

Good Working Practice

Good Practice 001 - Facilities and Equipments

Topics

- Equipment Cleaning for Drug Products
- Identification of Equipment Areas and Processes
- Equipment Cleaning for Active Pharmaceutical Ingredients (APIs)
- Calibration
- Preventative Maintenance
- Cleaning and Sterilization of Aseptic Manufacturing Equipment
- Areas and Facilities Cleaning and Maintenance
- Pest Control
- Water Purification, Storage, and Distribution for Pharmaceutical Production
- Air Handling Systems & Air Classifications for Aseptic Operations
- Clean Steam Systems
- Aseptic Area Environmental Control

Good Practice 002 - Materials

Topics

- Reevaluation of Stored Materials
- Disposal of rejected and waste material
- Material Status Indication
- Material Supplier Approval
- Raw Materials and Packaging Materials - Receipt
- Sampling of Production Materials and Finished Goods
- Storage and Distribution of Drug Products, Medical Devices, and Related Materials
- Subdividing Dispensing & Transferring Materials to Production Areas
- Quarantine Shipment

Good Practice 003 - Labeling and Packaging

Topics

- Instructions for Filling, Labeling and Packaging Pharmaceutical Drug Products and API's for Commercial Purposes
- Creation, Revision, and Approval for Artwork Used on Packaging Components
- Receipt, Approval, and Use of Labels and Labeling
- Container Closure Integrity for Sterile Drug Products
- Packaging System Integrity for Sterile Medical Devices

Good Practice 004 - Operations

Topics

- Inspecting for Manufacturing and Packaging Defects-Aseptic
- Instructions for Manufacture of APIs and Drug Products
- Uniform Practices for Manufacturing Operations
- Personnel Qualification Program for Aseptic Processing Areas and Preparation for Aseptic Areas

- Aseptic Processing Facility Environmental Monitoring
- Use and Recovery of Solvents in API Manufacturing
- Metal Detection
- Weighing and Measuring Practices in Manufacturing Operations
- Gamma Radiation Sterilization
- Preventing Cross Contamination
- Control of Manufacturing and Packaging Defects Non-Sterile
- Sterilization/Depyrogenation Validation: Non-Product
- Gowning Practices for Aseptic Processing Areas and Preparation for Aseptic Areas
- Cleaning Depyrogenation and Sterilization of Containers and Closures
- Sterilizing Filters and Filtration Systems
- Moist Heat Terminal Sterilization of Aqueous Parenteral Products
- Media Fills for Sterile Drug Products and Aseptically Processed Medical Devices
- Batch and Lot Identification
- Aseptic Manufacturing Practices