FREQUENTLY ASKED QUESTIONS

Model Quality Assurance System (MQAS) for Procurement Agencies Audit

What is a MQAS audit?
A MQAS audit is an audit that has as objective to verify whether a pharmaceutical supplier (wholesaler or distributor) complies with WHO MQAS standards[1] and WHO GSDP standards[2].

What is the difference between a MQAS audit and a Good Storage and Distribution Practices (GSDP) audit?
The MQAS audit includes all the elements that are part of a GSDP audit plus the prequalification system of the supplier: Criterion B "Continuous product qualification" (see graphic below).

What does 'prequalification' mean?
As per the WHO definition in the MQAS standard, the prequalification refers to:

'The activities undertaken in defining a product or service need, seeking expressions of interest from enterprises to supply the product or service, and examining the product or service offered against the specification and the facility where the product or service is prepared against common standards of good manufacturing practice (GMP). The examination of the product or service and of the facility where it is manufactured is performed by trained and qualified inspectors against common standards. Once the product is approved, and the facility is approved for the delivery of the specified product or service, other procurement agencies are informed of the decision. Prequalification is required for all pharmaceutical products regardless of their composition and place of manufacture/registration, but the amount and type of information requested from the supplier for assessment by the procurement agency may differ."

In other words, the prequalification, as per the MQAS meaning, is the process to qualify a product and a manufacturing site by assessing a product dossier and conducting GMP audits to ensure this particular product complies with the required quality standards.

[1]https://cdn.who.int/media/docs/default-source/medicines/norms-and-standards/guidelines/distribution/trs986-annex3-syst%C3%A8me-mod%C3%A8le-d-assurance-de-la-qualit%C3%A9-de-l-oms-pour-les-agences-d-approvisionnemen.pdf?sfvrsn=322ee5f3_2
[2]https://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

How many suppliers can be included in a MQAS audit?
One supplier per MQAS audit. The audit can include more than one site (warehouse).

What is in a MQAS 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 MQAS and 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 MQAS activities.

MQAS Q.A. CRITERIA		MQAS ACTIVITIES		LEVEL OBTAINED
Criterion A	General quality assurance requirements	1	QA system	4
		2	Documentation system	4
		3	Computerised systems	3
		4	Human resources	4
		5	Self inspection	3
Criterion B	Continuous product qualification	6	Product Qualification	4
		7	Manufacturing site assessement	4
		8	Qualification decision (qualified sources monitoring)	4
N/A	Not included	9	Procurement	N/A
Criterion C	Quality control & reception	10	Control at reception	4
		11	Quality control	4
Criterion D	Storage & handling specific products	12	Warehouse organisation	3
		13	Physical storage conditions	3
		14	Management of the cold chain	3
		15	Stock Control	3
		16	Handling non conformity products	4
Criterion E	Dispatch & Transport	17	Dispatch	2
		18	Transport	4

How long does a MQAS audit take?
Our MQAS audits takes 6 days: 1.0 days preparation, 3.0 days on-site visit and 2.0 days analysis and reporting. However, these days are not consecutive. The process of an MQAS 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 MQAS audit?
That depends on the specifics of the audit: which country, the size of the supplier, the number of sites to be included, travel involved and other elements.

What resources are required for a MQAS audit?
Typically, a MQAS 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 MQAS 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 MQAS audit?
This depends on who requests the audit. It can be one organisation, a group of organisations, or the supplier itself.

Is a MQAS audit report sufficient to validate a supplier?
Yes, a MQAS 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 MQAS audit organised?
In the organisation of a MQAS 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 MQAS audit is received by one or more organisations (NGOs or others). A pharmaceutical wholesaler / distributor may also request a MQAS 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 organization – other participating organizations.

4. Using information received from the lead organization 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 organization
6. If required an introductory meeting is organized between the lead organization, QUAMED and other participating organizations.
7. When the TOR and the budget are confirmed, QUAMED will send service agreements to the participating organizations 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 MQAS audit by visiting the supplier's premises and by assessing the MQAS compliance, as per the QUAMED Quality Management System.
13. The expert uses the standardized MQAS audit report template to record findings.

C. Analysis and writing of draft report

14. The auditor uses the QUAMED MQAS 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

1. The supplier's response and CAPA plan are integrated in the draft report
2. The final report is shared with the supplier and the organization(s) that has requested the audit.