INSPECTION AGENDA – DRUG & MEDICAL DEVICE DISTRIBUTOR

Inspection Activity

I. Opening Meeting

- ☐ Introductions
- ☐ Inspection scope
- ☐ Attendance record

II. Document Review

2.1 Organization, Management & Personnel

- ☐ Organizational Chart
- ☐ Job Description / Duties and responsibilities of personnel involved in supply chain
- ☐ Training Plan
- ☐ Training Records
- ☐ Competency evaluation of personnel
- ☐ Qualified Person (for medical device)
- ☐ Pharmacovigilance Officer (for ADRs)

2.2 QMS & Documentation

- ☐ License to Operate
- ☐ Risk Management Plan (RMP)
- ☐ SOPs
- ☐ Franchise agreement (if applicable)
- ☐ Records
  - *Distribution Records*
  - *Importation documents*
  - *Receipts from suppliers*
  - *Receipts issued to customers*
  - *Product complaints*
  - *Product recall*
  - *Adverse Drug Reaction (ADR)Reports*
  - *Certificates of Product Registration & Notification (for medical device)*
  - *Batch Notifications (for antibiotics)*

- *Lot Release Certificates (for vaccines)*
- List of products per supplier with CPR number and its validities
- *MDRP (EO 821 & EO 104 / IEC materials) / GMAP / EDPMS*

2.3 Contract activities

- Distribution agreements with suppliers (quality agreements)
  - With FDA Licenses (for local suppliers) / GMP Certificates / ISO 13485 QMS Certificates (for medical device)-(for foreign suppliers)
- Agreement with third party (TP) logistics or carrier (when applicable)

III. Walk-through Inspection

3.1 Warehouse facilities

- Restrictions to entry
- Adequate/ sufficient and labeled or identified areas for products:
- Commercial stocks
- Rejects /Returns/Recalled
- Facilities & equipment
  - Pallets /Racks
  - Calibrated Temperature /RH Monitoring Device
  - Storage conditions (must be in compliance with the recommendations of manufacturer or instructions on the label)
  - Temperature monitors
- Sanitation /Pest Control Records
- Arrangement of stocks (to avoid mix-ups)
- Stock Rotation ((first expiry/first out (FEFO) system must be observed)

3.2 Records

- Recorded temperature and relative humidity (RH) monitoring data
- Calibration records of temperature/RH monitors
- Stock Reconciliation/ Inventory
- Dispatch Records

3.3 Products

- Labeling requirements
- Registration / Notification (for medical device)

3.4 Transport & Dispatch of products

- Vehicle Maintenance

- Personnel in-charge for transport of products (must be knowledgeable on handling ie. Compliance to Storage requirement for products)

3.6 Other Additional Requirements for TTSPPs

For Temperature-controlled rooms, cold rooms and freezer rooms:

- Uninterrupted power supply (UPS)
- Calibrated continuous temperature monitoring system
- Continuous humidity monitoring devices with sensors located at points representing humidity extremes
- Preventive maintenance on all temperature controlled rooms or equipment
- Temperature-controlled road vehicles equipped with calibrated temperature monitoring devices
- shipping containers
- Stabilizing medium: dry ice, ice or gel packs, cool water packs or warm packs, bubble wrap

V. Report Writing

- Consolidation of findings

VI. Exit Meeting

- Attendance record
- Discussion of findings /Signing of Inspection Report