



Model Quality Assurance System
for procurement agencies
audit report

Auditee name XXXXXXXXXXXXX
Site XXXXXXX
Country XXXXX
Date XXXXXXXXXXXXX
Reference no. XXXXXXXXXXXXX



Foreword

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About QUAMED

QUAMED is a non-profit association whose goal is to contribute to improving access to quality medicines. Further information at: www.quamed.org

Author(s)

XXXXXXXXXXXXXXXXXXXXXXXXXXXX	e-signature	date
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QUAMED internal approval

XXXXXXXXXXXXXXXXXXXXXXXXXXXX	e-signature	date
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Report validity

This report is valid for three years from the date of approval, unless major changes impacting the report outcomes occur during this period.

EXECUTIVE SUMMARY

Presentation of the context of the audit

This WHO Model Quality Assurance System for procurement agencies (MQAS) audit was organized by QUAMED XXXXXXXX. The purpose of the audit was to assess the compliance of XXXXXXXX, against the current World Health Organization (WHO) Model Quality Assurance System for procurement agencies (MQAS) and the current WHO Good Distribution Practices (GSDP) guidelines. The MQAS audit was performed from XXXXXXXX by XXXXXXXX XXXXXXXX, QUAMED auditor. This is the first MQAS audit conducted by QUAMED. However, QUAMED conducted GSDP technical visits in XXXXXXXX and XXXXXXXX.

Summary and conclusions

XXXXXXX that operate in various fields, including supply of health products. The pharmaceutical division operates XXXXXXXX XXXXXXXX, where offices and warehouse are located. XXXXXXXX provides health products (mainly pharmaceutical and medical devices) to pharmacies and hospital XXXXXXXX, but also have a contracting department in charge of dealing with non-governmental organizations (NGOs) and United Nations agencies requests. These supplies are not only XXXXXXXX but also XXXXXXXX.

XXXXXXX has all required licenses and certificates to operate. The pharmaceutical division has a clear segregation of duties between quality assurance department and warehousing and contracting (procurement) departments. Training program is well implemented. XXXXXXXX invested in building a strong Quality Management System, with comprehensive quality manual and policy, and a full set of standard operating procedures well managed. The management of deviations is in place, but the risk level is not sufficiently clear. The same issue has been observed in the internal audit.

XXXXXXX does not conduct product prequalification in the sense of the MQAS guidelines. XXXXXXXX fully relies on the XXXXXXXX for the product qualification. Considering the current regulatory situation XXXXXXXX it is deemed rather acceptable that XXXXXXXX does not duplicate the work and does not conduct its own product qualification. XXXXXXXX only procures products registered XXXXXXXX.

The warehouse is a state-of-the-art building constructed in 2017 with adequate capacity. Design, product flow and product segregation are excellent. The reception and release processes are satisfactory. Quality control is not carried out, but XXXXXXXX tests almost all products commercialized XXXXXXXX in its laboratory. Firefighting measures, security measures, as well as hygiene and sanitation systems are satisfactory. Temperature control is performed by an efficient HVAC system that allows adequate storage conditions (15 to 25°C, less than 60% HR). Cold chain management is also adequate. Dispatch and transport systems are also satisfactory, as well as the management of returned and recalled products. Some errors in documentation (missing signatures, etc.) have been noticed.

This audit identified the following observations:

Type of Observations	Number
Critical	0
Major	0
Other	7
Remarks	1

Based on the current audit performed XXXXXXXX) is deemed:

- **to operate at an acceptable level of compliance with the requirements of World Health Organization Model Quality Assurance System for Procurement Agencies.** However, it should be noted that **product prequalification was not in the scope of this audit**, as product prequalification is not conducted as per the MQAS standard. Procurement follows customer and XXXXXXXX requirements.

- **to operate at an acceptable level of compliance** with the requirements of World Health Organization Good Storage and Distribution Practices.

However, the corrective and preventive action plan ([Annex 2](#)) must be implemented to allow compliance of all of the observations identified.

To be completed by QUATC:

QUAMED GSDP/MQAS level	
XXXXXXX	LEVEL 3

CONTENT

EXECUTIVE SUMMARY	2
CONTENT	4
ACRONYMS	5
INTRODUCTION AND BACKGROUND INFORMATION	6
GENERAL INFORMATION ON THE AUDIT	6
METHODOLOGY	7
MQAS Module 1: GENERAL REQUIREMENTS	8
MQAS Module 2: PREQUALIFICATION	10
MQAS Module 3: PURCHASING	12
MQAS Module 4: RECEIVING AND STORAGE	12
MQAS Module 5: DISTRIBUTION	15
MQAS Module 6: RE-ASSESSMENT	16
DISCUSSION AND CONCLUSION	17
Annex 1: Audit agenda	19
Annex 2: CAPA	21

ACRONYMS

API	Active Pharmaceutical Ingredient
BP	British Pharmacopoeia
CAPA	Corrective Action Preventive Action
CE	European Conformity
CTD	Common Technical Dossier
DG ECHO	Directorate General for European Community Humanitarian Office
EDQM	European Directorate for the Quality of Medicines
EMA	European Medicines Agency
EP	European Pharmacopoeia
FDA (US)	Food and Drug Administration (United States Regulatory Authority)
FEFO	First Expired First Out
FIFO	First In First Out
FPP	Finished Pharmaceutical Product
GMP	Good Manufacturing Practices
GDP	Good Distribution Practices
GSDP	Good Storage and Distribution Practices
HQ	Headquarters
IAPQ	Inter-Agency Product Questionnaire
ICH	International Conference on Harmonization
INN	International Non-Proprietary Name
ISO	International Organization for Standardization
LMA	Local Market Assessment
ML	Maturity Level
MOH	Ministry of Health XXXXXXX
MQAS	Model Quality Assurance System (for Procurement Agencies)
NGO	Non-Government Organization
NRA	National Regulatory Authority
PA	Procurement Agency
PIC/S	Pharmaceutical Inspection Cooperation Scheme
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
RH	Relative Humidity
SOP	Standard Operating Procedure
SRA	Stringent Regulatory Authority
USAID	United States Agency International Development
WHO	World Health Organization
WHO PQP	WHO Pre-Qualification Program
WLA	WHO-listed authority

INTRODUCTION AND BACKGROUND INFORMATION

This WHO Model Quality Assurance System for procurement agencies (MQAS) audit was organized by QUAMED and XXXXXXXX.

The purpose of the audit was to assess the compliance of XXXXXXXX against the current World Health Organization (WHO) Model Quality Assurance System for procurement agencies (MQAS)¹ and the current WHO Good Distribution Practices (GSDP) guidelines².

The MQAS audit was performed from XXXXXXXX, QUAMED auditor. XXXXXXXX declared no conflict of interest with regards to this assignment. This is the first MQAS audit conducted by QUAMED. However, QUAMED conducted GSDP technical visits in XXXXXXXX and XXXXXXXX.

The agenda of the audit is presented in [Annex 1](#).

GENERAL INFORMATION ON THE AUDIT

XXXXXXX is an umbrella of business divisions that run business in various fields (agriculture, health, pharmaceuticals, veterinary, chemical...). The pharmaceutical division operates from XXXXXXXX, where offices and warehouse are located. XXXXXXXX provides health products (mainly pharmaceutical and medical devices) to pharmacies and hospitals XXXXXXXX, but also have a contracting department in charge of dealing with non-governmental organizations (NGOs) and United Nations agencies requests. These supplies are XXXXXXXX Therefore, XXXXXXXX deals with stock products (for pharmacies and hospitals) and non-stock products (for NGOs and UN agencies). Non-stock items are supplied XXXXXXXX. All products are registered XXXXXXXX.

Organization name	XXXXXXX	
Web site	XXXXXXX	
Facility physical address	XXXXXXX XXXXXXXX XXXXXXXX XXXXXXXX XXXXXXXX XXXXXXXX XXXXXXXX XXXXXXX XXXXXXXX XXXXXXXX	
Postal address	XXXXXXX	
Telephone		
Contact information	Name	XXXXXXX
	Position	XXXXXXX XXXXXXXX
	Email	XXXXXXX XXXXXXXX
Audit targets	QA system general requirements Prequalification Purchasing Receiving and Storage Distribution and transport Re-assessment	
Product category supplied (e.g. pharmaceuticals, medical devices,	Pharmaceutical and medical devices, including some diagnostic products and some lab items	

¹ WHO. Model quality assurance system for procurement agencies. In: Annex III of the WHO technical report series 986: WHO Expert Committee on Specifications for Pharmaceutical Preparations, forty-eighth report. World Health Organization, 2014.

² WHO good storage and distribution practices for medical products, Annex 7, WHO Technical Report Series 1025, 2020

diagnostics, laboratory items etc.)	
Audit date	XXXXXXXX XXXXXXXX
Auditor(s)	XXXXXXXX XXXXXXXX

METHODOLOGY

The current audit was conducted against the WHO Model Quality Assurance System for Procurement Agencies 2014 (MQAS), and the current WHO Good Storage and Distribution Practices (GSDP) guidelines.

The WHO MQAS guideline is composed of six modules, that cover the QA system general requirements of a procurement agency, as well as the supply chain elements, from prequalification, purchasing, receiving and storage and distribution. The WHO GSDP guidelines cover the general requirements regarding the Quality Management System, as well as the supply chain processes, as receiving, storage and distribution.

The status of compliance with the WHO MQAS is determined by the nature and number of observations according to SOP-Q-017 'Technical aspects of a MQAS audit'.

Any deficiency observed is classified as critical, major or other (as defined below) and reference is given to related chapters of WHO MQAS and GSDP guidelines.

CRITICAL	Critical observation is a departure from current WHO Model Quality Assurance System for procurement agencies guidelines and WHO Good Storage and Distribution Practices guidelines that may result in a medical product causing a <u>significant risk</u> to the patient and public health. This includes an activity increasing the risk of falsified medical products reaching the patients. This may also involve fraud, misrepresentation or falsification (of products, information). A combination of several major Observations that indicates a serious systems failure may be also classified as a critical observation. Critical Observations require immediate actions.
MAJOR	A major observation is a non-critical deficiency which indicates a major deviation from current WHO Model Quality Assurance System for procurement agencies guidelines and WHO Good Storage and Distribution Practices guidelines that <u>may increase the risk</u> to public health and safety. A combination of several Observations classified as 'other', none of which on their own may be major, may together represent a major deficiency. Major Observations require high priority actions.
OTHER	An observation classified as 'other' may be defined as a deficiency which cannot be classified as either critical or major, but which indicates a departure from current WHO Model Quality Assurance System for procurement agencies guidelines and WHO Good Storage and Distribution Practices guidelines. A deficiency may be other either because it is judged as minor or because there is insufficient information to classify it as major or critical. Observations classified as 'other' require actions within a reasonable timeframe.
REMARK	A remark is an issue which is not specifically a deviation from a requirement of the current WHO Model Quality Assurance System for procurement agencies guidelines and WHO Good Storage and Distribution Practices guidelines. A remark should be seen as supportive for further improvements. Actions may or may not be taken based on the decision of the management of the auditee.

Notes :

- *Several Observations on the same activity, none of which on its own may be critical or even major, but which may together represent a critical or major deficiency, should be explained and reported as such.*

- *Classification of an observation is based on the assessed risk level and may vary depending on the nature of the products, e.g. in some circumstances an example of another observation may be categorized as major.*
- *An observation that was reported at a previous audit and was not corrected may be reported with a higher classification.*
- *One-off minor lapses or less significant issues are usually not formally reported but are brought to the attention of the supplier during the audit.*

MQAS Module 1: GENERAL REQUIREMENTS

1. Operating conditions

Operating licenses

XXXXXXX has the following official documents:

- XXXXXXX XXXXXXX XXXXXXX XXXXXXX).
- XXXXXXX XXXXXXX XXXXXXX XXXXXXX XXXXXXX

Adequate resources

XXXXXXX has adequate resources to operate.

2. Personnel

Overview

The quality assurance department is composed by 2 staff members (one at HQ, one at the warehouse). The contracting department is composed of three people. A position of responsible pharmacist and regulatory affairs manager is also available.

Organizational chart

Two organization charts were provided for the pharma division (dated 05/10/2021) and signed. It confirms the independence of quality assurance department related to the operational functions.

Job descriptions

Job descriptions for the QA personnel were reviewed: The content is adequate (minimum qualification, link to the organogram, roles and responsibilities).

Training management

'Training procedure' XXXXXXX presents the training arrangements. The SOP content was found adequate. A training matrix is available, showing the training needs for each type of position within the company. An annual training program is also available for different departments. Training sessions were conducted according to the schedule for the regulatory affairs department. Training records ('training reports') are also available. Overall, the training system is deemed satisfactory.

Management of conflict of interest and code of conduct

A code of conduct is available on the website (in XXXXXXX), and according to the XXXXXXX XXXXXXX, contains elements on conflict of interest. It is signed by all XXXXXXX when they sign the employment contract.

3. Documentation system

Quality manual and quality policy

The quality manual (XXXXXXX) was signed on 28/10/2021. It contains all key required information (including a organization chart, the job description of key personnel and summary statement related to the key QMS functions), as well as a quality policy. Overall, the quality manual was found satisfactory.

Overview of the Quality Management System (QMS)

XXXXXXX has a comprehensive and well managed quality management system; Numerous SOPs, forms and records are available and well maintained.

Management of SOPs

The SOP ‘Standard operating procedure creation’ (XXXXXXX) and ‘Document control’ (XXXXXXX) provide elements about the management of SOPs. The content of both SOPs and forms were found satisfactory. During the audit, SOPs and records were available and updated. The overall system is deemed efficient.

4. Management of deviations, non-conformities and CAPA

SOPs review

‘Deviation handling procedure’ (XXXXXXX) was reviewed and the overall content was deemed comprehensive. However, the section 6.2 on risk assessment is not clear enough between the categorization of level I, II and III and may bring confusion (definitions of level I, II and III may be improved). ‘CAPA procedure’ (XXXXXXX) was found satisfactory (reporting, responsibilities, link with risk assessment, follow-up and archiving).

Deviation reports review

Sampled deviation reports from 2021 and 2022 were reviewed. Overall, reports are well completed and comprehensive. Investigations are done as well as root cause analysis. All documents were well signed. However, the section of ‘risk classification’ is not well completed according to the SOP. In many reports reviewed, the section is kept blank, or filled ‘minor’ which is not one of the classifications of the abovementioned SOP.

CAPA records

CAPA handling log sheets are available for 2021 and 2022. 4 CAPAs were recorded for 2022, from internal audits (3) or deviations (1). CAPA handling reports are well completed, with correct risk assessment and conclusion. CAPA are followed up according to the SOP.

Observation

No. 1	Other	Section 6.2 of ‘Deviation handling procedure’ (XXXXXXX) on risk assessment is not clear enough between the categorization of level I, II and III (definitions). In practice, the sections related to ‘risk classification’ in sampled deviation reports from 2021 and 2022 are not well completed according to the SOP. In many reports reviewed, the section is kept blank, or filled ‘minor’ which is not one of the classifications of the abovementioned SOP. (WHO GSDP Section 6.2)
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5. Complaints management

SOP

The SOP ‘Handling of products complaints’ (XXXXXXX) presents the arrangements and responsibilities related to product complaints management. Responsibilities of investigations, CAPA and decision-making are under the QA manager and the responsible pharmacist. SOP content was deemed adequate.

Records

A complaint log sheet is available and contains fourteen complaints received so far in 2022. The log is well completed. Customer notifications files were available and a random sampled were reviewed:

- XXXXXXXX): Managed effectively with the manufacturer.
- XXXXXXXX). No conclusion yet from the manufacturer. It is likely an issue from the patient side.

Records were found adequate, even though manufacturers sometimes did not reply to the complaints.

6. Self-inspection (internal audit)

SOP

The SOP 'Internal quality audit (self inspection)' (XXXXXXX) presents the arrangements related to self-inspection. It contains elements describing the schedule, the conduct of an audit, and the link with the CAPA and the follow-up of the audit. Audits are managed by the QA manager. SOP content was found satisfactory.

Schedule

A schedule for 2022 is in place, with eight audits planned. So far, three audits were carried out, and three are delayed. The schedule for 2021 was partially adhered, with two audits out of five postponed to 2022 due to sickness or Covid-19 pandemic.

Records

Two internal audit reports were reviewed (XXXXXXX and release procedure XXXXXXXX. Records were found appropriate except the fact that observations are classified as 'minor', 'intermediate' and 'major' while the SOP lists the criticality as 'minor', 'major' and 'critical'.

Observations

No. 2	Other	<i>Records of internal audit (XXXXXXX) were found appropriate except the fact that observations are classified as 'minor', 'intermediate' and 'major' while the SOP lists the criticality as 'minor', 'major' and 'critical'. Furthermore, audit schedules in 2021 and 2022 were not always respected (3 audits delayed so far in 2022). (WHO GSDP sections 11.2 & 6.2)</i>
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7. Infrastructures

XXXXXXX have all required infrastructures to operate (warehouse, IT systems, offices, transport vehicles).

8. Computerized systems

The main computerized system at XXXXXXXX is the ERP. The ERP was validated in 2021: The document called 'ERP validation plan' (June 2021) contains all requirements and acceptance criteria for testing the ERP system. Tests results are compiled in the 'XXXXXXX). This document contains a series of tests related to the functionalities of the ERP, including quality assurance tests, access tests of the system. The ERP has single access using specific account, with privileges given. The QA personnel has the right to change the pharmaceutical status of a product (from 'hold' status to 'released' status for instance). Regular backups of the data are carried out on two different servers. Overall, the validation work and use of the ERP is deemed satisfactory.

MQAS Module 2: PREQUALIFICATION

1. Product qualification

Overview and link with XXXXXXX

XXXXXXX manages two types of products / activities:

- Regular activities with stock products for pharmacies and hospitals.
- Unregular activities (based on request for quotations and needs) with non-stock items for NGOs and United Nations agencies. This is managed by the contracting department.

This is the second case that is studied here.

XXXXXXX does not conduct product prequalification in the sense of the MQAS XXXXXXXX XXXXXXXX XXXXXXXX n for the product qualification: XXXXXXXX and is not listed as a WHO-listed authorities of level 3 and 4 according to the Global Benchmarking Tool initiative managed by WHO. However, the XXXXXXXX XXXXXXXX is known to well regulate the pharmaceutical market, even there is no factual evidence of this. Considering the current regulatory situation in XXXXXXXX, it is deemed rather acceptable that XXXXXXXX does not duplicate the work and does not conduct its own product qualification.

SOP

The SOP called 'Procurement procedure' (XXXXXXX) give information on selection, approval and monitoring of pharmaceuticals, medical supplies and equipment for the contracting department. The current qualification standards are as follows:

- a. Supplier must comply with GSDP requirements
- b. Products must be XXXXXXXX
- c. In case of products not registered by the XXXXXXXX, check the following standards:
 - o Approved manufacturer or supplier by OFDA/USAID
 - o Approved manufacturer by two or more European countries
 - o Approved manufacturer by XXXXXXXX

Points a) and b) are acceptable as this means that only XXXXXXXX registered products can be purchased from suppliers approved/authorized by XXXXXXXX. However, point c) is problematic in the sense of it only covers the GMP status of the product manufacturer, but it does not cover the product dossier content. XXXXXXXX has no capacity to assess product dossier. It was reported that only XXXXXXXX were procured now, and this option was only used in the past, but this is no more a current practice.

Observation

No. 3	Other	<p><i>Section 6.1.2 of the 'Procurement procedure' (XXXXXXX) describes the possible procurement of XXXXXXXX registered products. However, this section contains information about assessing the GMP status of the manufacturing site using available information, but it does not cover the product dossier review. XXXXXXXX does not have the capacity to assess product dossier, and do not procure now products that are not registered by XXXXXXXX. Therefore, this section is not applicable and may bring confusion. (WHO MQAS section II.1)</i></p>
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2. Manufacturing site assessment

MSG does not conduct GMP audit. The company fully relies on XXXXXXXX XXXXXXXX.

3. Qualification decisions (qualified source monitoring)

This section is not applicable. The product list available is based on the registered products XXXXXXXX available on XXXXXXXXXXXXXXXXXXXX.

MQAS Module 3: PURCHASING

The purchasing mechanism is linked to the selection and qualification system, which was described in the previous section. As already mentioned, only XXXXXXXX are procured and provided by the contracting department to NGOs and UN agencies.

Regarding monitoring of the performance of the suppliers, there is no system in place as XXXXXXXX contracting department work with irregular suppliers (based on the requests from NGOs). However, they did not report any issue in logistics performance.

MQAS Module 4: RECEIVING AND STORAGE

1. Control at reception & release

SOPs

Product receipt is managed according to 'Goods Receiving Procedure' (XXXXXXX). The SOP was found comprehensive, with roles and responsibilities well detailed as well as deviations processes. Cold chain products are included. However, the sampling regime is not detailed in the SOP. In practice, the following rule (square roots of the number of cartons plus one) is usually used for small consignment while a regime with less samples is adopted for larger consignment (e.g. XXXXXXXX). This may be easily explained in the SOP.

Product release is conducted according to SOP 'Product release procedure' (XXXXXXX), which was found satisfactory.

Receiving and hold areas

The receiving area was found of adequate size, clean with pest control features. Temperature and relative humidity are not monitored in the area, but the HVAC system maintains adequate conditions. The area was however temperature mapped. This is acceptable considering that products stay a maximum of six hours in the area, and therefore the risk of product degradation is negligible.

The hold area is large and kept under locks. It contains products that have been checked at reception but not yet release by quality assurance team.

Practices

A reception checklist is filled for every invoice. The content of the checklist was found satisfactory, and forms were well completed.

Regarding the release procedure, XXXXXXXX in controlling the market for pharmaceuticals and some medical devices. These products should be sampled and sent to the XXXXXXXX. XXXXXXXX provides product release letters. Therefore, XXXXXXXX is linked to the availability of release letters from XXXXXXXX and also from the data extracted from the dataloggers used during transport to XXXXXXXX. The documentation reviewed for sampled invoices (XXXXXXX) was found satisfactory and comprehensive. The QA department is in charge of moving the goods in the ERP system for the 'Q' status (hold / quarantine) to the release status. No occurrence of rejected batches were found. It should be noted that only JFDA released products are purchased by the contracting department.

Observation

No. 4	Other	<i>Goods Receiving Procedure' (XXXXXXX) does not contain the sampling regime used for small and large consignments (WHO GSDP section 12.12)</i>
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2. Quality control

XXXXXXX performs quality control of pharmaceutical products manufactured in XXXXXXXX XXXXXXXX. According to information from the internet, XXXXXXXX XXXXXXXX is certified ISO 17025. XXXXXXXX has a specific testing regime

that are communicated to the manufacturers and the distributors. XXXXXXXX is in charge of the ‘release’ of the batches on the market, after quality control and/or documentation review.
 For all these reasons, XXXXXXXX does not conduct any quality control activities, which is deemed acceptable considering the country context.

3. Organization of warehouse

General information and capacity

XXXXXXX is used for the storage of pharmaceutical products and medical devices. The capacity was found adequate (XXXXXXX m3 and approximately 10m height), with about XXXXXXXX pallets capacity. At the time of visit, no products to be supplied to NGOs or U.N. agencies were stored. The warehouse was built in XXXXXXXX and is a state-of-the-art store, with good design, product flow, product segregation, as well as information.

Firefighting measures

The store has all well-maintained features to fight against fire (water hoses, fire extinguishers, fire detectors).

Security measures

Security is well managed inside and outside the store. The compound is closed by a wall with security guards. CCTV is installed, as well as access control by fingerprints. Badges for visitor are in place. All these features are described in ‘Security arrangements procedure’ (XXXXXXX).

Hygiene and sanitation

Hygiene and sanitation were found satisfactory in the storage area. A ‘Gowning XXXXXXXX to/from operating area’ (XXXXXXX) is in place and well implemented by the staff. The SOP ‘Cleaning of warehouse’ (XXXXXXX) is comprehensive. The warehouse was found clean. Warehouse cleaning log sheets are completed but it was noticed some missing date and signature in some sheets. Regarding pest control, the SOP ‘Rodent and insects elimination procedure’ (XXXXXXX) details the pest control system in place, which include rodent baits stations and insect killer lamps. Pest control is partially externalized to a contractor. Weekly check records (XXXXXXX) and monthly check records (done by the contractors) were found satisfactory.

Storage of hazardous products

There are no hazardous products XXXXXXXX.

Observation

No. 5	Other	Warehouse cleaning log sheets are completed but it was noticed some missing date and signature in some sheets. (WHO GSDP section 17.6)
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4. Physical storage conditions

SOPs

Different SOPs describes how adequate storage conditions should be maintained:

- ‘Storage conditions monitoring (XXXXXX
- ‘Responding to excursions in temperature and humidity range’ (XXXXX).
- ‘Calibration and validation policy’ (XXXXX).

Storage conditions are from 15°C to 25°C and less than 60% of relative humidity.

Temperature and humidity control system in place

A HVAC system is in place, covering the entire warehouse. Dedicated cooling systems are installed in cold rooms.

Temperature and humidity mapping studies

Temperature and humidity mapping studies were conducted in XXXXX. Another one planned this summer. The protocol and report were found appropriate. Temperature and humidity limits were well within the acceptable range, in all studied locations.

Monitoring system & calibration of devices

An online monitoring system is used (XXXXXXX). The system allows real time information on the storage conditions at the dataloggers locations. Thirty dataloggers are installed in the main store, while six covers the cold chain equipment.

A calibration / validation list / plan is available. Calibration reports were available for sensors in the warehouse. The calibration reports however mentioned an acceptance criterion of $\pm 2^{\circ}\text{C}$ in all reports, while the SOP mentioned $\pm 0.5^{\circ}\text{C}$. In sampled reports reviewed, the correction required was however less than 0.5°C . Furthermore, the calibration range is 15 to 25°C . It would be better to cover more than the range of the accepted limits of the warehouse (for instance 10 to 30°C), to make sure potential out-of-limits values are still within the calibrated range of the devices. The same remark is valid for the cold chain sensors (calibrated between $+2$ and $+8^{\circ}\text{C}$).

Review of data

All data reviewed for the first half of 2022 were all within the specified ranges (15 to 25°C , less than 60%RH).

Observations

No. 6	Other	<i>The acceptable criterion in the calibration certificates of the sensors is $\pm 2^{\circ}\text{C}$, while the SOP mentioned an acceptable range of $\pm 0.5^{\circ}\text{C}$. In sampled reports reviewed, the correction required was however less than 0.5°C. (WHO MQAS section IV.5.3.1)</i>
No. 7	Remark	<i>The calibration range is 15 to 25°C. It would be better to cover more than the range of the accepted limits of the warehouse (for instance 10 to 30°C), to make sure potential out-of-limits values are still within the calibrated range of the devices. The same remark is valid for the cold chain sensors (calibrated between $+2$ and $+8^{\circ}\text{C}$).</i>

5. Cold chain Management

SOPs

Cold chain management is usually detailed with the SOP describing the relevant process product receipt, dispatch). A good level of detail was noticed while reviewing the SOPs. Another SOP 'XXXXXXX (XXXXXXX) adequately describes how to pack cold boxes.

Maintenance of the cold chain from the suppliers to XXXXXXX

All cold chain shipments are conducted with a datalogger. The XXXXXXX for cold chain products as part of the release procedure. XXXXXXX also reviews the data and sends it the suppliers to get their go-ahead. Print-out of temperature data are attached to the release files for each invoice.

Cold chain equipment

Walk-in cold chain chambers are installed within the warehouse. There are connected between them. Different sections of the cold rooms are dedicated for hold area, released goods, recalled goods and products in preparation. Cold chain boxes and 'ice packs' (gel based) are harmonized and appropriate for the use. All cold chain equipment was found in good state of cleanliness and maintenance. Power is backed up by two generators that switch on automatically.

Maintenance and monitoring of the temperature in the cold room

Temperature mapping studies and performance qualification work (XXXXXXX were conducted successfully in January XXXXXXX. The temperature records for the first six months of 2022 showed no excursions.

Preparation of orders

The preparation of orders is well detailed in SOP. Equipment used for cold chain packing is standardized advanced, validated equipment (XXXXXXX). The preparation of the cold boxes was found satisfactory.

Delivery of cold chain consignments

Dataloggers are included in all consignments and are managed until the responsibility of the products is handled to the customer(s). The customer may also collect the consignment at XXXXXXX. It should be noted that a milted amount of cold chain products is ordered by customers of the contracting department.

6. Stock control

Management of near to expiry products

‘Handling of expired or near to expired product procedure’ (XXXXXXX) was found well detailed. Products are automatically moved by the ERP system to the electronic near expiry location in the ERP if the remaining shelf life is less than four months. Physical products are also moved to the secured near expiry location.

Inventory management (periodic stock count)

XXXXXXX has a procedure that well describes periodic stock count: ‘Inventory check procedure’ (XXXXXXX). The stock count is performed on a quarterly basis by inventory control department. The SOP includes discrepancies checks. Reports were not available for review (in another building).

7. Handling of regulated/controlled products (narcotics and psychotropics)

Narcotics and psychotropics are managed in a different store. However, NGOs and U.N. agencies cannot purchase narcotics and psychotropics from XXXXXXX, and therefore this section was not assessed.

8. Handling of non-compliant products

‘Handling of expired or near to expired product procedure’ (XXXXXXX) and ‘Reject disposal procedure’ (XXXXXXX) are used to manage non-compliant and non-useable products. The procedure includes liaising with XXXXXXX XXXXXXX. Storage of rejected products is done in a separated location outside the store.

MQAS Module 5: DISTRIBUTION

1. Dispatch

SOP

A SOP ‘Customer and order preparation and distribution procedure’ (XXXXXXX) details the order preparation steps, including cold chain items, as well as the dispatch and transport arrangements. It is well detailed and contains all necessary steps with clear responsibilities.

Dispatch area

The dispatch area is large, clean and well organized. As per the receiving area, there is no temperature and humidity datalogger. The same remark applies here. Storage conditions were well maintained.

Practices and records

Orders are all checked by the warehouse personnel, and randomly checked by the QA officer. Invoices are supposed to be signed by warehouse personnel once the consignment has been verified. In practice, there are many missing signatures. Batch information is well included in the delivery documents (managed through the ERP system), therefore batch traceability is ensured.

Observation

No. 8	Other	<i>As per section 6.16.2 of the SOP ‘Customer and order preparation and distribution procedure’ (XXXXXXX), invoices are supposed to be signed once the orders have been verified. However, it was noticed that a significant number of sampled invoices were not adequately signed. (WHO GSDP section 17.6)</i>
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2. Transport

Transport is carried out using XXXXXXX or external trucks by a contracted company. Different transport systems are used for NGOs and UN agencies based on the needs and the destination. Storage conditions are maintained during transport, and calibrated dataloggers (same system as the warehouse, but with mobile devices) are used to monitor the transport conditions. Overall, transport system implemented by XXXXXXX is deemed satisfactory.

3. Management of returned products

A SOP ‘Returned goods handling procedure’ (XXXXXXX) covers the management of returned products. Cold chain products are not authorized to be returned. The responsibilities of assessing the quality of the products, and consequently accepting or rejecting the products are with the quality assurance team. Voucher copies were available, well filled. QA department is in charge of the decision-making as per the SOP.

4. Management of product recalls

SOP review

‘Handling of recall batches’ (XXXXXXX) contains all required information on management of recalls, including the mock recalls procedure once a year in case of absence of recalls in the past 12 months.

Practices and records

A recall files was reviewed (XXXXXXX) and contains all elements required (information to the customers, reconciliation, reports). A mock recall was also initiated early XXXXXXX and found satisfactory.

MQAS Module 6: RE-ASSESSMENT

1. Monitoring of products, manufacturers and suppliers (including contracted out services)

As prequalification is not conducted as per the MQAS guidelines, this section is not applicable.

DISCUSSION AND CONCLUSION

XXXXXXX) is an umbrella of business divisions that operate in various fields, including supply of health products. The pharmaceutical division operates XXXXXXX, where offices and warehouse are located. XXXXXXX provides health products (mainly pharmaceutical and medical devices) to pharmacies and hospital XXXXXXX, but also have a contracting department in charge of dealing with non-governmental organizations (NGOs) and United Nations agencies requests. These supplies are not XXXXXXX XXXXXXX XXXXXXX XXXXXXX.

XXXXXXX has all required licenses and certificates to operate. The pharmaceutical division has a clear segregation of duties between quality assurance department and warehousing and contracting (procurement) departments. Training program is well implemented. XXXXXXX invested in building a strong Quality Management System, with comprehensive quality manual and policy, and a full set of standard operating procedures well managed. The management of deviations is in place, but the risk level is not sufficiently clear. The same issue has been observed in the internal audit.

MSG does not conduct product prequalification in the sense of the MQAS guidelines. XXXXXXX fully relies on the XXXXXXX for the product qualification. Considering the current regulatory situation XXXXXXX, it is deemed rather acceptable that XXXXXXX does not duplicate the work and does not conduct its own product qualification. XXXXXXX procures products registered by the XXXXXXX.

The warehouse is a state-of-the-art building constructed in 2017 with adequate capacity. Design, product flow and product segregation are excellent. The reception and release processes are satisfactory. Quality control is not carried out, but XXXXXXX tests almost all products commercialized in Jordan in its laboratory. Firefighting measures, security measures, as well as hygiene and sanitation systems are satisfactory. Temperature control is performed by an efficient HVAC system that allows adequate storage conditions (15 to 25°C, less than 60%HR). Cold chain management is also adequate. Dispatch and transport systems are also satisfactory, as well as the management of returned and recalled products. Some errors in documentation (missing signatures, etc.) have been noticed.

This audit identified the following observations:

Type of Observations	Number
Critical	0
Major	0
Other	7
Remarks	1

Based on the current audit performed, XXXXXXX is deemed:

- **to operate at an acceptable level of compliance with the requirements of World Health Organization Model Quality Assurance System for Procurement Agencies.** However, it should be noted that **product prequalification was not in the scope of this audit**, as product prequalification is not conducted as per the MQAS standard. XXXXXXX XXXXXXX XXXXXXX XXXXXXX requirements.
- **to operate at an acceptable level of compliance with the requirements of World Health Organization Good Storage and Distribution Practices.**

However, the corrective and preventive action plan ([Annex 2](#)) must be implemented to allow compliance of all of the observations identified.

QUAMED GSDP level	
XXXXXXXXXXXXXXXXXX	LEVEL 3



ANNEXES



Annex 1: Audit agenda

1. AUDIT OBJECTIVE AND SCOPE

The aim of this audit is to assess the compliance of the auditee against the World Health Organization (WHO) Model Quality Assurance System for Procurement Agencies (MQAS)³ and the WHO Good Storage and Distribution Practices (GSDP)⁴ standards, and to define its GSDP levels as per QUAMED standardized assessment system. The scope of the audit is to audit the warehouse activities of XXXXXXXX.

2. GENERAL INFORMATION ABOUT THE SUPPLIER

Organization name	XXXXXXXX	
Facility physical address	XXXXXXXX	
Key contact information	Name	XXXXXXXX
	Position	XXXXXXXX
	Email	XXXXXXXX
	Phone	XXXXXXXX
Audit date	XXXXXXXX	
Auditor name(s)	XXXXXXXX	

3. PROPOSED AGENDA

The audit will be conducted as follows:

Day 1 – [09:00] – close of business

- Presentation of QUAMED, Expectations and purpose of the visit (QUAMED auditor)
- General presentation of XXXXXXXX, the company profile, the network of wholesalers associated with XXXXXXXX, the quality systems in place, description of significant changes since the last visit in case of re-audit.
- Review of quality assurance system and documentation:
 - Quality manual
 - Review of the main SOPs and tools

³ [WHO model quality assurance system for procurement agencies](#), Annex 3 WHO Technical Report Series 986, 2014

⁴ [WHO good storage and distribution practices for medical products](#), Annex 7, WHO Technical Report Series 1025, 2020

- Clarification of roles and responsibilities
- Visit of the premises according to the product flow:
 - Receiving process
 - Storage area: organisation, storage conditions, compliance with Good Storage Practices
 - Quarantine area / rejected products area
 - Preparation of orders, dispatch and transport
 - Controlled substances management
 - Returned products management
 - Cold chain management (if any)

Day 2 opening of business– closing of business

- Review of documentation related to:
 - Recalls
 - Deviations and non-conformities
 - Complaints
 - CAPA
- Quality control policy:
 - Sampling plan
 - Laboratory selection
 - Management of Out of Specification (OOS) results

Day 3 opening of business– closing of business

- Review of the source validation process (product prequalification):
 - Overall process and implementation
 - Audit reports from manufacturing sites.
 - Review of product dossiers
 - Monitoring
- Time for extra investigation as needed
- Conclusion preparation (QUAMED auditor alone)
- Debriefing (all): Presentation of the key findings. Clarifications. Presentation of the next steps.

Please note that this proposed agenda may be subject to changes during the course of the audit based on findings.

Annex 2: CAPA

Obs. number	Classification of the observation	Observations (With Reference to the WHO GSDP)	Auditee proposed Corrective actions / preventive actions	Timeline	Comment(s) from QUAMED auditor
No. 1	Other	Section 6.2 of 'Deviation handling procedure' (XXXXXXXX) on risk assessment is not clear enough between the categorization of level I, II and III (definitions). In practice, the sections related to 'risk classification' in sampled deviation reports from XXXXXXXX and XXXXXXXX are not well completed according to the SOP. In many reports reviewed, the section is kept blank, or filled 'minor' which is not one of the classifications of the abovementioned SOP. (WHO GSDP Section 6.2)			
No. 2	Other	Records of internal audit (XXXXXXXX 22) were found appropriate except the fact that observations are classified as 'minor', 'intermediate' and 'major' while the SOP lists the criticality as 'minor', 'major' and 'critical'. Furthermore, audit schedules in 2021 and 2022 were not always respected (3 audits delayed so far in 2022). (WHO GSDP sections 11.2 & 6.2)			
No. 3	Other	Section 6.1.2 of the 'Procurement procedure'(XXXXXXXX) describes the possible procurement of XXXXXXXX. However, this section contains information about assessing the GMP status of the manufacturing site using available information, but it does not cover the product dossier review. XXXXXXXX does not have the capacity to assess product dossier, and do not procure now products that are not registered by XXXXXXXX. Therefore, this section is not applicable and may bring confusion. (WHO MQAS section II.1)			
No. 4	Other	'Goods Receiving Procedure' (XXXXXXXX) does not contain the sampling regime used for small and large consignments (WHO GSDP section 12.12)			
No. 5	Other	Warehouse cleaning log sheets are completed but it was noticed some missing date and signature in some sheets. (WHO GSDP section 17.6)			

No. 6	Other	The acceptable criterion in the calibration certificates of the sensors is $\pm 2^{\circ}\text{C}$, while the SOP mentioned an acceptable range of $\pm 0.5^{\circ}\text{C}$. In sampled reports reviewed, the correction required was however less than 0.5°C . (WHO MQAS section IV.5.3.1)			
No. 7	Remark	The calibration range is 15 to 25°C . It would be better to cover more than the range of the accepted limits of the warehouse (for instance 10 to 30°C), to make sure potential out-of-limits values are still within the calibrated range of the devices. The same remark is valid for the cold chain sensors (calibrated between $+2$ and $+8^{\circ}\text{C}$).			
No. 8	Other	As per section 6.16.2 of the SOP 'Customer and order preparation and distribution procedure' (XXXXXXX invoices are supposed to be signed once the orders have been verified. However, it was noticed that a significant number of sampled invoices were not adequately signed. (WHO GSDP section 17.6)			