



Terms of Reference for an ISO accreditation support consultant (ISO 17021, ISO 17065, ISO 19011)

About QUAMED

QUAMED is a **not-for-profit association** with a mission to **improve access to quality medicines** for all. QUAMED is a **global membership organization** that brings together international Non-Governmental Organizations (NGOs), pharmaceutical procurement centers, and engaged individuals focused on assuring the quality of medicines delivered in low- and middle-income countries. For more information, please visit our website : www.quamed.org

One of QUAMED's main activities is to conduct pharmaceutical assessment on behalf of its members or customer. The assessments may be short technical visits or audits. Audits are assessments of pharmaceutical suppliers against World Health Organization (WHO) **GSDP** (Good Storage and Distribution Practices), **MQAS** (Model Quality Assurance System for Supply Agencies) and **GMP** (Good Manufacturing Practices) standards. QUAMED has also developed a new program called '**Quality Certification Program**' (QCP) which will be officially launched in 2023. QCP is to offer a recognized quality certification to pharmaceutical wholesalers and manufacturers according to sound technical criteria and standards defined by the WHO. It is QUAMED's expectation that such a recognized certification will reward commitment to meet WHO standards and contribute to positively shaping the market to favour quality medicines. Importantly, QUAMED anticipates that wholesalers and manufacturers benefiting from a formal QUAMED certification would be more likely to gain access to the tenders of quality-minded donor-funded programs and of quality-minded central medical stores and other purchasers.

QUAMED acknowledges that its audit quality and robustness and its QCP program must be recognized at international level. One of the objectives is to develop **ISO certification**. For the moment, **QUAMED is certified ISO 9001:2015** since November 2022. Our ambition is to continue to gain more ISO certification in audit-related topics. This may be through **ISO certification related to the following standards: ISO 17021:2015 (or eventually if more suitable ISO 17065:2015), ISO 19011:2018.**

Our needs

To reach our objectives, **QUAMED is looking for a short-term expert** who will analyse our organisation and will support the operational team, and especially the executive director and the quality and compliance coordinator, in the following activities:

- **Structure the ISO certification strategy** by advising the most appropriate ISO standards that QUAMED should apply for

- **Conduct a gap analysis** against the ISO standard(s) chosen
- **Develop a project planning** to address the identified gaps with the operational team.
- Support the operational team on development or upgrading of processes and SOPs:
This will probably be a light support.

The expert will be **hired as an independent consultant** and will work with the operational team **remotely**. All meetings, communications and document consultation will take place virtually. The level of effort is expected to be **5 working days**, over the period **from January to March 2023**.

Qualification required

The candidate should have the following competencies:

- Knowledge of ISO standards related to auditing practices (especially ISO 17021:2015, ISO 17065:2015, ISO 19011:2018).
- Knowledge of the accreditation process in Belgium is an asset (QUAMED is a Belgian organisation)
- Past experience in supporting organisations on ISO 17021 / ISO 17065 / ISO 19011 accreditation
- QUAMED's working language is English. Ability to work both in English and French is an added benefit.

How to apply

- Applications (Curriculum Vitae including a short presentation describing your abilities to meet the essential requirements (max 1500 words) as well as names and contact details of a minimum of 2 references) should be sent by email to anthony.bourasseau@quamed.org
- All the applicants will be informed by e-mail of the results of the selection process.
- **The deadline for application is the 25/01/2023.**