

Pharmaceutical Product Lifecycle Management (PLM) Checklist 2026

Product Development & R&D Documentation

Verification of initial formulation records, stability study design, and early-stage toxicity data integration.

Formulation Development Completion Date

Development Stage

- ☐ Pre-clinical
- ☐ Clinical Phase I/II/III
- ☐ Registration/NDA
- ☐ Commercialization

Required Stability Studies Completed

- ☐ Accelerated Stability
- ☐ Long-term Stability
- ☐ Stress Testing
- ☐ Photostability

Upload Formulation Master Record

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Summary of Key R&D Deviations

Write something...

R&D Lead Verification Signature

Technology Transfer & Scale-Up Verification

Review of process transfer protocols from R&D to commercial manufacturing, including pilot batch consistency and equipment suitability.

Transfer Start Date

Enter date...

Transfer Type

- ☐ R&D to Pilot Scale
- ☐ Pilot Scale to Commercial
- ☐ Site-to-Site Transfer
- ☐ Post-Approval Change

Originating Facility/Lab ID

Write something...

Scale-Up Critical Parameters Verified

- ☐ Mixing/Agitation Speed
- ☐ Temperature Profiles
- ☐ Pressure Settings
- ☐ Addition/Dosing Rates
- ☐ Filtration/Centrifugation Parameters

Gap Analysis Summary

Write something...

Scale-Up Protocol Document

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Technical Lead Approval

Regulatory Submission & Registration Compliance

Ensuring all CMC (Chemistry, Manufacturing, and Controls) data, dossiers, and updated regulatory filings are aligned with 2026 global standards.

Submission Date

Enter date...

Regulatory Body Name

Write something...

Submission Type

- ☐ New Drug Application (NDA)
- ☐ Abbreviated New Drug Application (ANDA)
- ☐ Supplement/Variation
- ☐ Annual Report

Required Documentation Verified

- ☐ CMC Documentation
- ☐ Stability Data Reports
- ☐ Clinical Study Reports
- ☐ Manufacturing Site Licenses
- ☐ Labeling and Package Insert Drafts

Final Dossier Draft

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Regulatory Affairs Lead Approval

Commercial Manufacturing & Process Control

Audit of master production records, in-process control (IPC) parameters, and adherence to validated manufacturing processes.

Batch Manufacturing Date

Batch/Lot Number

Production Line Identification

- ☐ Line A - Sterile
- ☐ Line B - Non-Sterile
- ☐ Line C - Oral Solid Dosage

In-Process Yield Percentage

Critical Process Parameters (CPP) Verified

- ☐ Temperature Control
- ☐ Mixing Speed/RPM
- ☐ Pressure Settings
- ☐ pH Levels
- ☐ Granulation Time

Batch Production Record (BPR) Scan

 Upload File

Production Supervisor Verification

Post-Approval Change Management

Evaluation of post-approval variations, site transfers, or formulation updates and their impact on established regulatory filings.

Change Control Identification Number

Write something...

Change Impact Level

- ☐ Minor (No impact on quality/safety)
- ☐ Moderate (Potential impact on validated state)
- ☐ Major (Significant impact on product quality/efficacy)

Description of Proposed Change

Write something...

Affected Manufacturing Areas

- ☐ Raw Materials
- ☐ Equipment/Machinery
- ☐ Analytical Methods
- ☐ Packaging/Labeling
- ☐ Facility/Environment

Implementation Deadline

Enter date...

Risk Assessment Report

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Quality Assurance Approval

Post-Market Surveillance & Pharmacovigilance

Monitoring of adverse event reporting, signal detection, and integration of real-world evidence into the product lifecycle.

Adverse Event Report Date

Enter date...

Reported Symptom/Reaction Description

Write something...

Seriousness Assessment

- ☐ Serious
- ☐ Non-Serious

Associated Risk Factors

- ☐ Drug-Drug Interaction
- ☐ Patient Age
- ☐ Dosage Error
- ☐ Storage Temperature Deviation

Causality Assessment Summary

Write something...

Supporting Clinical Evidence/Lab Reports

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Pharmacovigilance Officer Verification

Supply Chain & Distribution Integrity

Verification of finished product stability during distribution, secondary packaging compliance, and end-to-end traceability.

Distribution Shipment Date

Transport Mode

- ☐ Air Freight
- ☐ Road Transport
- ☐ Sea Freight

Temperature Deviation Degree (if applicable)

Distribution Integrity Checks Completed

- ☐ Tamper-Evident Seal Inspection
- ☐ Cold Chain Temperature Log Review
- ☐ Packaging Integrity Verification
- ☐ Shipping Manifest Reconciliation

Proof of Delivery / Waybill Document

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Logistics Supervisor Verification

Product Retirement & End-of-Life Management

Protocol for discontinuation of products, management of remaining stock, and regulatory notification procedures.

Product Discontinuation Date

Enter date...

Reason for Product Retirement

Write something...

Inventory Depletion & Stock Clearance Plan

Write something...

Regulatory Bodies Notified

- ☐ FDA
- ☐ EMA
- ☐ MHRA
- ☐ Other National Competent Authorities

Official Discontinuation Notice/Letter

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Quality Assurance Authorization

< Previous

> Next

✓ Finish

 Generate Sample Report