INSPECTION AGENDA – STERILE AND MEDICAL DEVICE MANUFACTURERS

Inspection Activity
Opening Meeting ● Introduction from FDA Lead Inspector ● Discussion of Scope, Inspection Plan and GMP Standard ● Timetable of Activities ● Attendance Sheet ● Company Introduction and Overview **Design and Lay-out Review prior to Site Inspection** ● (Warehouse, Production Areas, Utilities, Quality Control Laboratory including cleanroom air classification, material and process flow) **Site Inspection** ● Warehouse (Starting & packaging materials, Bulk &Finished Goods) ○ Receipt (Handling and Storage) ○ Storage Areas (quarantine, approved, reject) ○ Storage condition (temperature and RH monitoring) ○ Approval for use ○ Dispatch ○ Label reconciliation ● Production Facilities ○ Building maintenance and structure ○ Gowning and hand washing ○ Dispensing of starting materials (including control measures) ○ Bulk Manufacture (formulation and/or filtration) and Staging ○ Cross contamination and Contamination prevention measures/ control strategies

- Preparation of packaging materials (e.g. washing of containers, sterilization of packaging materials, garments, equipment parts)
- Filling operations (aseptic process implementation)
- In process checks
- Monitoring (air cleanliness and environment)
- Cleaning of premises and equipment
- Packaging operations
- Control of labels and pre-printed packaging materials
- In-process checks
- Coding
- Line Clearance
- Reconciliation
- Sterilization (*terminal*)

- Utilities
  - Air Handling Units
    - Design and Structure
    - Operation and Maintenance
    - Monitoring and testing
  - Water System
    - Design and Structure
    - Operation and Maintenance
    - Monitoring and testing
  - Compressed Gas and other gas
    - Design and Structure
    - Operation and Maintenance
    - Monitoring and testing
  - Clean Steam
    - Design and Structure
    - Operation and Maintenance
    - Monitoring and Testing
  - Sterile Gases

        - Generation or Procurement
        - Maintenance
        - Testing

- Quality Control Laboratory
    - Laboratory Staff training and assessment
    - Sampling
    - Handling of samples, reference standards, microorganism
    - Test Specifications
    - Method Validation
    - In-process Testing
    - Finished Product Testing
    - Instrumentation Room (status: CSV, calibration, maintenance, logbooks)
    - Validation of major QC instruments
    - Qualification of Sterility Room
    - Water Analysis
    - Microbiological Laboratory
        - Sterility tests
        - Bacterial Endotoxin test
        - Equipment / Laminar Flow hood
        - 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
    - Environmental Monitoring (Production and QC Lab)

- Stability Studies (Accelerated and Real Time)
- Out-of- Specification
- Retention Samples
- Other related QC tests and records

- Documentation
  - Document control (*history, issuing, superseded, obsolete)*
  - Pharmaceutical Quality System
    - Quality Risk Management
    - Product Quality Review
    - Change Control
    - Deviation
    - CAPA
    - Supplier Qualification
    - Batch Release Procedure
  - Personnel
    - Organizational Chart
    - Job Description
    - Training Program and records
    - Gowning qualification
    - Personnel hygiene
    - Health examination records

  - Qualification and Validation
    - Validation Master Plan
    - Process Validation
    - Media Fill
    - Disinfectant Validation
    - Cleaning Validation
    - Validation of aseptic process
    - Washers
    - Sterilizers (autoclave; dry heat)

        - Filters (integrity and microbial)
        - Container Closure integrity
        - Utilities Qualification (HVAC, Water, Gases)
        - Computer System
    - Batch Manufacturing and Packaging Record Review
        - Traceability of materials
        - Line Clearance
        - Reconciliation
        - Release for supply
    - Approved Marketing Authorization
        - Product Dossier
    - Engineering Services (procedure and records)
        - Preventive Maintenance
        - Calibration
        - Pest Control
        - Waste Disposal
- Handling of Product Complaints and Recall
- Outsourced Activities (qualification of suppliers)
- Self-Inspection

Report Writing
Discussion of audit findings