Comprehensive GxP Documentation List for 21 CFR Part 211 Compliance

This document provides a comprehensive list of GxP documents required for an aseptic pharmaceutical manufacturing facility operating in the state of Texas, in compliance with FDA's 21 CFR Part 211. The list encompasses validation lifecycle documentation, quality system documents, laboratory control system documents, IT and data integrity records, internal audit documentation, periodic reviews, and trending practices.

1. Validation Lifecycle Documentation

- Validation Master Plan (VMP)
- Process Validation Protocols and Reports (IQ/OQ/PQ)
- Cleaning Validation Master Plan and Reports
- Sterilization Validation (e.g., Autoclave, VHP, Gamma, E-beam)
- Media Fill Study Protocols and Reports
- Container Closure Integrity Testing (CCIT) Validation
- Computer System Validation (CSV) Documentation including URS, FRS, IQ/OQ/PQ
- Traceability Matrix and Risk Assessments

2. Quality System Documentation

- Quality Manual
- Standard Operating Procedures (SOPs)
- Document Control Procedures
- Change Control Records
- Deviation and Non-Conformance Reports
- Corrective and Preventive Actions (CAPA)
- Management Review Meeting Minutes
- Quality Agreements with Vendors and CMOs
- Batch Release and Disposition Records

3. Laboratory Control System Documentation

- Laboratory SOPs
- Analytical Method Validation Protocols and Reports
- Certificates of Analysis (CoAs)
- Stability Study Protocols and Data
- Out-of-Specification (OOS) Investigation Reports
- Environmental and Microbial Monitoring Data
- Equipment Calibration and Maintenance Logs
- Reference Standard Documentation

4. IT & Data Integrity Documentation

- IT Security and Access Control Policy
- Audit Trail Review Procedures
- Data Backup and Recovery SOPs
- System Administration Logs
- Electronic Signature Authentication Records
- 21 CFR Part 11 Compliance Assessments
- Disaster Recovery and Business Continuity Plans

5. Internal Audits and Self-Inspections

- Internal Audit Schedules and Plans
- Audit Checklists and Reports
- Corrective Action Plans and Follow-Up Records
- GMP Self-Inspection Reports
- Regulatory Inspection Readiness Documents

6. Periodic Reviews and Trending

- Annual Product Quality Review (APQR) Reports
- Deviation and CAPA Trending Reports

- Environmental Monitoring Trending Summaries
- Equipment Downtime and Failure Logs
- Training Compliance Metrics
- Change Control Impact Assessments

7. Personnel and Training Documentation

- Training Matrix and Curriculum
- GxP Training Records (Initial and Refresher)
- Aseptic Technique and Gowning Qualification Records
- Job Descriptions and Qualification Requirements
- Operator Observation and Certification Records

8. Materials and Supply Chain Documentation

- Raw Material Specifications and COAs
- Vendor Qualification and Audit Records
- Material Receipt and Quarantine Logs
- Inventory Management Records
- Material Dispensing and Reconciliation Logs

9. Sterility Assurance Program Documentation

- Media Fill Protocols and Reports
- Cleanroom Qualification Reports
- Airflow Visualization (Smoke Study) Reports
- Disinfection Efficacy and Sanitization SOPs
- Sterile Hold Time Study Documentation
- Rapid Microbial Method Validation (if applicable)