



## Terms & Conditions QUAMED Quality Certificate

A QUAMED Quality Certificate is a certificate issued by QUAMED under its Quality Certification Program (QCP), available to all eligible interested parties. The certificate is issued by QUAMED after a stringent and independent decision-making process based on audits reports carried out by QUAMED validated auditors.

The audit standards employed by QUAMED are the World Health Organisation (WHO) standards. The Quality Certificate is proof that the audited organisation complies with these standards at the time of the audit.

The QUAMED Quality Certificate can be given for:

- *Model Quality Assessment System for Procurement Agencies*, as per “WHO Model quality assurance system for procurement agencies. In: Annex III of the WHO technical report series 986: WHO Expert Committee on Specifications for Pharmaceutical Preparations, forty-eighth report. World Health Organization, 2014.
- *Good Storage and Distribution Practices*, as per “WHO good storage and distribution practices for medical products, Annex 7, WHO Technical Report Series 1025, 2020”
- *Good Manufacturing Practices*, as per “WHO good manufacturing practices for pharmaceutical products: Main principles. In Annex 2, WHO Technical Report Series 986, 2014” and other related relevant guidelines.

In all cases, the most recent and up to date WHO document refers as per the WHO website.

Each certificate has a unique number, based on internal QUAMED numbering system. The period of validity of the certificate is mentioned on the certificate and is usually a period of three years. The period of validity of a certificate cannot be extended.

Without prejudice to the provisions of these Terms & Conditions relating to the Trademarks (see below), in its communications with its customers or business partners, whatever the medium, the auditee can make a reference to the fact that it has received a QCP certificate. This reference should specify the type and the number of the QCP certificate received. Notwithstanding the above, the auditee must abstain from making any improper use of the certificate or the certification logos and/or from damaging the reputation of QUAMED and/or the QCP procedure.

### **Audit report**

The audit report is shared with the auditee. It is accessible through the QUAMED database if the auditee has agreed to this. Access to the audit report is defined in the audit acceptance agreement signed by the auditee before the start of the audit.

### **Publication of the QUAMED Quality Certificate**

QUAMED will publish the certificate on its website through the following information:

- Number of the certificate
- Type of the certificate, including potential restrictions
- Name of the certificate owner
- Address of the certified facility
- Validity date of the certificate
- Remarks (if applicable)

### **Responsibilities of the auditee during the period of validity of the Certificate**

The auditee who has received a QCP certificate is required to inform QUAMED of any significant changes that could have an influence on the validity of the certificate outcome. These changes will be evaluated by QUAMED, and a follow-up assessment (on-site or virtual) (e.g., audit) can be required to confirm the validity of the QCP certificate.

When QUAMED is formally informed by third parties of a significant change that has occurred within the auditee's organization, a follow-up assessment (on-site or virtual) can also be carried out by QUAMED. The validity of the certificate will be in this case reassessed.

### **Suspension and/or withdrawal of QUAMED quality certificate**

QUAMED reserves the right to suspend or withdraw an issued certificate or to suspend the QUAMED Quality Certification process at any moment.

In general, suspension or withdrawal of a certificate / Quality Certification process is to be considered if:

- QUAMED Quality Certification owner fails to comply with the standard for which it has been certified;
- QUAMED Quality Certification owner ceases to operate;
- QUAMED Quality Certification owner fails to fulfil the requirements of the QCP procedure (eg failure to notify changes in due time);
- QUAMED Quality Certification owner makes improper use of the certificate or certification logos or damages the name and/or business reputation of QUAMED and/or QCP procedure;
- In the event of proven serious facts against the Certification owner or the QCP Applicant, such as, for example, critical drug quality problem, violation of WHO standards, corruption, falsification, counterfeiting, unethical behaviour, or other major issues.

When a certificate is suspended or withdrawn, QUAMED retains the right to mention this information on its website.

### **Renewal of the QUAMED Quality certificate**

Nine months before the expiry of the QUAMED Quality Certification, an e-mail is sent to the owner of the QUAMED Quality Certificate to inform it about the upcoming expiry. The QUAMED Quality Certificate owner has the following possibilities:

- To apply for renewal of the QUAMED Quality Certification in the same category;
- To apply for a renewal and an extension of the scope of the certification (for instance from GSDP QUAMED Quality Certification to MQAS QUAMED Quality Certification);
- Not to apply for the renewal of the QUAMED Quality Certification: in this case, the certificate will become invalid at the expiry of the period.

### **Limits of the QUAMED Quality certificate**

The QUAMED quality certificate is issued following an audit carried out within a specific period for a specific pharmaceutical site. The certificate certifies that at that point in time, the auditee complied



with the applied standards. However, QUAMED cannot be held liable if, at any time after the issuance of the certificate, the auditee no longer complies with the standards (i.e., in the event that such incompatibilities with the standards have arisen post-certification). This includes instances where the auditee has lied or has concealed important information or facts to obtain the certificate.

#### **Disclaimer**

The information contained and accessed on or through the QUAMED website, database, audit reports or QCP certificates is provided by QUAMED for general guidance and is intended to offer general information of interest. QUAMED has used its best endeavours to ensure that the information contained on its website, its database, its audit reports and its certificates is accurate and reliable. However, errors may sometimes occur. Therefore, QUAMED expressly disclaims all express or implied warranties of any kind as to any matter whatsoever relating to the information. In no event shall QUAMED be liable for any indirect or consequential loss or damage (whether for loss of profit or otherwise) arising out of or in connection with the use of information on its website, database audit reports or QCP certificates.

#### **Trademarks**

The QUAMED certificates and audit reports contain trademarks which are owned and registered by QUAMED, to distinguish and identify its services. No license to use any of these trademarks is hereby granted or implied. The certificate holders are allowed to reproduce (copy) the certificate for marketing purposes or to distribute to its customers and partners. In no instance though, is the certificate holder allowed to alter the certificate.