



Pharmaceutical Drug Master File (DMF) Compliance Checklist 2026

Administrative & Submission Overview

Verification of administrative completeness, including applicant details, DMF type (Type II, III, or IV), and -holder information accuracy.

DMF Identification Number

DMF Type

- ☐ Type II (Drug Substance)
- ☐ Type III (Drug Product)
- ☐ Type IV (Excipient)

Submission Date

Applicant/Manufacturer Name

Cover Letter Attachment

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Regulatory Affairs Officer Approval

Module 1: Regional Administrative Information

Review of region-specific application forms, cover letters, and necessary regulatory agency contact information for 2026 compliance.

DMF Type

Write something...

Applicant Name

Write something...

Submission Date

Enter date...

Cover Letter Document

 Upload File

Regulatory Jurisdiction

- ☐ FDA (USA)
- ☐ EMA (EU)
- ☐ PMDA (Japan)
- ☐ NMPA (China)

Regulatory Affairs Officer Approval

Module 2: Summaries & Overview of Quality

Assessment of high-level summaries regarding the drug substance, manufacturing processes, and quality control protocols.

Drug Substance Overview Summary

Write something...

Executive Summary of Quality Control Measures

Write something...

DMF Type Classification

- ☐ Type II (Drug Substance)
- ☐ Type III (Drug Product)
- ☐ Type IV (Excipient)

Last Quality Summary Review Date

Enter date...

Quality Overview PDF Document

 Upload File

Quality Assurance Reviewer Signature

Module 3: Drug Substance Composition & Manufacturing

Detailed audit of chemical structures, physical properties, manufacturing descriptions, and process-related impurities.

Drug Substance Chemical Name

Write something...

DMF Type

- ☐ Type II (Drug Substance)
- ☐ Type III (Drug Product)
- ☐ Type IV (Excipient)

Manufacturing Process Description

Write something...

Impurity Types Present

- ☐ Organic Impurities
- ☐ Inorganic Impurities
- ☐ Residual Solvents
- ☐ Degradation Products

Flowchart of Manufacturing Process

 Upload File

Last Manufacturing Process Review Date

Enter date...

Module 3: Control of Drug Substance

Verification of specifications, analytical procedures, validation data, and batch analysis testing protocols.

Specification Compliance Status

- ☐ Compliant
- ☐ Non-Compliant
- ☐ Pending Re-validation

Last Analytical Method Validation Date

Enter date...

Impurity Threshold Limit (%)

Enter a number...

Analytical Method Validation Report

 Upload File

Description of Impurity Profile & Control Strategy

Write something...

Quality Assurance Reviewer Signature

Module 3: Container Closure System & Stability

Review of packaging components, compatibility studies, and stability data under various climatic conditions.

Container Closure Material Type

- ☐ Glass Vial
- ☐ Blister Pack
- ☐ Pre-filled Syringe
- ☐ Ampoule
- ☐ Other

Last Stability Study Completion Date

Enter date...

Container Closure Integrity Test (CCIT) Method

Write something...

Storage Conditions Tested

- ☐ 25°C / 60% RH
- ☐ 30°C / 65% RH
- ☐ 40°C / 75% RH
- ☐ Refrigerated (2-8°C)
- ☐ Frozen (-20°C)

Stability Data Summary Report

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Quality Assurance Reviewer Signature

Module 4: Physicochemical, Biological & Microbiological Characterization

Verification of structural elucidation, impurities profiles, and biological activity assays where applicable.

Characterization Type

- ☐ Physicochemical
- ☐ Biological
- ☐ Microbiological

Structural Elucidation Summary

Write something...

Impurities and Degradation Profile Details

Write something...

Analytical Characterization Reports

 Upload File

Characterization Completion Date

Enter date...

Reviewer Verification

Reference Standard & Reagent Compliance

Audit of the management, traceability, and qualification of all analytical standards used in the DMF testing processes.

Reference Standard Name

Write something...

Expiration Date

Enter date...

Certificate of Analysis (CoA)

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Storage Condition

- ☐ Ambient Temperature
- ☐ Refrigerated (2-8°C)
- ☐ Frozen (-20°C)
- ☐ Ultra-Low Freezer (-80°C)

Compliance Verification Steps Completed

- ☐ Identity Confirmed
- ☐ Purity Verified
- ☐ Label Integrity Checked
- ☐ Storage Alignment Verified

Quality Assurance Reviewer Signature

Document Integrity & Version Control

Ensuring all uploaded documents follow the latest electronic submission standards and possess appropriate digital signatures.

Last Document Review Date

Document Version Status

- ☐ Draft
- ☐ Under Review
- ☐ Approved
- ☐ Obsolete

Verification Checklist Items

- ☐ Digital Signature Verified
- ☐ Correct File Format (PDF/A)
- ☐ Hyperlinks Functional
- ☐ Metadata Accuracy Confirmed

Version History Log

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Quality Assurance Reviewer Signature

Discrepancy Notes & Remediation Plan

Write something...

Post-Submission & Lifecycle Maintenance

Procedures for managing amendments, annual reports, and notification of changes to manufacturing or site locations.

Last Amendment Submission Date

Enter date...

Amendment Type

- ☐ New Submission
- ☐ Major Amendment
- ☐ Minor Amendment
- ☐ Annual Report

Changes Requiring Update

- ☐ Manufacturing Site Change
- ☐ Change in Specification
- ☐ New Impurity Profile
- ☐ Packaging/Container Change
- ☐ Analytical Method Update

Summary of Changes Implemented

Write something...

Updated Regulatory Correspondence

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Quality Assurance Approval Signature

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✔ Finish

🔧 Generate Sample Report