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PHARMACEUTICAL TECHNICAL SOLUTIONS, INC.

Biopharma MFG Facility Site MFG Operational Readiness Activities

Overall Manufacturing Operational Readiness Key Activities

MFG Operational Readiness Activities

- ❑ Define Biopharma Process/ Equipment-Systems
- ❑ MFG Batch Records, Sampling Plans, & BOM
- ❑ SOP's-Forms, Work Instructions, & Training
- ❑ QC Labs Methods & Equipment

Tech Transfer Readiness Activities

- ❑ Process Flow Drwgs/ Critical Process Parameters
- ❑ Define MFG Process Equipment/ System
- ❑ MBR-Forms, Work Insts, Sampling Plan, & BOM

Supply Chain Readiness Activities

- ❑ Establish GMP Warehouse SOP's & Forms
- ❑ Establish Raw Materials, Gowns, & Consumables
- ❑ Establish Supplier Quality Management SOP

Quality Readiness Activities

- ❑ Establish Quality Manual, QMS SOP's, & Forms

Engineering-Facilities Readiness Activities

- ❑ CMMS Equipment-System Integration
- ❑ Calibration, HEPA Certification, & TOP Verification
- ❑ MFG Facility & Support Areas Mechanical Completion
- ❑ Cleanroom Final Balancing & Certification
- ❑ IT Systems: BMS, EMS, CMMS, ERP, & ELN

Validation/ Commissioning Readiness Activities

- ❑ MFG Facility EMPQ, Process & Support Systems
- ❑ Commissioning Plan: Utilities/ HVAC Systems/ BMS
- ❑ JIT GMP Warehouse & Support Areas
- ❑ Facility Readiness (Floors/ Walls/ Ceilings)

QC Labs Readiness

- ❑ QC Lab Equipment-System List
- ❑ QC Labs SOP's/ Forms & ELN System (LIMS)
- ❑ QC Labs Equipment/ Method Validation

Resource Plan

- ❑ Resource Hiring Plan, Training Plan, & Safety Plan

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Biopharma MFG Facility Project Management Tools

Integrated Project Schedule:

- ❑ MFG Facility Design, Construction, Commissioning, Validation, MFG OPS, & Released for MFG: Key Project Milestones

SOPs/ Forms Tracker:

- ❑ SOPs/ Forms Development, Review, and Approval: Departments, Owners, Reviewers, Approvers, and dates

MFG Facility Site Equipment Tracker:

- ❑ MFG Facility Site Equipment Tracker: Dept., Model/ Make, Capacity, New, Relocate, Order, Receipt, Install, Cal, Cx, & VAL

Biopharma MFG Facility Operational Readiness Dashboards:

- ❑ Commissioning Readiness Dashboard: Testing, SATs, Build Field Verification, Final Balancing/ HEPA Cert, TOP, & Cx
- ❑ Validation Readiness Dashboard: Clean Utilities, Equipment/ Systems, QC Labs, & GMP Warehouse Validation Activities
    - ❑ EMPQ Readiness Dashboard: Biopharma MFG Facility Cleanrooms EMPQ Activities
- ❑ Facilities-Engineering Readiness Dashboard: Implement CMMS System (PM, Calibration, HEPA Cert), Safety, & Utilities
- ❑ Supply Chain/ GMP Warehouse Readiness Dashboard: Controls, Materials, Consumables, Resources & ERP
- ❑ MFG Readiness Dashboard: MFG Equipment, MBRs, Sampling Plans, BOMs, Training, Resources, & Tech Transfer
- ❑ Quality Manual/ QMS Readiness Dashboard: QMS SOP's, Forms, Specifications, EDMS, Resources & QC LIMS
- ❑ QC Labs: Labs Equipment, QC ELN System VAL, Training, Resources, & Analytical Method Validation

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Construction/ Commissioning Operational Readiness Activities

Construction/ Commissioning

- ❑ Construction Mechanical Completion (MC) Oversight
- ❑ Define Master Equipment/ System List
- ❑ Order Process Equipment/ Systems
- ❑ Equipment Receipt Verification (ERV)
- ❑ Author/ Approve Commissioning (Cx) Activities
- ❑ Asset Induction CMMS (PM's/ CAL/ HEPA Certs)
- ❑ Pre-Mechanical Completion (PMC) Field Verification against design drawings/ URS's
- ❑ Mechanical Completion (MC) Field Verification

Construction/ Commissioning

- ❑ Verify/ Approve General Contractor Turn Over Package (TOP)
- ❑ Verify Operations/ Maintenance Manual Library and support SOP's
- ❑ Manage the Calibration execution
- ❑ Verify Equipment/ System Startup/ SAT
- ❑ Execute Utility/ HVAC System Function Testing
- ❑ Oversee the HEPA Certification/ HVAC Balancing
- ❑ Manage the HVAC System/ Utility Training Development and Execution
- ❑ Generate/ Approve Cx Protocols & Reports

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Manufacturing Operational Readiness Activities

Safety & Compliance

- ❑ Permits & Licenses
- ❑ Blood Borne Pathogen/ Vector/ Raw Materials

GMP Document Management

- ❑ EDMS (Veeva/ Master Control)
- ❑ SOP-Forms/ Work Instructions Master List
- ❑ Bill of Materials (BOM)
- ❑ Manufacturing Batch Records (MBR)/ Forms
- ❑ Sampling Plans

GMP Warehouse/ Materials

- ❑ Material Management Systems (Oracle/ SAP)
- ❑ Supplier Quality Management SOP

QC Labs Readiness

- ❑ QC Lab Equipment-System List
- ❑ QC Labs SOP's/ Forms & ELN System (LIMS)
- ❑ QC Labs Equipment/ Method Validation

Tech Transfer Readiness Activities

- ❑ Process Flow Drwgs/ Critical Process Parameters
- ❑ Define MFG Process Equipment/ System
- ❑ MBR-Forms, Work Insts, Sampling Plan, & BOM

Engineering/ Facilities

- ❑ Final As Built Drawings
- ❑ Mechanical Completion Field Verification
- ❑ Asset Induction into CMMS
- ❑ HVAC Systems/ Utilities Function Tests
- ❑ Cleanroom Final Balancing & Certification

Validation Master Plan/ Cx Plan

- ❑ Master Equipment List with Val Requirements
- ❑ Execute Validation & Cx Risk Assessments
- ❑ EMPQ Execution Strategy
- ❑ QC Labs Equipment/ Method Val Requirements

Resource Plan

- ❑ MFG/ ENG/ QA/ QC & WH Training Strategy

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Validation Plan Operational Readiness Activities

Validation Plan (MFG/ QC Labs/ GMP Warehouse) Operational Readiness Activities

- ❑ Finalize Master Equipment/ System List
- ❑ Develop and the manage the execution of the Validation Plan
- ❑ Execute VP Risk Assessments
- ❑ Develop/ Approve Design Qualification based on BOD & URS's
- ❑ Design/ Approve CTF & Support Areas P&ID's
- ❑ Develop Operational SOP's/ Forms
- ❑ Develop CTF, Support Areas, & GMP Warehouse Equipment/ Systems SOP's/ Forms
- ❑ Develop/ Execute Cell Therapy Facility EMPQ

Validation Plan (MFG/ QC Labs/ GMP Warehouse) Operational Readiness Activities

- ❑ Execute Equipment/ System IQ, OQ, & IOQ
- ❑ Execute Equipment/ System IOPQ's & PQ
- ❑ Manage the MFG, ENG, QA, QC, & VAL Process Training Development and Execution
- ❑ Qualify/ Validation QC Labs Analytical Equipment and Methods
- ❑ Execute Media Simulation PQ's
- ❑ Execute Shakedown/ Engineering Runs
- ❑ Execute GMP Runs
- ❑ Execute PPQ Runs

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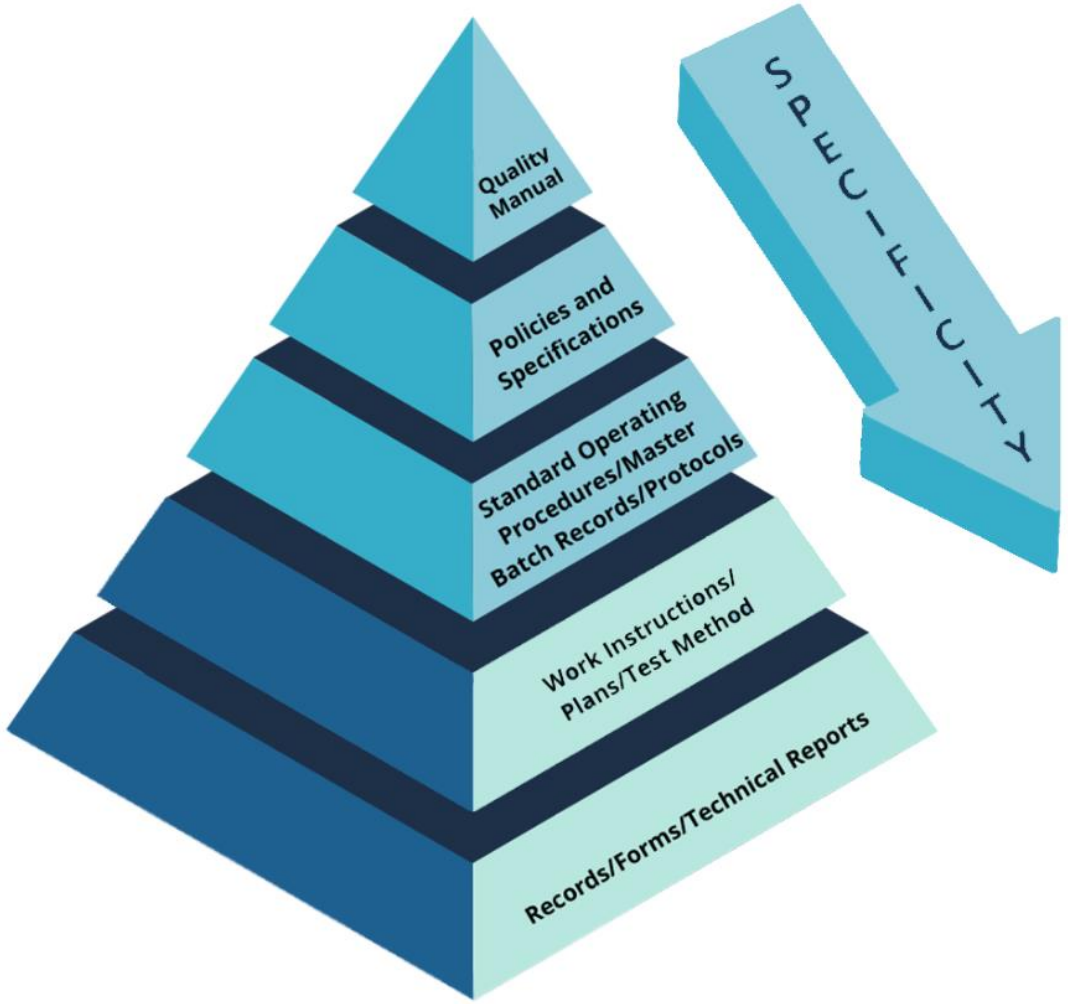
Quality Manual/ Quality Management System

Quality Manual



Quality Management Systems

- Quality Policies
- Quality Risk Assessment
- Commissioning/ Validation
- Change Control
- Deviation/ CAPA
- Document Control
- Internal/ External Audits
- Supplier Qualification Management
- Clinical Quality
- Commercial Quality
- Management Review
- Record Management/ Retention
- Supporting Quality Procedures

Biopharmaceutical Site Automated Systems

- Building Management System: HVAC System, AHU's, Exhaust Fans, Temperature, and Humidity (Delta, Johnson Controls, etc.)
- Environmental Monitoring System: Cleanroom Pressure, Temperature, and Humidity/ GMP Warehouse Temperature (Delta, Environmental, Johnson Controls, etc.)
- Computerized Maintenance Management System: Equipment PM's, Repairs, Calibrations, and HEPA Certifications (Blue Mountain, Maximo, etc.)
- Biopharmaceutical Site Door Access Control System
- QC Labs Systems: Electronic Notebook, Lab Consumables, LIMS Data, Sample Management (Labware, Thermo, Horizon, etc.)
- Materials Management System: (ERP: Oracle, SAP, SAGE)
- Security and Fire Systems: Cameras, Dual Action Dry Fire System, Water Fire System