GDP Technical visit

Proposed visit Plan

Company:	……
Purpose:	Assess compliance with WHO Good Distribution Practices and IRC requirements for procurement of pharmaceuticals
Scope:	All operations associated with the sourcing, receipt, storage, and distribution of pharmaceutical products.
Standard:	WHO Technical Report Series TRS No. 1025 - Annex 7. Good storage and distribution practices for medical products https://www.who.int/publications/m/item/trs-1025-annex-7
Proposed Plan:	Exact timing for each of the activities will depend of the points raised and we appreciate flexibility in this matter. See below

Date	- Introduction of IRC team and **supplier name** representatives - Meeting with the senior management to cover the first part of the assessment and reviewing documents (listed below) - Tour of the facility: follow the warehouse flow from the receiving area, the storage, to the dispatch area. (this will include taking some photos of the facility, for IRC internal use only) - Physical inspection of the storage areas - Important aspects as prequalification of sources, traceability, and recall procedures will be reviewed. - Quality Assurance General Organization - Staff, key personnel - Closing notes

Technical people to meet:

- Pharmacist, Quality Assurance Responsible
- Warehouse Responsible

Documents to review:

Please have these documents available to be checked by IRC team on the day of the visit, And prepare copies to provide to the IRC if possible.

- ✓ A list of the available SOP's to be reviewed, that should include but not limited to:
    - Quality manual (if any)
    - Pre-qualification of products, suppliers, and manufacturers
    - Batch Re-call
    - Complaints Management
    - Cold chain Management
    - Narcotics Management
    - Warehouse operations (cleaning, pest control)
    - Out of Temperature specification (Warehouse and Cold Room/Fridge)
    - Other Quality Assurance SOP's

- ✓ Company's organogram
- ✓ Contracts of any sub-contracted activities (i.e. Pest control, Transport, Waste Management).
- ✓ Job descriptions of the QA pharmacist, and warehouse supervisor.
- ✓ Company registration certificate with the National Drug Regulatory Authority
- ✓ License to carry out wholesale/distribution/importation
- ✓ Quality assurance certificate if available
- ✓ T° monitoring sheets for the 3 months and current one (for the General warehouse and Cold Storage)
- ✓ Product list indicating manufacturer and country of origin
- ✓ GMP certificates of the manufacturers
- ✓ Certificates of Analysis
- ✓ If you are a local agent for a certain manufacturer, please prepare the letter from the mother company indicating that you are an authorized agent to distribute their products
- ✓ List of manufacturers and suppliers that you procure from
- ✓ List of WHO prequalified medicines if you procure any
- ✓ A copy of an invoice template
- ✓ Previous Audit Reports/Outcomes including CAPA reports (not older than 3 years)
- ✓ CE Certificates for the medical equipment and devices