

Practices (GMP) audits.

What is the QUAMED quality certification programme (QCP)?

The QUAMED Quality Certification Programme (QCP) is a programme that provides a recognized quality assurance assessment certification for public and private sector pharmaceutical suppliers (distributors and manufacturers) according to internationally recognised criteria as defined and adopted by the WHO.

HOW DOES IT WORK? INVITATION The pharmaceutical supplier (or a purchaser) invites QUAMED Audit by validated auditor. to organize an audit. A positive result means a **QCP** certificate valid for a List with QCP three-year period. certificates published of the QUAMED website. There are three different **MQAS** QCP certificates: We will focus on GSDP and • for Good Storage and MQAS because QUAMED Distribution Practices has been involved in (GSDP) audits, developing the current • for Model Quality MQAS standards. Assurance System (MQAS) audits and • for Good Manufacturing

POTENTIAL BENEFITS OF QCP CERTIFICATE



FOR DONORS AND IMPLEMENTERS

- Reduced risk of purchasing sub-standard and/ or falsified medicines, when procuring from suppliers with a QUAMED certification
- The opportunity to easily identify suppliers compliant with WHOquality standards
- Access to reliable audit information.



FOR SUPPLIERS

 Increased market access: suppliers with a formal QUAMED accreditation are more likely to gain access to the tenders of quality-minded donorfunded programs and of quality-minded central medical stores and other procurement agencies



FOR ALL STAKEHOLDERS

- It will contribute to improving access to quality assured products as it will be easier for purchasers to identify reliable suppliers.
- QUAMED will maintain and publish the list of suppliers that have received a QUAMED QCP certificate. The list will be accessible to the public following the example set by the WHO Prequalification program publication of prequalified manufacturers.

There are only two other organizations that publish a list with accepted suppliers: USAID and ECHO.

The QCP list will be public and complementary to these two lists.

Suppliers can **apply** to the QCP by **contacting QUAMED directly** (info@quamed.org). When they have funding secured, the audit can take place. The QCP audits are in addition to our regular audits.



QCP

QUALITY CERTIFICATION PROGRAMME

The QUAMED QCP is an innovative solution addressing the pharmaceutical quality assurance problem in countries that do not have a national regulatory authority with maturity level 3 according to WHO's Global Benchmarking Tool. Using the QCP, the purchasers and the vendors can establish an objective and expert opinion on the level of Good Storage and Distribution Practices (GSDP) and Model Quality Assurance System (MQAS) for procurement agencies compliance.

The quality assurance of medicines and other health products is a challenge for pharmaceutical suppliers both in the private sector and the public sector.



QUAMED

QUAMED is a global membership organization. International Non-Governmental Organizations (INGOs), national pharmaceutical procurement centres and engaged individuals constitute most of its members. There are currently <u>50 members</u>. The governance and organizational structure is composed of the General Assembly, the Board of Directors, a Technical Committee, and the Operational Team.



QUAMED'S MISSION

The mission of QUAMED is to increase access to quality medicines and other health products in low- and middle-income countries (LMICs) by:

- organising GSDP, MQAS and GMP audits and sharing the results with relevant stakeholders.
- offering pharmaceutical Quality Assurance related training and technical assistance, and
- actively advocating for access to quality assured medicines.



QUAMED is aligned with and supporting WHO GPW13 Target of 1 Billion more people with coverage of Universal Health Care (UHC), and accordingly SDG 3.8 Target of access to safe, effective, quality and affordable essential medicines and vaccines for all.



TARGETGROUP

Pharmaceutical suppliers (wholesalers distributors and procurement agencies) in the public sector and private sector that are supplying, or would like to supply, the public health sector and particularly to health programs funded by international or public resources.

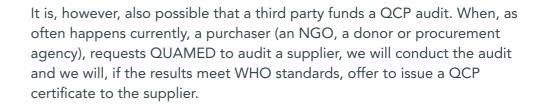
Organizations that could benefit from QCP:

- Suppliers of medicines and other health products who would like to supply the markets described above.
- Organizations such as non-governmental organizations (NGOs), central medical stores (CMS) and others that procure essential medicines for public sector facilities in the countries with a regulatory authority with maturity level 3 or lower.
- Manufacturers of essential medicines who would like to export to the markets described above.



FUNDING

The suppliers that invite QUAMED to organize a QCP audit, will be the ones that fund the audit. This is in line with good practices in the private sector where the 'seller' needs reliable arguments to convince the 'buyer' to purchase from a particular source. It is at the origin of the ISO standards where the buyer wants to see an independent third-party opinion about an aspect of the seller's organization. It is also in line with the WHO prequalification programme that requires a contribution from the pharmaceutical manufacturers.



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Quamed is a non-profit association based in Belgium.

embers (individuals and organizations) have tensive experience in the pharmaceutical, ug regulation and drug supply sectors in n-governmental organizations, international ganizations and other institutions. They have orked, and continue to practice, in a wide riety of geographical and socio-economic ntexts (Western Europe, Africa, Asia, Latin

America and Eastern Europe) in collaboration with organizations such as WHO, the Global Fund, UNICEF, UNITAID and a large number of international NGOs and purchasing organisations.

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