QUAMED services

Our services

- MQAS Audit
- GSDP Audit
- **Technical visit GSDP**
- **GMP Audit**
- GMP technical visit
- Evaluation of sources
- Evaluation of product files

- Verify manufacturers' compliance with WHO GMP (Good Manufacturing Practice) standards.
- In general 1 day of preparation + 2 to 3 days / site + 2 days of report. The duration on site depends on :
  - audit type
  - its scope
  - type of manufacturing site
  - type of production
- Qualified and validated auditors by QUAMED
- Site visit and detailed review of documents
- GMP rating + CAPA

QUAMED services

Our services

- MQAS Audit
- GSDP Audit
- **Technical visit GSDP**
- **GMP Audit**
- GMP technical visit
- Evaluation of sources
- Evaluation of product files

- Site Visits:
  - Realization according to the logical flow of products (warehouses, production areas, equipment, quality control laboratory, ...).
  - Verification of the conformity of the premises and equipment
  - Verification of the knowledge and application of procedures by the personnel
- Detailed Document Review:
  - Verification of the processes, procedures, records and related documents of the audited facility's organization

QUAMED services

Our services

- MQAS Audit
- GSDP Audit
- **Technical visit GSDP**
- **GMP Audit**
- GMP technical visit
- Evaluation of sources
- Evaluation of product files

- Observations:
  - Identification and reporting of inconsistencies, discrepancies and non-conformities
  - Classification of observations

***CRITICAL**: significant violations of WHO requirements (MQAS and/or GSDP) and QA practices that require immediate action.*
***MAJOR**: non-compliance with WHO requirements (MQAS and/or GSDP) and QA practices that require priority action*
***OTHER**: deviation from WHO requirements (MQAS and/or GSDP) and QA practices that require action within a reasonable time frame.*
***NOTE**: Recommendations*

  - Sharing observations with the focal point of the audited structure during the audit (relevance and responsiveness of the staff involved)
  - Sharing of the CAPA with the audited structure 7 days after the audit for comments (CAPA plan)

QUAMED services

Our services

- MQAS Audit
- GSDP Audit
- Technical visit GSDP
- **GMP Audit**
- GMP technical visit
- Evaluation of sources
- Evaluation of product files

- GMP rating: Determination of the level and effectiveness of the implementation and maintenance of processes and procedures (18 criteria with 5 levels of compliance (0 to 4).

Site licensing		4
Quality Assurance		4
Sanitation & hygiene		3
Qualification & Validation		4
Complaints & Product recalls		3
Contract production/ analysis		4
Self Inspection		4
Personnel & training		4
Premises	Ancillary zones	3
	Storage zones	4
	Production zones	4
	Laboratories	3
Equipment		3
Materials		3
Documentation		3
Good Practices in Production		4
Good Practices in QC		3
Sterile Manufacturing (if applicable)		4

QUAMED services

Our services

- MQAS Audit
- GSDP Audit
- Technical visit GSDP
- **GMP Audit**
- GMP technical visit
- Evaluation of sources
- Evaluation of product files

- **Report**:
  - Determination of compliance status with WHO GMP standards according to the nature and number of observations
  - The conclusion must specify the site(s)/building(s)/workshop(s) and which line(s)/product(s) involved.
  - Elaboration of the draft report based on the observations made and the rating
  - Sharing of the draft report reviewed by QUAMED with the audited structure for comments (4 to 5 weeks after audit)

- **Transmission of the audit report :**
  - Finalization and transmission of the final report validated by QUAMED to the customers 3 weeks after reception of the CAPA of the audited
  - Deposit of the report on the QUAMED database (validity 3 years)