



## INSPECTION AGENDA – HOSPITAL PHARMACY

### Inspection Activity

#### I. Opening Meeting

- Introductions / Inspection scope/Attendance record

#### II. Ocular inspection of Premises / Storage facilities and Products

- Pharmacy signage
- Storage and sanitary conditions
- Segregated area for expired, damaged, recalled or returned products
- Equipment – Bioref / dedicated refrigerator, generator Set (if selling TTSPPs)
- Dispensing apparatus including ice packs for dispensing of TTSPPs
- Product compliance to registration and labeling requirements – may collect product (different areas – CSR, OR, DR, ER, Nurse stations/e-carts, others)

#### III. Document and Records Review

- License to Operate
- Pharmacist's credentials
- Organizational structure with duties and responsibilities of personnel
- Records of training, competency evaluation of personnel
- Attendance to FDA licensing seminar
- Risk Management Plan
- Standard Operating Procedures (SOPs)
- Invoices issued by suppliers (lot #, exp. Date and transport temp requirement)
- Stock reconciliation records
- Prescription book – both full and partially filled prescriptions must be recorded in Rx book
- Senior Citizens and PWD records
- *MDRP (EO 821 & EO 104 / IEC materials) /GMAP / EDPMS / Hospital Formulary*
- Temperature Monitoring records (bioref/ refrigerator if with TTSPPs and room)
- Calibration Certificates of temperature monitoring device/s and/or bioref

#### IV. Report Writing

- Consolidation of findings

#### V. Exit Meeting

- Attendance record /Discussion of findings or deficiencies /violation