INSPECTION AGENDA – MEDICINAL GAS

Inspection Activity

Opening Meeting
● Introductions, Attendance record, Inspection standard and scope
● Major Changes
● Key personnel
● Buildings and facilities overview (for initial; if applicable)
  ○ Floor plan / Lay-out plan
  ○ Product and personnel flows
On-site inspection
● Plant Tour
  ○ Warehouse
  ○ Production
  ○ Quality Control Laboratory
Document Inspection
● *Establishment Records:*
  ○ License to Operate
  ○ List of Products Manufactured
  ○ Site Master File
● *Registered Pharmacist's Records:*
  ○ PRC ID, PTR
● *Pharmaceutical Quality System:*
  ○ Quality Manual
  ○ Quality Risk Management
  ○ Finished Product Release procedure
  ○ Procedure, Records and logs:
  ▪ Deviation
  ▪ Change control

- CAPA

- *Personnel:*
  - Organizational Chart
  - 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 (Packaging Materials / Cylinders and Finished Goods)
    - Housekeeping & Pest control
    - Receipt, handling & storage
    - Identification and avoidance of mix-ups
    - Sampling
    - Storage areas – quarantine, release, reject
    - Approval for use
    - Temperature & humidity monitoring
    - Dispatch
    - Inventory control
    - Storage for rejects, returns and recall
  - Equipment
    - Storage of starting material (VIE/mobile tank)
      - Design
      - Maintenance
      - Usage and requirements (e.g. liquid levels, pressure etc)
    - Cleaning and Purging
    - Qualification of pipelines and manifolds (for shared equipment of different gases)
    - Repair and Maintenance
    - Delivery tankers (incl. Maintenance and Qualification records)
    - Condition of pipelines, manifolds, tester, valves and other equipment
    - Calibration of in-line process monitors and other equipment

- Air separation unit*
  - Air inlet
    - Position
    - Sequence
    - Repair and Maintenance including Cleaning
  - Filters & /Molecular Sieves
    - Type / Specifications
    - Regeneration and Maintenance
    - Installation
    - Integrity test
  - Air compressors
    - Maintenance frequency (incl. oil used, checking of bearings, etc.)
    - Change and consumption of oil
    - Water quality
    - Pressure
  - Separation Columns
    - Proper design (valves, sensors)
    - Maintenance
    - Usage and Specifications (Liquid levels, pressure)
- Engineering and Services:
  - Pest Control
  - Housekeeping
  - Quality of water used for testing (e.g. hydrostatic testing)
  - Back-up system

- *Documentation:*
  - Batch Record/Production Record Review
  - Document control (history, issuing, superseded, obsolete)
  - SOPs
  - Delivery documents
  - Records
  - Specifications

- Distribution records
- *Production:*
  - Process Validation (shared manifold for medicinal and industrial gases)
  - Process Flow
    - Air separation/ LOX vaporization
    - Unloading of bulk gas
    - Filling of gas
    - Inspection of cylinders
  - Control of materials (starting, in-process, finished and returned materials)
  - Line Clearance Procedures
  - Traceability of valves and cylinders
- *Quality Control:*
  - Sampling and receipt of samples
  - QC or line Testing Procedure and Results (bulk gas, finished products)
  - Equipment Calibration and Maintenance
  - Handling of OOS
  - Test Methods & References (i.e. official pharmacopeia) and Specifications
  - Analysts work books/records & test results (if available)
  - Training & assessment
- *Outsourced Activities*: Contract Manufacturing Agreement, Testing laboratories agreement, others
- *Complaints and Product Recall* (procedure and records)
- *Self-inspection* (procedure and records)

Report Writing

Exit Meeting