INSPECTION AGENDA – DRUG, MEDICAL DEVICE and COSMETIC REPACKER/ PACKER

Inspection Activity
Opening Meeting ● Introduction from FDA Lead Inspector ● Discussion of Scope, Inspection Plan and GMP Standard ● Timetable ● Attendance Sheet ● Company Introduction and Overview **Design and Lay-out Review prior to Site Inspection** (Warehouse, Repacking/Packing Area) **Site Inspection** Warehouse (Starting Materials and Finished Goods) ● Receipt ● Sampling ● Storage area (quarantine, approved, reject, cool room) ● Storage condition (temperature, humidity) ● Approval for use / release prior to repacking or packing ● Dispatch Premises and Equipment ● Plan or description of manufacturing areas with scale ● Nature of construction and finishes ● Special areas for the handling of highly toxic, hazardous and sensitizing materials Production ● Brief description of production operations using flowsheets and charts, if possible, specifying important parameters ● Arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage ● Arrangements for reprocessing or rework

- Arrangements for the handling of rejected materials and products
- Brief description of general policy for process validation Repacking / Packing Facility
- Building Maintenance and Structure
- Gowning Areas / Changing Rooms
- Repacking/Packing Area
- Storage condition (temperature, humidity)
- Line Clearance
- In-process controls
- Cross contamination prevention measures
- Equipment (status: cleaning, maintenance, calibration)
- Control of labels and pre-printed packaging materials
- Coding
- Storage of finished goods
- Retention Sample

Utilities and Engineering Services (if applicable) Air Handling Units

- Design and Structure
- Operation and Maintenance
- Monitoring Pest Control and Waste Disposal

Documentation

Pharmaceutical Quality System

- Quality Risk Management
- Change Control
- Deviation
- CAPA
- Supplier Qualification
- Batch Release Procedure

Personnel

- Organizational Chart
- Job Description
- Training and Assessment
- Personnel Hygiene

- Health Examination

Arrangements for the preparation and revision and distribution of documentation

- Description of the documentation system
- Responsible for the preparation, revision and distribution of documents
- Storage of the master documents
- Procedures on the preparation of the documents
- Control of the documentation

Related to Product Quality

- Equipment specification
- Training procedures
- Documentation control of process deviations
- Calibration and test documents
- Validation documents
- Reconciliation of batches of raw materials, major packing components
- Personnel Hygiene
- Health Examination

Batch Packaging Records Review

- Packaging Specifications

Other Relevant Documents

Standard Operating Procedures

Receiving and Dispatch

- Cleaning and Sanitization of Premise and Equipment
- Storage conditions to each category of materials
- Quality Control check
- Reprocessing / Reworking
- Handling of excess packaging materials
- Out-of-Specifications Product Complaint and Recall Outsourced Activities Self-Inspection
- Franchise agreement (if applicable)

Report Writing

Discussion of audit findings