QUAMED Quality Medicines for All	**Title :**	**QUAMED audit of international procurement agencies**		
	N°:	SOP-Q-005	Version:	01
	Effective Date:	27/06/2013	Pages :	6
	Written by: Sandrine Cloez Date : 17/06/2013	Review by: Corinne Pouget Date :17/06/2013	Approved by: Raffaella Ravinetto Date : 27/06/13	

1 General information

1.1 Aim and application

Description of the process of the preparation, conduct and reporting of the audit of International Procurement Agencies (IPA). This SOP also partly (for the conduct and reporting) applies to audits of Procurement Agencies/distributors carried out in the context of a Local Market Assessment.

1.2 Legislation and standards

The content of this procedure is based on WHO MQAS and WHO GDP[i] recommendations

2 Responsibilities

The Coordinator of the project is responsible of:

- verifying that the requirements described in this document are respected
- planning and organising the audits, in particular the first contact with the companies to be audited

The Quamed experts are responsible of:

- logistical aspects of audits after approval by the selected IPA
- conducting and reporting on the audit according to the standards taken in reference, and any partner specific requirement
- respecting the ethical and confidentiality behaviour

3 Definitions and abbreviations

GDP:	Good Distribution Practices
MQAS:	a Model Quality Assurance System for procurement Agencies- WHO
Auditee:	the responsible person(s) of the IPA audited by Quamed.
Partner Institutions:	The legal entities (not-for-profit and academic organizations) participating directly in QUAMED
QUAMED coordinator:	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
Steering Committee (SC):	The group that steers and supervises QUAMED; its composition and duties are defined in QUAMED Consortium Agreement

4 Method

The preparation, conduct and reporting of the audits are done according to the Process flow on Organisation of an audit of an International Procurement Agency (see below).

a) Preparation

The IPAs to be audited are selected based on requests and priorities collected from the partner institutions, or organisations involved in Quamed activities (eg DG ECHO), or Quamed team (coordinator and project experts). A programme is done annually and presented to the Quamed partners for a comment/approval at the end of the previous year.

The audits are then planned by the Quamed coordinator according to priorities and availabilities of the selected Quamed technical experts.
The IPA to be audited are contacted by the coordinator (see appended template 'introduction audit letter') to present Quamed and the objective and purpose of the audit, and ask for acceptance and proposing dates. The IPA are informed that, in case of refusal, the Quamed partners will be informed of the reasons presented.

Each audit is performed by a Quamed technical experts (the expert) selected for its field of expertise as per SOP "Quamed expert appointment", possibly accompanied by some representative(s) of the partner institutions.

An audit generally lasts 2 days in order to check the level of compliance of the practices and Quality Assurance system applied at the IPA site with the WHO GDP Guidelines and WHO MQAS; a particular attention is given to the procedure for selection/qualification of the products and sources. A follow-up of previous audits is done if relevant, by checking the effective implementation of the corrective/preventive actions proposed.

When an audit is accepted by the IPA, confirmation is sent by the expert (or by the coordinator in case of external temporary contracted expert) indicating the date, the presence of accompanied persons if any, and asking for documents (SMF or filled in procurement agency questionnaires). The audit acceptance letter (see appended template) is also sent to the IPA and will be collected duly signed at the latest at the opening of the audit.
Logistical issues are generally treated directly by the expert (or by the coordinator in case of external temporary contracted expert).

The expert (or the coordinator in case of external temporary contracted expert) will contact the Quamed partner directly interested by the audit in order to collect any particular request on information/issue to be checked during the audit (follow-up of previous visits, review of files of specific selected products, …).

The expert will then sent a proposed audit agenda (see template in annexe) to the IPA at least 5 days before the audit.

b) Conduct of the audit

The audit is conducted as follows:

1. Opening meeting: presentation of participants, presentation of QUAMED, scope and aim of the audit *(expert).*
2. Approval of the agenda *(all)*
3. Brief presentation of the audited structure *(IPA)*
4. Follow-up of previous audit (if relevant): presentation of any change and CAPA implemented
5. Visit of the premises, preferably following the process flow:

   Reception area, Quarantine area, Storage area, Preparation of orders, Cold chain, Controlled substances, Damaged / expired/returned/recalled products,…
6. Review of QA system and documentation:
   - Quality manual
   - Annual quality review (if any)
   - SOPs: management of complaints and recalls,
   - Tools/forms
   - Definition of responsibilities (who is doing what)
7. QC policy:

   Sampling plan, Selection of laboratories, OOS results management

8. In depth review of the products/sources validation process:
   - Procedure
   - Review of some examples (Manufacturing sites audit reports and evaluation of product dossiers)
   - Monitoring
9. Time for extra investigation if needed
10. Debriefing (expert and IPA representatives)

    After having prepared the conclusions alone, the expert will give an oral overview of the audit and its outcomes and present all the observations noticed and to be included in the audit report; any nonconformities observed must be classified as minor/major/critical and refer to WHO guideline.

    The IPA should be invited at this time to discuss the nature or wording of nonconformities in order to clarify any misunderstanding; however long discussion should be avoided and the IPA should be invited to provide arguments and discussion on the outcomes of the audit by writing after receipt of the report. A corrective/preventive action with supportive objective evidences should be requested.

    The expert will remind the steps and actions following the audit (see § c).

c) Reporting

A report will be written according to a template (see appended form 'Report Template'). All observations noticed during the audit and presented to the procurement agency during the closing meeting must be clearly listed in the report. Reference to the WHO guidelines should be specified as far as possible for each observation. Normally no additional observations (i.e. not mentioned at the debriefing meeting) should be included in the report.
The report will be sent to the audited company within 4 weeks after the audit.

The audited company is given 1 month to answer and possibly send a proposal of corrective action plan, which will be reviewed by the expert and attached to the final report.

The outcome of the audit will be presented in a rating table (annex 5) that will be addressed to the audited company with the final report and entered in the QUAMED database.

In case of a dispute concerning the content of the report, amicable agreement between the QUAMED expert and the auditee will be sought first. If an amicable agreement is not obtained the issue will be settled by the QUAMED steering committee.

All observations made in the context of the audit must remain confidential and be treated as per the consortium agreement. Under no circumstances any observations can be communicated outside QUAMED network without the prior approval of the auditee and QUAMED coordinator.

In case the auditee is a Quamed partner institution (eg a procurement center), the report will be reviewed by an additional expert from the list of experts appointed by QUAMED Steering Committee. If deemed necessary, the Steering Committee may request the report to be reviewed by an experimented QA expert who is not involved in QUAMED. The Steering Committee will validate the report at the end of the process before it is included in the database for the benefit of QUAMED partner institutions.
The access to the report and rating through the database can be limited to defined partner institutions in case a commercial conflict of interest may arise between partners; the decision of restriction of information is to be discussed and decided by the SC.

Process flow

Actions	Responsibility	deadlines
elaboration of annual programme based on requests and priorities collected from Quamed partners and the Quamed team (at the end of the year/early next year)	coordinator	
Planning of an audit according to priorities and availabilities of experts	coordinator	
Contacting the company to be audited informing on Quamed, objective of the audit, proposed dates, …*standard letter*	coordinator	1-2 months before the

		audit
Receipt of the company's answer: – If yes organization of the audit, inform the expert in charge – If no, inform the requesting partners and report it in the database (end of the process)	coordinator	<2days after answer
Confirmation of the audit: sent to the company with dates, name of auditor(s), and requesting information (SMF or filled in questionnaire); *manufacturer and procurement agency questionnaires*	expert (or coordinator)	<2days
Information of requesting partners to collect any specific request on items to be checked during the audit (follow-up of previous visits, review of files of specific selected products, …)	expert (or coordinator)	<2days
Logistical organization: transport, hotel, visa…	expert (or coordinator)	
Sending audit programme to company ; *standard programme*	Expert	1 week before audit
Audit progress according to the programme: opening of the audit, visit of premises and review of documents, closure meeting with oral presentation of the outcomes	expert	
Drafting audit report; *report template*	expert	
Sending report to the company, invited to answer the observations by a CAPA within 1 month	Expert in charge	< 1 month after audit
In case the audited company is a Quamed partner: -organization of a SC meeting to be held one month later (possible by conference call or mail) for validation of the report (see below).,e review of the report by one other Quamed expert;	Coordinator Quamed expert	<1 week after the sending of the report
Answer received from the company: – No: one reminder sent to the company, with additional 1 week – Yes: review of the answer; possibility to contact company once for clarification or additional comment if expert no satisfied	Expert	1 month after sending report
Finalization of the report including the auditor's opinion on the answer provided by the company, or mentioning the absence of answer	Expert	1 week after receipt of the answer (except if conflict)
In case of conflict with the company on the outcomes of the audit: First amicable agreement to be sought Otherwise, issue to be settled by Quamed SC	Expert and Coordinator SC	
In case the audited company is a Quamed partner, decision on: -validation of the report -prior review by a (non-Quamed) QA expert - level of access to the information entered in the database	SC	1 week after finalization of report
Sending the final report and rating table to the company	coordinator	<2days
Entry of outcomes, report and rating in Quamed database.	Expert responsible of database	1 week
Archiving: all documents related to the audit are kept in QUAMED archives; in the Quamed database are posted: report, rating, SMF, any other	Coordinator Expert	

useful and non confidential information.	responsible of database	

5 Attachments and forms for completion; related documents

- Annex 1-QUAMED Procurement agency audit-agenda template
- Annex 2- Introduction audit letter
- Annex 3-Audit acceptance letter
- Annex 4- Report template -(SOP-Q-005/F01)
- Annex 5- Rating template -(SOP-Q-005/F02)

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)