FREQUENTLY ASKED QUESTIONS

Good Storage and Distribution Practices (GSDP) technical visits

What is a GSDP technical visit?

A GSDP technical visit (TV) is a type of assessment to check the level of compliance of suppliers (wholesalers or distributors) with current WHO GSDP standards[1]. GSDP technical visits are usually part of a Local Market Assessment (please refer to the FAQ note on Local Market Assessment, SOP-Q-014-A-005).

How many suppliers can be included in a GSDP technical visit?

One supplier per GSDP technical visit. If the suppliers have different distribution sites, different GSDP technical visits may be organised

What is in a GSDP technical visit report?

We produce a report for each supplier (or distribution site). For every supplier, the report contains:

- A presentation of the supplier (type of products supplied, company profile etc)
- Responses to a QUAMED standardised questionnaire containing different GSDP activities, which include a dedicated rating system: For each activity a percentage of compliance with the requirements of the GSDP standards is assigned (0 to 100%). See an example in the table below.

Physical storage conditions		Rating	Justification / additionnal information
7.1	Is there a SOP covering the monitoring, recording of temperature (and relative humidity when required) and the actions in case of deviations in the storage areas?	50%	
7.2	Are the temperature and relative humidity in all storage areas monitored and recorded? At which frequency? Does the company maintain adequate temperature monitoring records?	50%	
7.3	What is the maximum temperature reached/recorded during the hot season? Is this in line with the manufacturer's recommendations for the products stored?	50%	
7.4	What is the maximum temperature reached/recorded during the rainy season? Is this in line with the manufacturer's recommendations for the products stored?	50%	
7.5	Are the products protected from direct sunlight?	50%	
7.6	Is there proper ventilation in the facility (no boxes stored against the walls, fans etc.)?	50%	
7.7	Are all devices used to record temperature (and relative humidity if required) adequalty calibrated ((i.e. range, traceable to national standard)	50%	
7.8	Are the storage areas temperature controlled (airconditioning, heating , ventilation and air conditioning systems [HVAC]- etc)?	50%	
Global rating (percentage of compliance)		**50%**	automatic calculation
addtionnal comments :			

[1] See : https://www.who.int/medicines/areas/quality_safety/quality_assurance/qas19_793_good_storage_and_distribution_practices_may_2019.pdf?ua=1

- A conclusion section which highlights the global GSDP rating based on the technical visit, the key findings and observations. QUAMED recommends to not purchase from suppliers with an average GSDP level lower than 60%.
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ASSESSMENT RESULTS BY QUALITY ASSURANCE ACTIVITIES			
QA system	47%	**Global GSDP rating**	**50%**
Documentation system	50%		
Human resources	50%		
Control at reception	50%		
Quality control	50%		
Warehouse organisation	50%		
Physical storage conditions	50%		
Management of the cold chain	50%		
Stock Control	50%		
Handling non conformity products	50%		
Dispatch	50%		
Transport	50%		

- The final report is sent to customers 5 weeks after the technical visit. We do not share the full report with the suppliers, only a summary of the observations (for continuous improvement purpose).
- The report is accessible in the QUAMED database and valid for 3 years.

How long does a GSDP technical visit take?
A GSDP technical visit is usually integrated into a Local Market Assessment, which consists of three main phases: preparation, in-country visit and analysis/reporting. This can take anywhere from 2 months to 6 months. The preparatory phase often takes most time because of identification of the suppliers, budgeting and getting the funds together. Once the in-country visit has started, the whole process is often wrapped up within 2 months.

What is the cost of a GSDP technical visit?
That depends on the specifics of the technical visit: which country and how many suppliers will be included in the country visit. Due to cost efficiency, a single GSDP technical visit is usually not organised but grouped with other suppliers.

What resources are required for a GSDP TV?
Typically, the assessment takes 0.25 days preparation, 0.50 days per site, and 0.25 days of reporting. Technical visits are conducted by qualified experts validated by QUAMED according to our Quality Management System.

Who pays for the GSDP technical visit?
This depends on who requests the technical visit. It usually is a group of organisations (NGOs) but can also be one organisation.

How is a GSDP technical visit organised?
Because a GSDP technical visit does not take much time, it is always organised in conjunction with other GSDP technical visits, as part of a Local Market Assessment. No more than 14 GSDP technical visits can be organised during one in-country visit.

In the organisation of an GSDP technical visit, there are three main steps: A. Preparation, B. In-country visit, C. Analysis and 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.

A. Preparation: See the FAQ note on the Local Market Assesment for general organisational issues

1. The lead organisation or QUAMED sends a pre-visit questionnaire to the suppliers
2. The QUAMED expert will analyse the pre-visit questionnaires and make recommendations:
    a. Which type of assessment to use for which supplier: technical visit or an audit
    b. Which suppliers to remove from the list as they will most likely not achieve a satisfactory result even when a technical visit is organised.
3. The lead organisation agrees with the other participating NGOs on a final list of suppliers
4. The lead organisation makes the appointments with the suppliers and with the national pharmaceutical regulatory authorities, the national quality control laboratory and the WHO office, if required, and communicates the final calendar to QUAMED

B. In-country visit.

5. The lead organization arranges or facilitates the transport of the QUAMED expert.
6. The lead organisation will provide a staff person and/or interpreter to accompany the QUAMED
   expert on the suppliers' visits.
7. Our expert visits the supplier's premises and conducts an assessment of the GSDP compliance, as per the QUAMED Quality Management System.
8. The expert uses the standardized QUAMED GSDP technical visit tool to record findings.

C. Analysing and reporting

9. Within 30 days after the visit in-country, QUAMED produces the final technical visit report.
10. QUAMED sends an extract of the report to the suppliers visited so that deficiencies observed can be addressed.
11. QUAMED sends a copy of the final report to each of the participating NGOs and uploads the LMA report to its database.

Is a GDSP TV report sufficient to validate a supplier?

A GSDP TV is not an audit. It results cannot be used to validate a supplier. The GSDP TV report is one of the elements that should be considered when selecting a supplier, but it should not be the only element.

What is the difference between an GSDP audit and a GSDP technical visit?
During a technical visit, the QUAMED expert spends about half a day within the suppliers' premises. For a GSDP audit, the QUAMED auditor spends at least two days on site. This difference is significant in term of depth of the assessment: During an audit, the auditor has more time to analyse the practices and the documentation, and therefore the level of confidence in the outcomes of the assessment is much higher in an audit rather than a technical visit.

What are remote GSDP technical visits?
QUAMED has developed this assessment technique during the CoVID-19 pandemic. This allows remote / distant assessment of suppliers when travel to the country is difficult for the QUAMED expert (security, travel restrictions etc). A remote GSDP technical visit uses similar tool as an on-site GSDP technical visit, but I.T. communication tools are used (video conferencing, sharing electronic documentation). The QUAMED expert is assisted by a In-Country Assessment Facilitator (ICAF). The ICAF will be at the supplier location to support the assessment process.

Further information may be found in this publication in the Journal of Pharmaceutical Policy and Practices:
https://joppp.biomedcentral.com/track/pdf/10.1186/s40545-021-00323-w.pdf

A GSDP technical visit cannot be considered as a GSDP audit because not all the main pillars can be assessed as thoroughly as in a GSDP audit.