INSPECTION AGENDA – NON-STERILE AND MEDICAL DEVICE MANUFACTURERS

Inspection Activity

OPENING MEETING
● Introductions, Attendance record, Inspection standard and scope
● Brief description of the company (identify key personnel)
● Buildings and facilities overview (for initial; if applicable)
  ● Floor plan / Lay-out plan
  ● Product and personnel flows
● Major changes from the last inspection (if applicable)
 	
ON-SITE INSPECTION
● Plant Tour around premises
● Warehouse (starting materials, packaging materials and finished goods)
  ● Receipt (Handling and Storage)
  ● Storage Areas (quarantine, approved, reject)
  ● Storage condition (temperature and RH monitoring)
  ● Approval for use
  ● Dispatch
  ● Label reconciliation
● Production
  ● Dust extraction
  ● Surfaces and finishes
  ● Lighting and Ventilation
  ● Dedicated premises / areas
● Sampling
● Dispensing
● Processing
● Packaging
● Quality Control Laboratory

- Utilities
  - Water
  - HVAC
  - Compressed Air

DOCUMENT REVIEW

- *Establishment Records*
  - License to Operate
  - List of Products Manufactured (CPR)
  - Site Master File

- *Registered Pharmacist's Records:*
  - PRC ID, PTR

- *Pharmaceutical Quality System:*
  - Quality Manual
  - Quality Risk Management
  - Finished Product Release procedure
  - Product Quality Review
  - Supplier Qualification including audits
  - Validation Master Plan including protocols and records for:
    - Process Validation
    - Cleaning Validation
    - Computer Validation (if applicable)
  - Procedure, Records and logs:
    - Deviation
    - Change control
    - Corrective Action and Preventive Action (CAPA)

- *Personnel:*
  - Organizational Chart

- Consultants' credential (if applicable)
- Duties and Responsibilities/Job Description
- Training
  - Training program
  - Training records & traceability of training history
  - Assessment of effectiveness of training
- Medical and Health Examinations

- *Premises and Equipment:*
  - Warehouse (Starting Materials, Packaging Materials and Finished Goods)
    - Receipt, handling & storage
    - Quarantine, approval/release, reject
    - Storage for flammable and/or hazardous materials (if applicable)
    - Temperature & humidity monitoring records
    - Dispatch
    - Inventory control
  - Equipment
    - Storage
    - Cleaning
    - Qualification
    - Repair and Maintenance
    - Calibration
  - Engineering and Services
    - Pest Control
    - Housekeeping
    - Key control
    - Back-up system
  - Water
    - Lay-out
    - Qualification
    - Monitoring and Testing (method, specifications and results, including trending)
    - Maintenance

- HVAC
  - Lay-out
  - Qualification
  - Environmental Monitoring and Testing (method, specifications and results, including trending)
  - Maintenance
- Compressed air
  - Lay-out
  - Specifications of filters
  - Monitoring and Testing
  - Maintenance and Cleaning

- *Documentation*
  - Batch Record Review
  - Document control (history, issuing, superseded, obsolete)
  - Specifications for:
    - starting materials
    - packaging materials
    - bulk product
    - finished product
  - SOPs
  - Delivery documents
  - Lot/Batch Numbering System
  - Distribution records

- *Production (Process Flow)*
  - Gowning procedures
    - Laundry
  - Sampling
    - Method of sampling and inspection
    - Sampling tools and kits
  - Dispensing / Weighing

- Processing
  - Formulation
  - In-process and Line clearance checks
  - Rework/reprocessing
  - Storage of bulk product
  - Contamination and Cross-contamination control strategies
- Packaging
  - Control of labels & pre-printed packaging materials
  - Coding and coded materials
  - Control of mix-up
- In-process controls
- Storage of packed product (quarantine/awaiting approval)

- *Quality Control*
  - Sample receipt
  - Method validation
  - Testing Procedure and Results (starting materials, bulk, finished products)
    - Identification test procedure
  - Equipment Calibration and Maintenance
  - Handling of OOS
  - Test Methods & References (i.e. official pharmacopeia) and Specifications
  - Reference Standards and reagents
    - Special storage and directions
    - Traceability of primary and secondary standards
  - Analysts work books/records & test results (if available)
  - Training & assessment
  - Retention samples
  - Stability program
  - Microbiology Laboratory testing
    - Equipment / Laminar Flow hood/ BSC
    - Testing procedure, references and results
    - Media preparation

- Growth Promotion Testing
- Storage of Reagents
- Strains
    - Receipt
    - Certificate of Analysis
    - Identification tests
    - Passage (procedure and records)
    - Storage

- *Outsourced Activities* (Contract Manufacturing Agreement, Testing laboratories agreement, others)

- *Complaints and Product Recall* (procedure and records)
    - Mock recall

- *Self-inspection* (procedure and records)

REPORT WRITING

EXIT MEETING