How many suppliers can be included in a GSDP audit?

One supplier per GSDP audit. The audit can include more than one supplier's site (warehouse).

What is in a GSDP 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 GSDP 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 GSDP activities.

GSDP Q.A. CRITERIA		GSDP ACTIVITIES	LEVEL OBTAINED
Pillar A	General quality assurance requirements	1 QA system	2
		2 Documentation system	3
		3 Computerised systems	3
		4 Human resources	4
		5 Self inspection	2
Pillar B	Quality control & reception	6 Control at reception	1
		7 Quality control	1
Pillar C	Storage & handling specific products	8 Warehouse organisation	1
		9 Physical storage conditions	1
		10 Management of the cold chain	N/A
		11 Stock Control	0
Pillar D	Dispatch & Transport	12 Handling non conformity products	3
		13 Dispatch	2
		14 Transport	4

How long does a GSDP audit take?

Our GSDP audits takes 5 days: 1.0 days preparation, 2.0 days on-site visit and 2.0 days analysis and reporting. However, these days are not consecutive. The process of a GSDP audit includes preparation, in-country visit and analysis/reporting. Once the in-country visit has started, the process is usually finalised within 3 months.

¹https://cdn.who.int/media/docs/default-source/medicines/who-technical-report-series-who-expert-committee-on-specifications-for-pharmaceutical-preparations/trs1025-annex7.pdf?sfvrsn=9b8f538c_2

What are the costs of a GSDP 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 GSDP audit?

Typically, a GSDP audit takes 5 days (1.0 day of preparation, 2.0 days for the site visit, and 2.0 days of analysis and reporting). QUAMED GSDP 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 GSDP audit?

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

Is a GSDP audit report sufficient to validate a supplier?

Yes, a GSDP 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 GSDP audit organised?

In the organisation of a GSDP 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 GSDP audit is received by one or more organisations (NGOs or others). A pharmaceutical wholesaler / distributor may also request a GSDP 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 GSDP audit by visiting the supplier's premises and by assessing the GSDP compliance, as per the QUAMED Quality Management System.
 13. The expert uses the standardized GSDP audit report template to record findings.
- C. Analysis and writing of draft report
14. The auditor uses the QUAMED GSDP 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 are integrated in the draft report
 19. The final report is shared with the supplier and the organisation(s) that has commissioned the audit.