



Pharmaceutical Site Master File (SMF) Readiness Checklist 2026

Site Information and General Description

Verification of basic site details, including physical address, contact information, -site activities, and legal ownership details.

Site Name and Official Address

Site Registration/License Number

Scope of Site Activities

Last SMF Review Date

Site Classification

- ☐ Manufacturing Site
- ☐ Testing Laboratory
- ☐ Distribution Center
- ☐ Packaging Site

Site Map/Facility Layout

 Upload File

Reviewer Authorization

Quality Management System (QMS) Overview

Review of the site's quality policy, organizational structure, management responsibility, and the scope of the quality system.

Quality Policy Statement Summary

Write something...

QMS Certification Status

- ☐ ISO 9001 Certified
- ☐ GMP Compliant
- ☐ ISO 13485 Certified
- ☐ Other

Included Quality Processes

- ☐ Change Control
- ☐ Deviation Management
- ☐ CAPA
- ☐ Risk Management
- ☐ Audits
- ☐ Training

Last QMS Review Date

Enter date...

Quality Manual Reference

 Upload File

Quality Assurance Lead Verification

Personnel and Organizational Structure

Audit of organizational charts, job descriptions, training programs, and the segregation of quality and production functions.

Organization Chart Version Number

Write something...

Key Personnel Roles Verified

- ☐ Quality Assurance Manager
- ☐
- ☐ Quality Control Manager
- ☐ Warehouse/Logistics Manager
- ☐ Engineering/Maintenance Lead

Last Organizational Structure Review Date

Enter date...

Updated Organizational Chart PDF

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Training Program Compliance Status

- ☐ Fully Compliant
- ☐ Minor Gaps Identified
- ☐ Non-Compliant

Quality Assurance Auditor Verification

Premises and Equipment Documentation

Verification of facility layouts, cleanroom classifications, HVAC system descriptions, and equipment maintenance/calibration logs.

Cleanroom Classification Status

- ☐ ISO Class 5
- ☐ ISO Class 7
- ☐ ISO Class 8
- ☐ Unclassified

Last HVAC System Qualification Date

Enter date...

Equipment ID/Asset Number

Write something...

Required Maintenance Logs Present

- ☐ Preventative Maintenance Records
- ☐ Calibration Certificates
- ☐ Decontamination Logs
- ☐ Pressure Differential Logs

Facility Layout Blueprint/Map

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Verification Officer Signature

Documentation and Data Integrity Controls

Assessment of document control procedures, record retention policies, and ALCOA+ principles implementation for data integrity.

Compliance Standards Verified

- ☐ ALCOA+ Principles
- ☐ 21 CFR Part 11 Compliance
- ☐ EU Annex 11 Compliance
- ☐ GDP (Good Documentation Practices)

Document Control Procedure ID

Write something...

Last Document Review Date

Enter date...

Standard Operating Procedure (SOP) Evidence

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Data Integrity Gap Analysis Summary

Write something...

Quality Assurance Reviewer Signature

Production and Process Controls

Review of manufacturing processes, material handling, batch production protocols, and in-process control procedures.

Manufacturing Process Status

- ☐ Validated
- ☐ In-Progress/Validation Phase
- ☐ Under Revision

Production Area Compliance Checks

- ☐ Line Clearance Completed
- ☐ Material Reconciliation Performed
- ☐ In-Process Samples Collected
- ☐ Environmental Monitoring Verified

Batch Production Date

Process Deviation Notes

Write something...

Batch Record/Logbook Scan

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Production Supervisor Verification

Quality Control and Laboratory Operations

Evaluation of laboratory testing capabilities, analytical method validation, reference standard management, and stability testing protocols.

Laboratory Compliance Status

- ☐ Fully Compliant
- ☐ Minor Non-Compliance
- ☐
- ☐ Critical Deficiency

Last Analytical Method Validation Date

Enter date...

Testing Capabilities Present

- ☐ HPLC/GC Analysis
- ☐ Microbiological Testing
- ☐ Dissolution Testing
- ☐ Stability Testing
- ☐ Spectroscopy (UV/IR)

Summary of Recent Out-of-Specification (OOS) Results

Write something...

Reference Standard Certificate Upload

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Laboratory Manager Verification

Material Management and Supply Chain

Verification of raw material procurement, vendor qualification, incoming inspection, and storage/quarantine procedures.

Raw Material Status

- ☐ Quarantine
- ☐ Released
- ☐ Rejected
- ☐ Returned

Batch/Lot Number Verification

Write something...

Date of Receipt

Enter date...

Expiry Date of Material

Enter date...

Quantity Received

Enter a number...

Storage Condition Compliance

- ☐ Ambient Temperature
- ☐ Refrigerated (2-8°C)
- ☐ Frozen (-20°C or below)
- ☐ Controlled Humidity
- ☐ Light Sensitive

Certificate of Analysis (CoA) Upload

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Quality Assurance Inspector Signature

Validation and Qualification Programs

Review of the master validation plan, including equipment qualification (IQ/OQ/PQ), process validation, and cleaning validation status.

Validation Master Plan (VMP) Status

- ☐ Current and Valid
- ☐ Under Revision
- ☐ Expired/Needs Update

Qualification Types Covered

- ☐ Installation Qualification (IQ)
- ☐ Operational Qualification (OQ)
- ☐ Performance Qualification (PQ)
- ☐ Cleaning Validation
- ☐ Process Validation

Last Validation Audit Date

Enter date...

Next Scheduled Re-qualification Date

Write something...

Summary of Critical Validation Gaps

Write something...

Upload Validation Summary Report

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QA Officer Approval Signature



Self-Inspection and Audit Program

Assessment of the internal audit schedule, CAPA follow-up processes, and management review of audit findings.

Last Self-Inspection Date

Enter date...

Audit Frequency Compliance

- ☐ Compliant
- ☐ Non-Compliant
- ☐ Partial Compliance

Audit Scope Areas Covered

- ☐ Production
- ☐ Quality Control
- ☐ Warehouse/Logistics
- ☐ Engineering/Maintenance
- ☐ IT/Data Integrity

Summary of Major Findings

Write something...

Upload Audit Report/Evidence

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Quality Assurance Auditor Signature

< Previous

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✓ Finish

 **Generate Sample Report**