

# Pharmaceutical Regulatory Submission Preparedness Checklist 2026

## Regulatory Strategy & Dossier Structure

Verification of the submission format (e.g. eCTD), module completeness, and alignment with global regulatory requirements (FDA, EMA, MHRA).

### Submission Format Type

- ☐ eCTD (Electronic Common Technical Document)
- ☐ Paper-based (Legacy)
- ☐ Regional Format (Non-eCTD)

### Target Submission Deadline

### Submission ID / Protocol Number

### Target Regulatory Agencies

- ☐ FDA (USA)
- ☐ EMA (EU)
- ☐ PMDA (Japan)
- ☐ MHRA (UK)
- ☐ Other

### Regulatory Strategy Document

 Upload File

### Regulatory Affairs Lead Approval

## Module 1: Administrative & Prescribing Information

Review of application forms, proposed labeling, package inserts, and regional administrative documentation accuracy.

### Submission Type

Write something...

### Submission Target Date

Enter date...

## Draft Labeling & Package Insert

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### Required Administrative Documents Present

- ☐ Cover Letter
- ☐ Form FDA 356h
- ☐ User Fee Cover Sheet
- ☐ Prescribing Information
- ☐ Medication Guide

### Regulatory Affairs Manager Approval

### Submission Region

- ☐ USA (FDA)
- ☐ European Union (EMA)
- ☐ Japan (PMDA)
- ☐ Other

## Module 2: Summaries & Overviews

Validation of Quality, Non-clinical, and Clinical summaries to ensure consistency with detailed data presented in later modules.

### Submission Type

- ☐ New Drug Application (NDA)
- ☐ Abbreviated New Drug Application (ANDA)
- ☐ Biologics License Application (BLA)
- ☐ Supplemental Application

### Module 2.3 Quality Overall Summary (QOS) Status

Write something...

### Included Summary Components

- ☐ Pharmacology Summary
- ☐ Pharmacokinetics Summary
- ☐ Toxicology Summary
- ☐ Clinical Overview
- ☐ Clinical Summary

### Module 2 Summary Draft Review Document

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### Internal Review Completion Date

Enter date...

## Regulatory Affairs Manager Approval

## Module 3: Quality (CMC) Documentation

Review of Chemistry, Manufacturing, and Controls data, including drug substance, drug product, stability data, and manufacturing process descriptions.

### Drug Substance Manufacturing Site Status

- ☐ Fully Qualified
- ☐ Pending Qualification
- ☐ Under Investigation

### Last Stability Study Completion Date

Enter date...

### Drug Product Specification Document

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### Batch Number for Reference

Write something...

### Required CMC Documents Verified

- ☐ Certificate of Analysis (CoA)
- ☐ Method Validation Reports
- ☐ Impurity Profile Data
- ☐ Dissolution Profile

### Quality Assurance Reviewer Sign-off

## Module 4: Non-clinical Study Reports

Verification of pharmacology, pharmacokinetics, and toxicology study reports, including all necessary laboratory raw data summaries.

### Study Type Category

- ☐ Pharmacology
- ☐ Pharmacokinetics
- ☐ Toxicology
- ☐ Safety Pharmacology

### Study Completion Date

Enter date...

### Final Study Report (PDF)

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### Summary of Key Findings

Write something...

### Regulatory Compliance Standards Met

- ☐ GLP Compliant
- ☐ OECD Principles
- ☐ FDA Standard
- ☐ EMA Standard

### Lead Toxicologist Approval

## Module 5: Clinical Study Reports

Audit of clinical trial data, bioequivalence studies, statistical analysis plans, and safety/efficacy evidence summaries.

### Clinical Study Phase

- ☐ Phase I
- ☐ Phase II
- ☐ Phase III
- ☐ Phase IV

### Clinical Trial Completion Date

Enter date...

### Protocol ID Number

Write something...

### Clinical Study Report (CSR) Final Draft

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### Included Endpoints Verified

- ☐ Primary Endpoints
- ☐ Secondary Endpoints
- ☐ Safety Endpoints
- ☐ Exploratory Endpoints

### Summary of Adverse Events

Write something...

### Clinical Lead Verification

# Data Integrity & Technical Validation

Ensuring all electronic files are hyperlinked, searchable, PDF/A compliant, and free of broken references or formatting errors.

## Validation Checklist Completed

- ☐ Hyperlinks Verified
- ☐ PDF/A Compliance Confirmed
- ☐ Searchability/OCR Check Complete
- ☐ File Naming Convention Audit Finished

## Hyperlink Integrity Report

 [Upload File](#)

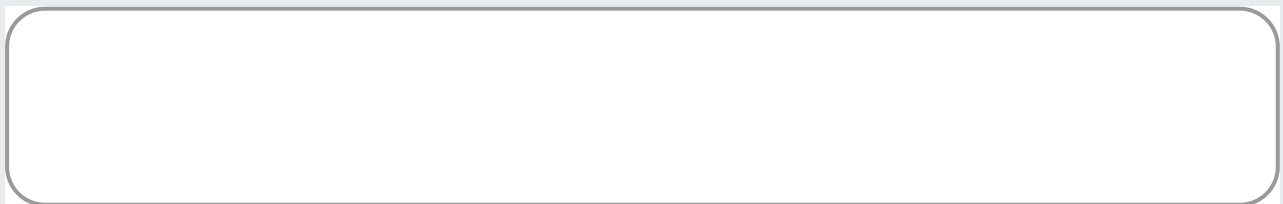
## Technical Validation Date

Enter date...

## Submission Format Type

- ☐ eCTD
- ☐ Paper-based (Legacy)
- ☐ Electronic Common Technical Document (eCTD) 4.0

## Quality Assurance Validator Signature



# Compliance & Regulatory Compliance Verification

Final check of GMP/GLP/GCP certificates, manufacturing licenses, and adherence to the 2026 updated regulatory guidelines.

**Required Regulatory Certifications Verified**

☐ GMP (Good Manufacturing Practice)☐ GLP (Good Laboratory Practice)☐ GCP (Good Clinical Practice)☐ GDP (Good Distribution Practice)

**Manufacturing License Verification Document**

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**Certificate Expiry Date Audit**

Enter date...

**Compliance Status**

☐ Fully Compliant☐ Minor Discrepancies Found☐ Non-Compliant - Remediation Required

**Regulatory Affairs Officer Approval**

### Audit Observation Notes

Write something...

## Submission Lifecycle & Archive Readiness

Verification of submission timelines, electronic submission gateway (ESG) testing, and post-submission response planning.

### Scheduled Submission Date

Enter date...

### Submission Pathway

- ☐ New Drug Application (NDA)
- ☐ Abbreviated New Drug Application (ANDA)
- ☐ Biologics License Application (BLA)
- ☐ Supplement/Variation

### Target Regulatory Agencies

- ☐ FDA (USA)
- ☐ EMA (EU)
- ☐ PMDA (Japan)
- ☐ TGA (Australia)
- ☐ Other

### Submission Gateway Transmission Receipt

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**Post-Submission Response Strategy**

Write something...

**Regulatory Affairs Lead Approval**

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🏁 Finish

🛠️ Generate Sample Report