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BUSINESS PROCESS DIGITALIZATION

# Product Information File Management System

A proposed digital workflow for managing product information file readiness, dossier sections, raw material evidence, safety reports, and completion tracking

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Business Process Digitalization

Workflow Design · Governance · Documentation · Reporting

# Executive Summary

Product Information File Management System addresses a specific process area within the broader product registration and regulatory affairs lifecycle. The workflow is designed for Regulatory Affairs, Quality, Scientific Affairs, Product Safety, and Compliance teams that need stronger control over product information file readiness, dossier sections, raw material evidence, safety reports, and completion tracking. In many organizations, this process is performed by committed teams, but the evidence, decisions, status updates, and follow-up actions are distributed across spreadsheets, email, shared folders, and informal coordination.

The central challenge is product information file evidence is scattered across folders, spreadsheets, raw material references, and manual completion trackers. This creates operational pressure because people must repeatedly ask for status, search for documents, confirm reviewer decisions, and prepare reports manually. It also creates governance risk because the organization may not be able to quickly prove which evidence was reviewed, why a decision was made, who approved it, and what follow-up remains open.

This white paper proposes a practical digital workflow for controlling structured product information files with section-level evidence, raw material details, completion percentages, and reporting. The objective is not to describe software features first. The objective is to clarify the business process: what must be submitted, what must be reviewed, which evidence must be retained, who owns each decision, and how management can monitor the process.

The proposed blueprint should be treated as a discussion framework. It can be implemented as a standalone workflow or as a module inside a broader Product Registration & Regulatory Affairs Platform. Liberty Jaya adapts the workflow to each organization's process, document standards, approval hierarchy, and reporting needs.

# Business Context

These workflows sit at the intersection of product governance, regulatory affairs, quality evidence, scientific review, marketing communication, and management control. The process is rarely owned by one department alone. Business teams may initiate the request, regulatory teams may validate requirements, scientific or quality teams may review evidence, and management may need status visibility before launch, release, renewal, or follow-up decisions. When these responsibilities are spread across teams, the organization needs a controlled workflow that connects ownership, evidence, status, approvals, and reporting. The objective is not to create a generic document repository. The objective is to build a working model where every record has clear context, required evidence, responsible reviewers, decision history, and follow-up visibility.

For this blueprint, the business context is focused on product information file readiness, dossier sections, raw material evidence, safety reports, and completion tracking. The process must support day-to-day users who submit or update records, reviewers who validate evidence, managers who monitor status, and compliance stakeholders who need a reliable history. It must also support exceptions: missing documents, rejected submissions, revised records, delegated reviewers, recurring follow-up, and report preparation.

# Typical Business Challenges

Organizations typically experience similar issues when this process is handled through spreadsheets, email, shared folders, and manual reminders:

- Product information file evidence is scattered across folders, spreadsheets, raw material references, and manual completion trackers.
- Request status is difficult to explain because every team maintains different notes or trackers.
- Supporting evidence is stored separately from the workflow record.
- Reviewer ownership becomes unclear when more than one department is involved.
- Approval decisions are difficult to reconstruct after launch, release, or closure.
- Management reporting requires manual consolidation from multiple sources.
- Audit preparation depends too heavily on individual memory and document search.

These issues are rarely caused by lack of discipline. They usually appear because the process has outgrown manual tracking. As volume increases, a team may still complete individual tasks, but the organization loses reliable visibility of the whole process.

# Regulatory & Governance Drivers

The governance requirement is lifecycle traceability. The organization must be able to show what was submitted, which evidence was reviewed, who reviewed it, what decision was made, which status is current, and what follow-up remains open. Requirements vary by product category, market, and internal policy. This white paper does not provide legal or regulatory advice. It explains the process controls commonly required to improve visibility, accountability, and audit readiness.

- Records should have a clear owner, status, and business context.
- Mandatory evidence should be defined before review or approval begins.
- Reviewer decisions should be retained with comments and timestamps.
- Delegation should be controlled when reviewers are unavailable.
- Rejected or revised records should preserve the reason and correction history.
- Reports should support operational follow-up and management review.

Good governance does not mean adding unnecessary bureaucracy. It means making the process easier to control, easier to explain, and easier to improve.

# Proposed Process Workflow

## Step 1: Select Registered Product

This step defines the business input, responsible owner, expected evidence, and output required before the workflow can move forward. It should be adapted to the organization's internal terminology and approval structure.

## Step 2: Create File Record

This step defines the business input, responsible owner, expected evidence, and output required before the workflow can move forward. It should be adapted to the organization's internal terminology and approval structure.

### Step 3: Upload Section Evidence

This step defines the business input, responsible owner, expected evidence, and output required before the workflow can move forward. It should be adapted to the organization's internal terminology and approval structure.

### Step 4: Complete Raw Material Data

This step defines the business input, responsible owner, expected evidence, and output required before the workflow can move forward. It should be adapted to the organization's internal terminology and approval structure.

### Step 5: Validate Section Readiness

This step defines the business input, responsible owner, expected evidence, and output required before the workflow can move forward. It should be adapted to the organization's internal terminology and approval structure.

### Step 6: Submit Complete File

This step defines the business input, responsible owner, expected evidence, and output required before the workflow can move forward. It should be adapted to the organization's internal terminology and approval structure.

### Step 7: Download Reports

This step defines the business input, responsible owner, expected evidence, and output required before the workflow can move forward. It should be adapted to the organization's internal terminology and approval structure.

## Proposed System Modules

### Product Information File Register

Links product information files to product records, notification references, manufacturer context, and status.

Expected controls include ownership, mandatory information, status tracking, evidence linkage, and reporting visibility.

### Bulk Upload Workspace

Allows teams to upload multiple files and assign them to the correct dossier section.

Expected controls include ownership, mandatory information, status tracking, evidence linkage, and reporting visibility.

### Section Readiness Tracker

Tracks completion percentages for required sections and highlights incomplete evidence.

Expected controls include ownership, mandatory information, status tracking, evidence linkage, and reporting visibility.

### Raw Material Evidence

Manages raw material codes, ingredient names, functions, concentrations, restrictions, and supporting links.

Expected controls include ownership, mandatory information, status tracking, evidence linkage, and reporting visibility.

### Safety Evidence

Controls safety reports, assessor evidence, undesirable effect reports, efficacy evidence, and supporting data.

Expected controls include ownership, mandatory information, status tracking, evidence linkage, and reporting visibility.

### Document Name Control

Standardizes document naming so files are easier to classify, review, and retrieve.

Expected controls include ownership, mandatory information, status tracking, evidence linkage, and reporting visibility.

### Completion Validation

Prevents submission until required sections and concentration details meet agreed readiness rules.

Expected controls include ownership, mandatory information, status tracking, evidence linkage, and reporting visibility.

### Dossier Reporting

Provides section reports, general reports, and checklist downloads for regulatory review.

Expected controls include ownership, mandatory information, status tracking, evidence linkage, and reporting visibility.

## Example User Journey

A regulatory specialist creates a product information file record from an approved product record. The system brings in product name, notification reference, manufacturer context, and validity information. The team uploads supporting files into required sections, classifies each document, and completes raw material information. The section tracker shows which parts are complete and which still need evidence. Before the file is considered complete, the system checks section readiness and total concentration rules. The team can then download reports and checklist evidence for review or audit preparation.

This journey shows why the workflow should not be treated as a simple upload form. The value comes from connecting context, evidence, ownership, decision history, and reporting into one controlled process.

## Expected Benefits

### Operational Benefits

- Clear product information file readiness.
- Section-level evidence visibility.

- Better raw material traceability.
- Reduced manual dossier completeness checking.
- Improved audit and regulatory review preparation.
- Less manual reconciliation between teams.
- Faster follow-up on incomplete records.

### Compliance Benefits

- Stronger evidence traceability.
- Improved audit readiness.
- More consistent approval history.
- Better control of revision and rejection records.

### Management Benefits

- Clearer visibility of workload and bottlenecks.
- Better accountability by owner and department.
- More useful management reporting.
- Stronger basis for process improvement.

## Customization Considerations

Every organization manages regulatory and product governance workflows differently. The blueprint should be adapted to product categories, internal roles, approval hierarchy, document standards, reporting needs, country requirements, and risk tolerance. Typical customization areas include status definitions, mandatory fields, document checklist rules, reviewer groups, delegation policy, reporting layout, retention rules, integration needs, and terminology used by each department. Liberty Jaya uses the blueprint as a starting point for process review rather than a fixed application template.

Typical customization areas include:

- workflow status definitions
- required evidence and document checklist rules
- reviewer roles and approval hierarchy
- delegation and escalation rules
- report filters and dashboard layout
- integration with product, quality, document, or reporting systems
- audit trail and retention requirements

## Integration Considerations

Common integration areas include product master data, document repositories, quality systems, marketing asset workflows, reporting platforms, email notifications, and identity or organization data. Integration should be driven by business value and evidence ownership. Many organizations can begin by centralizing workflow records and document evidence, then add integration after ownership, status definitions, and reporting expectations are stable.

The integration scope should follow the business process. If users first need clarity of ownership and evidence, begin there. If data consistency becomes the bottleneck, integrate master data. If reporting becomes the bottleneck, integrate with reporting tools.

# Implementation Roadmap

A practical implementation should begin with process mapping rather than screen design. The first workshop should identify the current request flow, document owners, reviewer groups, approval points, reporting needs, and recurring pain points. This prevents the project from becoming a direct copy of manual forms. The objective is to understand what the organization must control and where current visibility breaks down.

The second step is to define the minimum controlled workflow. This includes mandatory fields, required documents, status definitions, routing rules, reviewer responsibilities, rejection reasons, and closure conditions. The team should agree which records can remain in draft, which records can be submitted, which records require review, and which records are considered complete. Clear definitions are more important than adding many fields at the start.

The third step is to design reporting around real management questions. Leaders usually need to know which items are pending, which items are overdue, which items were rejected, which records are nearing expiry or follow-up date, and which departments own the next action. Reports should be designed to support follow-up, not only data export.

The fourth step is to pilot the workflow with a limited scope. A small set of product categories, departments, or document types is usually enough to validate status rules and user responsibilities. After the pilot is stable, the workflow can be expanded to additional categories, reports, integrations, and advanced controls.

# Reporting & Management Visibility

The reporting model should help teams manage work and help management identify risk. Operational users need lists of drafts, pending reviews, rejected items, incomplete evidence, and records waiting for follow-up. Reviewers need queues that show what requires action and what information is missing. Management needs summary views by status, category, owner, department, age, and due date.

Useful reports may include open records by status, overdue review items, rejected records by reason, document completeness by category, records approaching expiry, follow-up commitments, and monthly activity summaries. The report names and filters should match the language used by the organization so the reports become part of daily management routines.

Good reporting also supports improvement. If many records are rejected for the same reason, the request form or document checklist may need to be improved. If one approval point creates recurring delay, ownership or delegation rules may need review. If evidence is frequently incomplete, the organization may need clearer guidance for requesters.

# Governance Roles

A sustainable workflow requires clear roles. Requesters are responsible for submitting accurate information and supporting evidence. Reviewers are responsible for validating the record and documenting decisions. Process owners are responsible for maintaining rules, required documents, status definitions, and reports. Management is responsible for reviewing bottlenecks and unresolved risk. IT supports availability, access, and integration, but process ownership should remain with the business.

This role clarity prevents the system from becoming only a data entry tool. The workflow should reflect accountability: who must act, what evidence they need, what decision they can make, and how the decision is retained.

The implementation should also include user guidance and operating discipline. A workflow only creates value when users understand when to create records, how to classify evidence, when to return incomplete submissions, how to document decisions, and how to use reports for follow-up. Training should focus on process ownership and governance behavior, not only button navigation.

# Related Blueprint Opportunities

- Product Approval & Registration Workflow
- Controlled Document Management System
- Regulatory Submission Tracking Platform

These related workflows may be implemented as later phases or connected modules depending on organizational priorities.

# Conclusion

Product Information File Management System provides a structured way to control product information file readiness, dossier sections, raw material evidence, safety reports, and completion tracking. The expected outcome is better process visibility, clearer ownership, stronger evidence control, and more reliable management reporting.

The blueprint is intended as a discussion framework and implementation starting point rather than a fixed software specification.

# Liberty Jaya

## About Liberty Jaya

Established in 1995, Liberty Jaya helps organizations transform business rules, compliance requirements, approvals, documents, and reporting processes into digital systems. Liberty Jaya works with organizations that need practical systems for real business processes. The work starts by understanding process ownership, document evidence, approval responsibilities, reporting needs, and operational follow-up before defining the digital workflow.

## Call To Action

Need this workflow adapted to your organization?

Liberty Jaya can help:

- review the current process
- identify document and governance requirements
- define workflow ownership across departments
- prepare implementation scope
- customize the blueprint

Contact Liberty Jaya to discuss process review, workflow design, and implementation planning.

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