



## Terms & Conditions of QUAMED QCP Certificate

### 1. INTRODUCTION

The QUAMED Quality Certificate (the “**QCP Certificate**”) is issued by **QUAMED**, a not-for-profit association (*Association Sans But Lucratif - ASBL*) organized under Belgian law with registered office at 23 rue de Mont-Saint Guibert 1340 Ottignies (Belgium), and registered with the register of legal entities in Ottignies (Belgium) under number 715.557.518.

The QCP Certificate is granted to a certified entity (“**Holder**” or “**Client**”, such as defined in the Service Agreement) under QUAMED’s Quality Certification Program (QCP), pursuant to a separate QCP Certification Service Agreement (the “**Service Agreement**”), after a stringent and independent decision-making process based on audits reports documenting reviews carried out by QUAMED validated auditors, as described in separate policies and process documents available on QUAMED’s website (the “**QCP Policies**”). The Service Agreement entered into between QUAMED and the Client (hereinafter the “**Party**” or together the “**Parties**”) contains a framework applicable to the Parties during and following the termination of the audit activities and processes performed by QUAMED for the benefit of the Client and pursuant to the QCP (the “**Certification Services**” or the “**Audit**”).

QUAMED only certifies conformance of Systems within the scope of the certification to the World Health Organization (WHO) standards, as described in Section 3. The “**System**” or the “**Client’s System**” shall mean the organizational structure, responsibilities, activities, resources, and events that together provide organized procedures and their methods of implementation to ensure the Client’s ability to meet the standard(s) that has been or is to be certified by QUAMED (the “**Certification Standard(s)**”).

QUAMED does not certify that the products manufactured by Holder are safe, nor that any of its processes conform to applicable laws and regulations, or any other standards, codes of conduct and best practices.

The QCP Certificate is proof that the Holder’s Systems within the scope of the certification comply with these WHO standards at the time of the audit.

### 2. PURPOSE OF THESE TERMS & CONDITIONS

These Terms & Conditions set out the scope of the QCP Certificate and the Parties’ rights and obligation once the Certification Services have been performed pursuant to the Service Agreement and a QCP Certificate has been awarded. They also govern the use of QCP Certificate by the Client/Holder. In case of conflict between the provisions of these Terms and Conditions and the Service Agreement, the provision of the Service Agreement shall prevail.

### 3. TYPES OF CERTIFICATIONS

Under the QUAMED QCP, a QCP 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 to the WHO website.

#### **4. INFORMATION ON THE QCP CERTIFICATE**

The QCP Certificate contains the following information:

- The name and address of the certificate Holder.
- The number of the certificate. Each QCP Certificate has a unique number, based on an internal QUAMED numbering system.
- The period of validity of the Certificate (usually a period of three years). The period of validity of a certificate cannot be extended.
- The type of Certificate, i.e. QCP GSDP certificate, QCP GMP certificate or QCP MQAS certificate.
- The scope of the Certificate, as per the audit scope
- Remarks (if applicable).

#### **5. RESPONSIBILITIES OF THE HOLDER DURING THE PERIOD OF VALIDITY OF THE QCP CERTIFICATE**

The Holder 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 QCP 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 informed by third parties of a significant change that has occurred within the Holder's organization, an (on-site or virtual) assessment can also be carried out by QUAMED. The validity of the QCP Certificate will be in this case reassessed.

#### **6. SUSPENSION AND/OR WITHDRAWAL OF QCP CERTIFICATE**

QUAMED reserves the right to suspend or withdraw an issued QCP Certificate or to suspend the QUAMED QCP process at any moment.

In general, suspension or withdrawal of a QCP Certificate / QCP process is to be considered if:

- The Holder fails to comply with the standard for which it has been certified-
- The Holder ceases to operate-
- The Holder fails to fulfil the requirements of the QCP procedure (e.g., failure to notify changes in due time)-
- The Holder 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 Holder, such as, for example, critical drug quality problem, violation of WHO standards, corruption, falsification, counterfeiting, unethical behaviour, or other major issues.

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

## 7. RENEWAL OF THE QCP CERTIFICATE

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

- To apply for renewal of the QCP Certificate in the same category-
- Not to apply for the renewal of the QCP Certificate: in this case, the Certificate will become invalid at the expiry of the period.

## 8. SCOPE AND LIMITS OF THE QCP CERTIFICATE

The QCP Certificate is issued following an audit carried out within a specific period for a specific pharmaceutical site (see scope mentioned on the QCP Certificate). The QCP Certificate certifies that at that point in time, the Holder complied with the applied standards. However, QUAMED cannot be held liable if, at any time following the issuance of the QCP Certificate, the Holder 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 Holder has lied or has concealed important information or facts to obtain the certificate.

## 9. DISCLAIMER – RIGHTS OF THIRD PARTIES

The information contained and accessed on or through the QUAMED website, database, audit reports or the QCP Certificate 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, in its database, its audit reports and the QCP Certificate 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 provided. 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 or reliance on information on its website, database, audit reports or the QCP Certificate.

## 10. QUAMED BRANDS AND CERTIFICATION TRADEMARKS

10.1. **QUAMED Trademarks.** QUAMED exclusively owns all right, title and interest, including all related intellectual property rights, in and to the trademarks, service marks, certification marks, logos, trade dress, and other graphic images related to QCP Certificate and/or QUAMED Certification Service (collectively the “**QUAMED Trademarks**”), which constitutes the intellectual property of QUAMED. The Certificate and audit reports carry QUAMED Trademarks. Except as set forth in Article 10.2 below, nothing contained in these Terms & Conditions or in the Service Agreement between QUAMED and the Client (such as defined in the Service Agreement) or the QCP Holder, shall grant or shall be deemed to grant to the Client or QCP Holder, title, or interest in or to QUAMED’s Trademarks.

10.2. **Grant of License.** Prior to the award of the QCP Certificate, QUAMED grants the Client the limited right to state and/or display that it is applying for the QCP Certificate of the System, provided however, that it remains prohibited from using the QUAMED Trademarks before obtaining the QCP Certificate, in any manner that expresses or implies (as reasonably ascertained by QUAMED in its sole and absolute discretion) that the System has achieved, or will achieve, the QCP Certificate. In the event that the Client’s System is awarded QCP Certificate, then, subject to other terms set forth by this Article of Terms & Conditions, QUAMED grants the Client a worldwide, non-exclusive, non-sub-licensable, non-transferable, revocable (as set forth below), limited license to use, during the period of time during which the QCP Certificate remains valid, the Trademarks for the purposes of

communicating the level of QCP Certificate granted in relation to the Client's System. The Client agrees to use all the QUAMED Trademarks in accordance with all applicable laws, rules and regulations, and that it will comply at all times with the Trademark Usage Policy, and, and any other related standards associated with the use of the QUAMED Trademarks as provided by QUAMED in writing. The Client represents and warrants that it has reviewed such Trademark Usage Policy in its entirety. Notwithstanding the above, the Holder must abstain from making any improper use or altering of the QCP Certificate or the QUAMED Trademarks and/or from damaging the reputation of QUAMED and/or the QCP procedure.

**10.3. Reserved Rights.** All rights not expressly granted herein are reserved by QUAMED, and no license is granted hereunder for the use of any of the QUAMED Trademarks for any purpose beyond the uses set forth in this Agreement, or to any other intellectual property of QUAMED or its licensors.

**10.4. Further Client Commitments:** The Client agrees:

- 10.4.1. not to contest the ownership or validity of any of the QUAMED Trademarks, or of the license granted hereunder;
- 10.4.2. not to apply for nor register any of the QUAMED Trademarks nor any sign that includes any of the QUAMED Trademarks or any confusingly similar marks or variations thereof, and
- 10.4.3. not to voluntarily become a party to any litigation in which others contest the validity of any of the QUAMED Trademarks.

**10.5. Automatic Termination of Licence.** For the avoidance of doubt, the license granted herein shall automatically terminate with respect to the Client's System, without notice, upon (i) the expiration or revocation of the QCP Certificate, (ii) the Client's misuse of QUAMED Trademark in violation of the Trademark Usage Policy, or (iii) in the event of non-compliance by the Client with the provisions under these Terms & Conditions or those contained in the Service Agreement or the Certification Standard. On termination of the Licence, the Holder shall immediately cease to use any trademarks or logos associated with QUAMED, or to sell any products or services that have previously been labelled or marked using the QUAMED Trademarks and cease to make any claims that imply that they comply with the requirements for the QCP Certificate.

**10.6. Unauthorised Use.** The Holder acknowledges and agrees that any unauthorized use of QUAMED Trademarks constitutes both an infringement of intellectual property rights of QUAMED and a material breach of these terms and conditions. The same shall apply to any additional QUAMED Trademarks, acquired by it after the award of the QCP Certificate by Client. It is the responsibility of the Client/Holder to ensure that its use of such additional QUAMED Trademarks is compliant with the requirements under these terms and conditions. The Holder acknowledges and agrees that it shall not make any claim of, or seek any right to, title or ownership in and to any of the QUAMED Trademarks, nor shall submit any trademark or other intellectual property application for the content designs or logos confusingly similar to any of the QUAMED Trademarks. The Holder agrees that this disclaimer applies worldwide, including jurisdictions in which QUAMED Trademarks are registered and those in which QUAMED has not applied for registration.

**10.7. Damages and remedies.** The Client acknowledges that the QUAMED Trademarks and the goodwill associated therewith possess special, unique, and extraordinary characteristics, rendering the estimation of monetary damages that QUAMED would suffer as a result of the Client's unauthorized use of the QUAMED Trademarks complex. The Client acknowledges that QUAMED would suffer injury by such unauthorized use and agrees that injunctive and

other appropriate remedies are available in the event of a material breach by it of any QUAMED intellectual property rights. Such remedy shall not be exclusive of any other remedies available to QUAMED.

## 11. OTHER INTELLECTUAL PROPERTY RIGHTS

Save for the rights described with respect to the QUAMED Trademarks in Article 10 of these Terms & Condition, and the rights described with respect to the Results in this Article 11, this Agreement shall in no case imply an assignment, license or other transfer to the Client of any intellectual property rights of QUAMED (such as know-how, copyright, etc.).

All material produced by QUAMED as a result of the performance of the Certification Services, including but not limited to any visual images, data, reports and more generally all deliverables agreed by the Parties (collectively the “Results”) will remain QUAMED’s property, including any intellectual property rights related thereto.

Upon, and subject to, the entire payment to QUAMED of all amounts due by the Client to QUAMED, pursuant to Article 5 of the Services Agreement, the Client shall have the non-exclusive right to use the Results. Such right to use the Results includes any exploitation thereof such as sharing/displaying, but not selling the Results to third parties or deriving any financial benefit from them.

The Client agrees that the QCP audit report(s) will be available on QUAMED’s database for the entities or persons having subscribed an access right to QUAMED database. QUAMED represents that such subscribers have committed to the same limited use obligation as set forth in this article.

In case a QCP Certificate is issued, the Client understands and agrees that the following information will be published on the QUAMED website: Name, site address, the QCP Certificate’s number and the type, as well as its scope, issuance date and expiry date.

The Client further agrees that a representative of the Institute of Tropical Medicine in Belgium is authorized to use the Results in order to compile and analyze the Results and make available on QUAMED database or publish on other media, qualitative and quantitative data based on the Results. It is agreed that any release on QUAMED database or other publication of such data shall be subject to the confidentiality obligations set forth in Article 15 of the Service Agreement (i.e., for the avoidance of doubt, such data shall not contain any Confidential Information of the Client).

It is agreed that the QCP audit report is considered Confidential Information of QUAMED and is subject to the confidentiality obligations set forth in Article 15 of the Service Agreement. In addition, any Confidential Information of the Client contained in the QCP audit report shall remain Confidential Information of the Client.

## 12. GOVERNING LAW AND JURISDICTION

The Certificate shall be governed by and construed in accordance with Belgian law. Any dispute arising out of or in relation to the Certificate, which is not settled amicably, shall be subject to the exclusive jurisdiction of the courts of Brussels (French-speaking/Dutch speaking chambers).

## Document Signatures

Participant Name	Participant Type	Action	Task Performed On
Anthony Bourasseau	Reviewer	Approve Review	2023-11-03 14:05
Ed Vreeke	Reviewer	Approve Review	2023-11-03 14:11
Anthony Bourasseau	Approver	Approve Document	2023-11-03 14:14
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1.0	2023-11-05	Anthony Bourasseau	Upload to Simploud Initial Version

Effective