FREQUENTLY ASKED QUESTIONS

Assessment of product sources

What is an assessment of product sources?
This is an assessment of finished pharmaceutical product sources using a variety of product information (such name of the manufacturer, address of the manufacturing site, country of production, ...). The assessment will allow us to classify the product source according to the QUAMED GMP classification of sources.

What is the goal of an assessment of product source?
The goal is to establish objective information on the risks related to the purchase of particular products. This may help QUAMED members in their procurement process.

What are the QUAMED GMP classification of sources?
QUAMED uses a classification with 5 GMP levels, from '4', the highest proven GMP compliance, to '1', for proven unsatisfactory GMP compliance and a level 'unknown', when it is not possible to obtain valid and recent information.
The classification is as follows:

GMP Levels	
Level 4	• Manufacturing sites approved by a Stringent Regulatory Authority (SRA) or by a WHO-listed authority (WLA) of Maturity Level 4 (ML4), or by WHO-PQ (prequalification program) GMP inspections should have been conducted not more than 3 years ago, unless otherwise justified.
Level 3	• Manufacturing sites having successfully passed a QUAMED GMP audit; or • Manufacturing sites GMP approved by another organization officially recognized by QUAMED; or • Manufacturing sites GMP approved by a WLA ML 3 GMP audits/inspections should have been conducted not more than 3 years ago, unless otherwise justified.
Level 2	• Manufacturing sites with an acceptable level of GMP compliance with restrictions, after an audit by QUAMED and/or other official or recognised organisations GMP audits should have been conducted not more than 3 years ago, unless otherwise justified.
Level 1	• Manufacturing sites with proven unsatisfactory GMP compliance level, whatever the source of info (audits carried out by QUAMED and/or other official or recognised organisations). GMP audits should have been conducted not more than 3 years ago, unless otherwise justified.
Level unknown	• Manufacturing site with no GMP information or decision pending or obsolete info.

How does QUAMED get GMP information required to classify the product sources?
GMP status information can be obtained by QUAMED:

- By consulting official databases (e.g. websites of WHO-Prequalification programme (WHO-PQ), EudraGMDP, MHRA, USFDA, …) this information is publicly accessible and considered accurate, up-to-date and validated;
- From audits carried out by QUAMED;
- From manufacturers/suppliers having voluntarily submitted information to QUAMED (e.g. audit/inspection reports, GMP certificates, site master files (SMF), SOPs, …) during audits or technical visits;
- From QUAMED members having collected information from manufacturers / suppliers
- From organisations that have a partnership or a signed sharing information agreement with QUAMED.

How is the GMP classification information presented to QUAMED customers?
QUAMED has developed a product source assessment template, where sources are classified according to their GMP level. Information may also be gathered from the QUAMED database.

How long does an assessment of product sources take?
An assessment of product sources can take anywhere from 1 week to 3 weeks, depending on the number of products to be assessed.

What is the cost of an assessment of product sources?
That depends on the number of products to be assessed. This will be evaluated at the initial phase of the activity.

Who pays for the assessment of product sources?
This depends on who requests the assessment of product sources. It usually is a single organisation (NGO or other purchaser), but it may also be a group of organisations.

How is a product dossier evaluation organised?
In the organisation of a product dossier evaluation, there are three main steps: A. Preparation, B. Evaluation, C. Reporting.

These phases include the following steps and responsibilities. Please note that these are the general steps but that in particular cases the process may be slightly different. The process is described for a request of a single QUAMED member, which is usually the case.

A. <u>Preparation</u>

1. One organization contacts QUAMED with a list of product sources to be assessed.
2. QUAMED develops a draft budget in a standard format and shares it with the lead organization.
3. The organization agrees on the scope of work and budget.
4. QUAMED prepares service agreements for each of the participating organizations with their financial contribution mentioned.
5. QUAMED sends the service agreements to the participating organization for signature.

B. Evaluation

6. The validated and qualified QUAMED expert carries out the assessment of the product source as per the QUAMED Quality Management System.

C. Reporting

7. Usually within 2 weeks after the signature of the service agreement, QUAMED completes the product source assessment tool.
8. QUAMED sends a copy of the completed product source assessment report to the participating NGO(s) and uploads the information to its database.