INSPECTION AGENDA – DRUG TRADER

Inspection Activity

Opening Meeting
- Introductions, Attendance record, Inspection standard and scope
- Major Changes

On-site and Document Inspection
- *Establishment Records:*
  - License to Operate
  - List of Toll Manufacturers and Activities
  - Franchise agreement (if applicable)
- *Pharmaceutical Quality System:*
  - Quality Manual
  - Quality Risk Management / RMP
  - Finished Product Release procedure (including Batch Notification control) including filing of Certificates of Analysis and Batch Notification (if available)
- *Personnel:*
  - Duties and Responsibilities
  - Training (SOP and Records): GMP and GDP, GSP (if warehouse was handled by the company)

- *Registered Pharmacist's Records:*
  - PRC ID, PTR
  - Certificate of Attendance to Licensing Seminar
  - Number of LTO and products being handled

- *Premises and Equipment (Warehouse; if applicable):*
  - Inventory control including Computer System (if applicable)
  - Pest Control and Cleaning (Procedure and Records)
  - Temperature monitoring device calibration and records of monitoring including temperature mapping (if applicable)
  - Storage for rejects, returns and recall
  - Storage of retention sample

- *Documentation:*
  - Contract of Lease or TCT (office and warehouse; if applicable)
  - LTO and GMP Certificates of toll manufacturer
  - Certificate of Product Registration and list of products status
  - Audit to toll manufacturer and Vendor rating of PM and RM Suppliers (procedure and records)
  - System of Distribution
  - Dispatch Records (Sales Invoice, etc)
  - Monitoring of transport conditions
  - SOPs:
    - Receipt and Dispatch
    - Handling of rejects and returns
    - Destruction
    - Batch Notification control

- *Outsourced Activities*:
  - Contract Manufacturing Agreement
  - LTO and contract if distributors were available
  - Agreement with Pest Control Provider (if applicable)
- *Complaints and Product Recall* (procedure and records)
- *Pharmacovigillance system and records of PV activities*

Report Writing
Exit Meeting