QUAMED Quality Medicines for All	**Title:**	**QUAMED expert appointment**		
	N°:	SOP-Q-001	Version: 01	
	Effective date:	27/06/13	Pages:	5
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1 General information

1.1 Aim and application

The aim of this document is to describe the different QUAMED needs in terms of expertise and the way the experts are appointed. Therefore the document is applicable to all actors involved in the definition of expertise needs and in the selection of this expertise for the QUAMED project.

1.2 Legislation, standards or related documents

QUAMED consortium agreement.

2 Responsibilities

The Coordinator is responsible to verify that the requirements described in this document are respected.

3 Definitions and abbreviations

API:	Active Pharmaceutical Ingredient
CRO:	Contracted Research Organization
GDP:	Good Distribution Practices
GMP:	Good Manufacturing practices
GLP:	Good Laboratory Practices
MQAS:	a Model Quality Assurance System for procurement Agencies
PIC/s:	Pharmaceutical Inspection Co-operation Scheme
QC:	Quality Control
Partners Institutions:	The legal entities (not-for-profit and academic organizations) participating directly in QUAMED
Coordinating institution:	The Institute of Tropical Medicine (ITM)
QUAMED technical expert:	The technical expert who will render pharmaceutical or technical services in connection with QUAMED
Project expert:	Long term contracted technical expert members of QUAMED
SRA:	Stringent regulatory authorities

Steering Committee:	The group which steers and supervises QUAMED; its composition and duties are defined in Quamed Consortium Agreement

4 Method

The experts are scientists with professional experience in the selection of medicines and sources (evaluation of technical dossiers, audits/inspection of manufacturing/distribution sites...) gained in pharmaceutical industry, international NGOs and /or international organizations, national authorities.

They are either long-term contracted members of QUAMED (project experts) or consultants temporary hired by QUAMED to complement the team by their specific expertise or are members/representatives of partner organizations with specific expertise.

4.1 Appointment:
Their qualifications are evaluated on objective criteria, based on detailed curriculum vitae describing their qualifications and specific areas of expertise, and, at first, on results of pair review of dossiers, joint audits, with team members or inspectors or experimented experts involved in the project or similar activities for long.

The experts should be free from any commercial, financial or other interest, which may affect their judgment and decisions; a conflict of interest declaration has to be signed.

Selection of the experts is performed by the QUAMED coordinating institution with the support of one of the QUAMED project expert. Then experts are appointed by the Steering Committee.

4.2 Requested expertise

The selection criteria are listed below:

a) **Auditors** should have the following qualification, knowledge and experience to perform evaluation of procurement agencies according to WHO GDP and MQAS[i].

Educational Backgrounds:
Degree/diploma in pharmacy, chemistry or microbiology

Qualification and experience:

- Practical experience as GDP auditor, according to international standards (EU/WHO);
- Suitable qualifications, knowledge and experience of Quality Assurance in procurement of medicines;
- Good working knowledge of the WHO GDP guidelines and WHO MQAS;

Preferably

- Experience in working in developing countries;
- High level of proficiency in English and French;
- Advanced technical writing skills in both languages.

b) The **GMP/GLP auditors** should have the following qualification, knowledge and experience to perform evaluation at manufacturing site or quality control laboratory:

Educational Backgrounds:
Degree/diploma in pharmacy, chemistry or microbiology

Qualification and experience:
- The GMP/GLP inspectors who are officials (in activity or not any more) of national authorities or international organization (as WHO prequalification program) are qualified de facto.
- For non-official inspector:
  - Practical experience as GMP/GLP auditor, according to international standards (EU/FDA/WHO) and preferably in developing countries;
  - Suitable qualifications, knowledge and experience of Quality Assurance in industrial pharmaceutical production and QC;
  - Good working knowledge of the WHO GMP guidelines;
  - Proven regular training in current standards and knowledge for auditing pharmaceutical manufacturing;
  - Proven regular update in technical field as pharmaceutical engineering, QC methods and information system.

Preferably
- Experience in working in developing countries;
- High level of proficiency in English and French;
- Advanced technical writing skills in both languages.

c) The **assessors** should have the following qualification, knowledge and experience for the assessment of technical dossiers:

Educational Backgrounds:
Advanced degree in pharmacy, pharmacology, chemistry or microbiology

Qualification and experience:

- Experience of evaluation of pharmaceuticals and related quality issues such as quality specifications of finished product and APIs, stability data... preferably within stringent regulatory authorities, industrial pharmaceutical regulatory affairs or international organization (e.g. WHO-PQ, MSF, UNICEF, the Union, UNFPA...);
- Good working knowledge of the International standards of pharmaceutical products;
- Proven regular training in current standards and knowledge for pharmaceutical product dossier assessment;
- Proven regular update in specific technical area.

Preferably

- High level of proficiency in English and French;
- Advanced technical writing skills in both languages.

For specific topics as bioequivalence study, stability study, additional expertise may be required and experts should demonstrate:

- either experience of evaluation of bio availability data, comparative dissolution studies preferably within stringent regulatory authorities ;
- or specific experience in QC validation method;
- or personal experience in CRO (for bio availability data assessment).

4.3 Agreement

Once the expert has been appointed by the Steering committee, he/she should sign a contract with QUAMED. This contract describes clear responsibilities of the appointed expert and of QUAMED and defines the duties of the appointed expert.

Declaration of conflict of interest and Confidentiality agreement have to be signed together with the contract.

CV, contract and annexed forms (declaration of conflict of interest and confidentiality agreement) are filed by QUAMED coordinator.

A list of the current experts appointed by QUAMED is kept updated and available to QUAMED partner institutions on request.

5 Attachments and forms for completion

- Declaration of conflict of interest (F-Q-004)
- Confidentiality agreement (F-Q-003)

6 Revision

Revision	
Changes with respect to the previous published version:	First version

[i] WHO MQAS (a Model Quality Assurance System for procurement Agencies): http://www.who.int/medicinedocs/index/assoc/s14866e/s14866e.pdf
WHO Good Distribution Practices for Pharmaceutical Products. WHO Technical Report Series, No. 957, 2010, Annex 5 (2011)