



Quality Certification Programme (QCP)

Frequently Asked Questions

1. *What is the QCP?*

The QCP is a certification program managed by QUAMED, where QUAMED issues certificates to manufacturers or wholesalers to attest that their operations, systems and procedures comply with the WHO standards.

2. *What type of QCP certificates are issued?*

Three types of certificates are issued.

- Good Manufacturing Practices (**GMP**)
- Good Storage and Distribution practices (**GSDP**)
- Model Quality Assurance System for Procurement Agencies (**MQAS**)

3. *Who decides to issue a QCP certificate?*

The decision to issue a QCP certificates lies with the Independent Decision Committee (IDC). The IDC is a committee that is appointed by the QUAMED Board of Directors. The IDC consists of 4 internationally recognised experts and alternates. None of the members of the IDC work for QUAMED.

4. *What is the difference between QCP GMP certificate and WHO prequalification (PQ) programme?*

The WHO PQ programme prequalifies products while the QCP programme certifies that a manufacturer's system was found compliant with relevant WHO standards. The GMP QCP could be compared to the availability of a WHO Public Inspection Report (and not to the entire WHO PQ programme) on the WHO website.

5. *Does a QCP GMP certificate guarantee that the goods manufactured are always of good quality?*

No. A QCP GMP certificate certifies that during the visit of the auditor, the system, policies and procedures were in line with the WHO standards. However, even in that case a manufacturer can still manufacture sub-standard products for a variety of reasons.

A purchaser may decide to assess finished pharmaceutical product (FPP) dossier to ensure the quality, safety and efficacy of a FPP is adequate.

QUAMED's QCP is an audit of facilities and quality systems. It is not a product-related assessment, therefore a QCP certificate does not guarantee the quality of the products offered by the supplier.

6. Does a QCP GSDP certificate guarantee that the goods stored and distributed are always of good quality?

No. As per the previous statement, QUAMED's QCP is an audit of facilities and quality systems. It is not a product-related assessment, therefore a QCP certificate does not guarantee the quality of the products offered by the supplier.

7. How long is a QCP certificate valid?

A QCP certificate is valid for a period of three years, counting from the date mentioned on the certificate. The period may be reduced by IDC decision.

8. Is every QCP certificate unique?

Yes. Every QCP certificate is unique and carries a unique code.

9. How can I check whether a QCP certificate is genuine?

Scan the barcode on the certificate which will bring you to the list of valid QCP certificates on our website.

10. How can I check whether a QCP certificate is still valid?

The period of validity and the start and end dates are mentioned on the certificate. Scan the barcode on the certificate and it will bring you to the list of valid QCP certificates on our website.

11. How does the QCP programme fit with the National Regulatory Authority (NRA) regulations and the WHO Global Benchmarking Tool (GBT)?

The QCP programme is independent from the NRAs and from the WHO GBT. The QCP certificate does not replace any NRA regulations. The QCP certificate can be used as an additional quality assurance for purchasers especially in environments where the NRA has not yet achieved Maturity Level 3 or higher or cannot be considered as a 'stringent regulatory authority'.

12. Can I use a QCP certificate to apply for a market authorisation?

No. To date, no national regulatory authority has formally recognised QCP certificates. To apply for a marketing authorisation, please follow the instructions of the National Regulatory Authorities (NRA).

13. Can a QCP certificate contain exceptions or limitations?

Yes. Exceptions and / or limitations (called 'restrictions') can be issued. These will be mentioned on the certificate. For instance, GMP certificate may be granted for a site excepting the sterile product production line; a GSDP certificate granted to a wholesaler may exclude the management of cold chain products or the transport activities.

14. if a supplier introduces a change in its operations, does this affect the QCP certificate?

The holder of a QCP certificate is contractually obliged to inform QUAMED of changes in its operations, systems, policies or procedures that may affect the QCP certificate. Based on the assessment of the change, the IDC will take the decision to adapt, suspend or cancel the issues QCP certificate.

15. What are the terms and conditions of a QCP certificate?

See the link on our website: <https://quamed.org/qcp/>

16. How can I apply for a QCP certificate?

An email with a request for us to conduct a QCP audit should be send to info@quamed.org. In response, we will send a questionnaire that will allow us to collect more information on the organisation to be audited. The outcome of the questionnaire will determine whether we can move ahead with a QCP audit.

17. What are the costs of a QCP certificate or a QCP audit?

The costs of a QCP audit will be determined on a case-by-case basis.

18. How long does it usually take from the application to the issuance of the QCP certificate?

It is difficult to determine how long it takes from application to issuance of the QCP certificate.

Once the audit has taken place, we count:

- 30 days for the draft audit report to be produced,
- 30 days for the auditee to produce a CAPA plan,
- 5 working days for the auditor to review the CAPA plan and produce the final report, and
- 30 days to organize an IDC meeting and issue the certificate.

19. How does QUAMED ensure that impartiality and independence are obtained?

Impartiality and independence of the QCP is key for QUAMED. This is the reason why QUAMED has implemented a series of procedures to ensure this. These can be summarized as follows:

- Policy and SOP on management of conflict of interest

QUAMED has developed policies and SOPs on management of conflict of interest. The latter is also included in our risk matrix. All staff, board members, consultants and IDC members sign conflict of interest declarations based on the scope of work / assignment.

- Impartiality and independence of QUAMED auditors

QUAMED use external consultants to carry out audit activities. The recruitment is described in our Quality Management System, as well as the validation process of the auditors for each type of audits, and the renewal or suspension of auditors. Auditors must be free of conflict of interest to conduct an audit.

- Impartiality of Independent Decisional Committee

Independent Decisional Committee is key to ensuring that decisions related to granting a QCP certificate are taken in an impartial and independent manner. The IDC members are proposed by the QUAMED operational team and QUAMED Technical Committee based on a set of criteria, and they are selected and validated by the QUAMED Board of Directors. For full transparency, IDC meetings are also open to a representative (observer) from among the QUAMED members