QUAMED services

Our services

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

- Verify the compliance of procurement agencies (distributors, national procurement offices, etc.) with the MQAS (Model Quality Assurance System for Procurement Agencies) and the WHO GSDP (Good Storage and Distribution Practices) standards.
- In general 1 day preparation + 2 to 3 days / site (depending on the size of the sites) + 2 days reporting
- Qualified and validated auditors by QUAMED
- Site visit and detailed review of documents
- MQAS checklist + MQAS rating + observation classification

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- Site Visits:
  - Realization according to the logical flow of the products
  - Verification of the conformity of premises and equipment (basic rules)
  - 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

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- 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 the main observations with the focal point of the audited structure during the closing meeting of the audit (relevance and responsiveness of the staff concerned)

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- MQAS rating: Determining the level and effectiveness of implementation and maintenance of processes and procedures

MQAS Q.A. CRITERIA		MQAS ACTIVITIES		LEVEL OBTAINED
Criterion A	General quality assurance requirements	1	QA system	4
		2	Documentation system	4
		3	Computerised systems	3
		4	Human resources	4
		5	Self inspection	3
Criterion B	Continuous product qualification	6	Product Qualification	4
		7	Manufacturing site assessement	4
		8	Qualification decision (qualified sources monitoring)	4
N/A	Not included	9	Procurement	N/A
Criterion C	Quality control & reception	10	Control at reception	4
		11	Quality control	4
Criterion D	Storage & handling specific products	12	Warehouse organisation	3
		13	Physical storage conditions	3
		14	Management of the cold chain	3
		15	Stock Control	3
		16	Handling non conformity products	4
Criterion E	Dispatch & Transport	17	Dispatch	2
		18	Transport	4

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- **Report**:
  - Determination of WHO MQAS compliance status by nature and number of observations
  - Elaboration of the draft audit report based on the observations made and the rating
  - Sharing of the list of observations and the draft of the audit report reviewed by QUAMED with the audited structure (4 to 5 weeks after the audit for comments and proposal of a CAPA* plan by the audited)
  - Finalization and transmission of the validated final audit report to the auditee 3 weeks after receiving the CAPA plan

- **Sharing the audit report:**
  - Sharing of the audit report validated by QUAMED with the sponsor(s)
  - Availability of the report on the QUAMED database (validity 3 years)

*(*Corrective Action Prevention Action)*