



BUSINESS PROCESS DIGITALIZATION

Product Registration & Regulatory Affairs Platform

A proposed digital workflow for managing product registration, regulatory dossiers, claims review, product information files, post-market surveillance, and compliance reporting

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Business Process Digitalization

Registration · Dossiers · Claims · Product Information Files · Surveillance · Reporting

Executive Summary

Product registration is not a single submission activity. In regulated product businesses, registration connects product approval, formula and variant information, document readiness, claim review, product information files, post-market monitoring, consumer safety follow-up, renewal control, and management reporting. A product may begin as a business request, move through regulatory verification, require supporting certificates, trigger claim or artwork review, generate product information file requirements, and later require surveillance evidence after market release.

Many organizations still manage these activities through separate spreadsheets, email threads, shared folders, manual reminders, and disconnected departmental trackers. Each team may understand its own responsibility, but the full regulatory lifecycle becomes difficult to see. Regulatory Affairs may track registration status. Marketing may track public material and claims. Quality or scientific teams may manage product information files and supporting evidence. Post-market teams may monitor findings and recommendations. Management may only see status when a launch is delayed, a renewal becomes urgent, or an audit requires evidence.

The risk is not only administrative inefficiency. Weak lifecycle control can affect launch readiness, claim governance, dossier completeness, renewal planning, post-market accountability, consumer safety follow-up, and audit evidence. If a product registration record is not connected to product variants, supporting documents, claims, product information files, post-market surveillance, and related reports, the organization may struggle to answer basic governance questions: What is the current regulatory status? Which documents are missing? Which variants require monitoring? Which claims were reviewed? Which post-market findings require follow-up? Which registrations are near expiry?

The Product Registration & Regulatory Affairs Platform Blueprint describes a proposed digital workflow for managing this broader regulatory lifecycle. The goal is to move beyond a registration tracker and create a controlled workspace for product approval, dossier readiness, internal verification, claim review, product information file completion, post-market surveillance, safety or complaint cases, reporting, delegation, and audit traceability.

This white paper is written for Regulatory Affairs Managers, Quality Assurance Managers, Compliance Managers, Product Managers, Marketing Managers, Operations Managers, and IT Managers who need stronger control over product regulatory workflows. It is not a technical implementation document. It is a business process framework for discussing how product registration and regulatory affairs activities can be governed through a connected digital system.

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

Business Context

Product registration and regulatory affairs work is usually cross-functional. A product record may involve product development, marketing, regulatory affairs, scientific review, quality assurance, manufacturing, packaging, claims review, safety monitoring, and management approval. Each function contributes different evidence and decisions.

The process often begins when a new product, variant, formulation, or claim requires regulatory assessment. A requester provides product information, expected launch timing, product name, brand or category context, variant details, manufacturing or supplier information, and supporting documents. Regulatory or scientific

teams then review the record, validate required information, confirm submission readiness, and determine the next status.

After the product moves forward, the organization may need to manage additional regulatory assets:

- product approval and registration records
- variants, product codes, formulas, and launch timing
- heavy metal, microbiology, or analytical certificate evidence
- administrative documents and supporting certificates
- public material and marketing claim review
- product information file sections and completion percentages
- raw material information and restricted ingredient evidence
- post-market surveillance findings and recommendations
- consumer safety, complaint, or cosmetovigilance case records
- renewal, expiry, obsolete, and status reporting

These activities are connected. A product approval record may trigger post-market surveillance. A product information file may depend on product registration status and supporting formula information. A public claim may require scientific or regulatory review before use. A post-market finding may create a recommendation and require a future follow-up. A consumer safety case may need approval, release, closure, and reporting.

Stakeholders typically include:

- Requesters who initiate product registration, approval, claim, or product information file requests.
- Regulatory Affairs teams who review product data, document readiness, status, submissions, and expiry.
- Quality or scientific teams who validate supporting evidence, certificates, product safety, and surveillance findings.
- Marketing or brand teams who need claim and public material review before market use.
- Product or business teams who need launch readiness and regulatory status visibility.
- Management teams who need reporting on status, pending reviews, expired registrations, surveillance follow-up, and compliance risk.
- IT teams who support system adoption, access control, reporting, and integration requirements.

Because these responsibilities are distributed, the organization needs a governed workflow rather than a collection of separate forms and folders.

Typical Business Challenges

Organizations managing product registration and regulatory affairs manually often face recurring control problems:

- Product registration status is tracked separately from variants, formulas, certificates, product information files, claims, and surveillance records.
- Requesters lack visibility into whether a product request is still in draft, under verification, submitted, registered, rejected, expired, or obsolete.
- Regulatory teams spend time reconciling missing data, incomplete documents, and unclear ownership.
- Product launch planning is affected when expected launch dates, document readiness, and submission status are not visible together.

- Product information file completion is difficult to monitor when evidence is spread across folders and file uploads.
- Public claims and materials may be reviewed outside the main product regulatory record.
- Post-market surveillance may not be clearly linked to the registered product, product variant, finding category, recommendation, or next review date.
- Consumer safety or complaint cases may be tracked separately from product registration and reporting needs.
- Delegation and approval responsibility become unclear when reviewers are unavailable.
- Reports require manual consolidation from multiple trackers and document repositories.

These problems usually grow over time. A single product may have several variants. Each variant may have different supporting files, surveillance requirements, claims, or expiry conditions. When the product portfolio expands, manual coordination becomes fragile. The organization depends on individual memory, email history, and spreadsheet discipline.

The result is a process that appears operational but is difficult to govern. Teams can still work, but management cannot easily see lifecycle readiness, risk, and accountability across the product portfolio.

Regulatory & Governance Drivers

Product registration and regulatory affairs workflows exist because organizations must prove that products, claims, documents, and market activity are managed responsibly. Requirements vary by country, product category, and internal policy. This white paper does not provide legal or regulatory advice. The objective is to explain why control, visibility, and evidence are necessary.

Common governance drivers include:

- Product registrations require complete and accurate product information.
- Product variants, formulas, product names, and supporting documents must remain traceable.
- Submission status, registration status, expiry, renewal, and obsolete decisions must be visible.
- Claims and public materials should be reviewed before use to reduce compliance exposure.
- Product information files require structured evidence, section completion, and supporting documents.
- Post-market surveillance should be connected to product records, findings, recommendations, and follow-up dates.
- Consumer safety, complaint, or cosmetovigilance cases require controlled review, approval, release, closure, and reporting.
- Management requires reports that show registration readiness, pending reviews, expiry risk, surveillance status, and open cases.
- Audit preparation requires reliable evidence of documents, approvals, status changes, delegation, and reports.

The key governance principle is lifecycle traceability. A product should not be viewed only at the point of registration submission. It should be governed from request through approval, documentation, market use, surveillance, renewal, and closure.

Proposed Process Workflow

The Product Registration & Regulatory Affairs Platform Blueprint follows an end-to-end lifecycle. Each organization should adapt the workflow to its own product categories, regulatory obligations, and internal authority structure.

Step 1: Create Product Request

A requester creates a product record with product name, category, brand or business grouping, formula reference, variant information, expected launch date, manufacturing or sourcing context, and initial supporting documents.

The output of this step is a controlled product request with an owner, reference number, initial status, and required fields.

Step 2: Validate Product and Variant Information

The regulatory team reviews product and variant details. The workflow should support existing product codes, new variants, product name adjustments, formula references, sample requirements, and launch timing.

The output of this step is validated product data that can support registration, dossier preparation, and downstream monitoring.

Step 3: Review Dossier and Supporting Evidence

The team reviews required administrative, scientific, quality, and regulatory documents. This may include certificates, analytical evidence, microbiology or heavy metal information, label requirements, supporting files, and internal documents.

The output of this step is a dossier readiness view showing which evidence is complete, missing, under review, or requiring revision.

Step 4: Manage Internal Verification and Submission Status

The product record moves through internal verification, submission preparation, revision, submitted status, registered or notified status, rejection, expiry monitoring, and obsolete handling. Status rules should be clear and reportable.

The output of this step is a controlled registration lifecycle with visible status and accountability.

Step 5: Review Public Material and Product Claims

Claims or public materials are submitted for review. The regulatory or scientific reviewer assesses product name, formula, claim context, risk level, and approval hierarchy. The workflow should capture comments, decision, approval status, and supporting evidence.

The output of this step is a controlled claim review record connected to product governance.

Step 6: Compile Product Information File

The product information file workspace organizes required sections, supporting documents, raw material information, restriction evidence, safety reports, efficacy evidence, undesirable effect reports, and completion percentages.

The output of this step is a structured product information file record with section-level readiness and downloadable reporting.

Step 7: Trigger Post-Market Surveillance

Products or variants that require surveillance generate post-market records. The workflow captures product linkage, audit date, market or advertising findings, recommendations, attachment evidence, and next follow-up requirements.

The output of this step is a post-market surveillance record connected to product registration and product evidence.

Step 8: Manage Safety or Complaint Cases

Consumer safety, complaint, or cosmetovigilance cases are registered, reviewed, approved, released, closed, and reported. The workflow should support attachments, review responsibility, approval check, annual reporting, monthly reporting, and summary reporting.

The output of this step is a controlled case record and reportable safety history.

Step 9: Monitor Expiry, Renewal, Obsolete Status, and Reports

The system monitors nearing expiry, expired, registered, rejected, obsolete, and pending items. Reports should support product registration review, product information file readiness, claim review, post-market surveillance, and safety case reporting.

The output of this step is management visibility across the regulatory lifecycle.

Proposed System Modules

Product Registration Master

Central repository for product registration records, product names, categories, formulas, variants, expected launch timing, manufacturing context, registration status, and expiry information.

Expected controls include unique numbering, mandatory fields, status history, ownership, and searchable product records.

Requestor Workspace

Workspace for business or product teams to create product requests, complete product data, attach required evidence, and submit requests to regulatory review.

Expected controls include draft status, mandatory input rules, submission confirmation, attachment control, and requester visibility.

Regulatory Review Workspace

Workspace for regulatory or scientific teams to verify product data, validate readiness, update status, review documents, manage internal notes, and control approval decisions.

Expected controls include reviewer ownership, restricted fields, approval checks, rejection reasons, and controlled status transitions.

Variant and Product Code Management

Manages product variants, product codes, sample requirements, variant import or upload, and links to surveillance requirements.

Expected controls include variant validation, product name linkage, duplicate prevention, and downstream monitoring flags.

Dossier and Document Repository

Stores administrative documents, certificates, supporting evidence, internal files, analytical evidence, and product-related attachments.

Expected controls include document title, document category, upload history, renewal flag, internal-only document handling, and download access.

Claim and Public Material Review

Controls public material and marketing claim submissions, risk assessment, reviewer comments, decision status, and approval hierarchy.

Expected controls include claim record, formula linkage, product name review, risk level, approval workflow, and release status.

Product Information File Management

Manages product information file sections, completion percentages, bulk upload, raw material information, document names, safety reports, efficacy evidence, undesirable effect reports, and supporting data.

Expected controls include section completeness, required evidence, raw material master linkage, total completion validation, and report download.

Post-Market Surveillance

Controls surveillance records linked to product registration, variant requirements, audit dates, findings, recommendations, attachments, and next follow-up cycles.

Expected controls include product linkage, finding category, recommendation mapping, audit date, next surveillance generation, and status tracking.

Consumer Safety and Cosmetovigilance Case Management

Manages safety or complaint cases, attachments, review activity, approval check, release, closure, and periodic reporting.

Expected controls include case status, supporting files, reviewer approval, release status, closure status, and annual or monthly reports.

Delegation and Approval Control

Allows controlled delegation of review responsibility when approvers are unavailable and supports approval accountability across modules.

Expected controls include delegate user, delegated module, active period, approval responsibility, and traceability.

Reporting and Dashboard

Provides reports for product registration status, product information file readiness, claim review, surveillance, open cases, expiry risk, and management review.

Expected controls include filters by date, status, category, product, owner, report type, and downloadable output.

Example User Journey

New Product Registration and Lifecycle Control

A product team prepares a new product launch and needs regulatory review before the product can move forward. The requester creates a product registration request, enters product category, product name, formula reference, variant information, expected launch date, manufacturer information, and supporting files. The request remains in draft until mandatory information is complete.

After submission, the regulatory team reviews the product record. Some product information is validated, while several supporting documents are still missing. The reviewer updates the record, requests additional evidence, and keeps the status visible to the requester. When the required information is complete, the product moves into internal verification.

The product has several variants. Some use existing product codes, while others are new variants. The variant workspace helps control this information and identifies which variants require post-market surveillance. Supporting certificates and internal files are uploaded into the dossier repository, while administrative documents and certificate references are maintained by the regulatory team.

Marketing later submits public material and product claims for review. The claim review workflow captures the product name, formula context, supporting material, risk level, reviewer decision, and approval status. The decision is retained as part of the product's regulatory evidence.

The product information file is then prepared. Required sections are uploaded, raw material information is completed, safety and efficacy evidence is attached, and the completion percentage is monitored. The product information file cannot be considered complete until required sections meet the agreed completion rules.

After the product enters market activity, post-market surveillance is created for the relevant variants. Findings and recommendations are recorded, attachments are added, and a future follow-up date is generated when required. If a consumer safety or complaint case occurs, the case is registered, reviewed, approved, released, closed, and included in periodic reports.

Management can now see the product lifecycle from request to registration, claim review, product information file readiness, surveillance, case reporting, and expiry monitoring. Instead of asking each team for separate updates, the organization can review one connected regulatory workflow.

Expected Benefits

Operational Benefits

- Reduced manual tracking across registration, claim review, product information file, surveillance, and case workflows.
- Better launch readiness because product data, documents, variants, and submission status are visible together.

- Faster regulatory follow-up because missing evidence and pending reviews are easier to identify.
- Clearer collaboration between requesters, regulatory teams, scientific reviewers, marketing, quality, and management.
- Easier report preparation across product registration, product information file, surveillance, and safety cases.
- Better handling of reviewer absence through delegation and approval control.

Compliance Benefits

- Stronger evidence control across product records, supporting documents, claims, surveillance, and safety cases.
- Better traceability from product registration to variants, documents, product information files, and post-market records.
- Improved audit readiness through centralized status history, attachments, approval decisions, and reports.
- More consistent claim review and public material governance.
- Better renewal, expiry, and obsolete status control.
- Reduced risk of disconnected evidence during regulatory review or audit preparation.

Management Benefits

- Better visibility of registration pipeline, pending verification, submitted records, registered products, expired items, and obsolete records.
- Clearer accountability for product requests, document completion, claim review, surveillance, and case closure.
- Better understanding of bottlenecks affecting product launch and regulatory readiness.
- More practical reporting for regulatory management, quality review, and executive follow-up.
- Stronger foundation for regulatory affairs process improvement.

Customization Considerations

Every organization manages product registration and regulatory affairs differently. The blueprint should be adapted to product category, country requirements, internal approval matrix, document standards, claim policy, product information file structure, surveillance obligations, and reporting expectations.

Typical customization areas include:

- product category and registration status definitions
- requestor and regulatory team responsibilities
- variant structure and product code rules
- expected launch date and submission readiness rules
- dossier checklist and required evidence
- certificate and analytical evidence requirements
- public material and claim review hierarchy
- product information file section structure and completion rules
- post-market surveillance triggers and follow-up cycle
- safety or complaint case workflow
- delegation, approval, and release rules
- expiry, renewal, obsolete, and reporting logic

Liberty Jaya uses the blueprint as a starting point for process review. A practical project should begin by mapping the current regulatory lifecycle, identifying document owners, clarifying approval responsibilities, defining evidence requirements, and agreeing on management reports.

Integration Considerations

Product registration and regulatory affairs workflows may need to connect with existing business systems and repositories. Integration should be planned based on process control, evidence ownership, and operational value.

Common integration areas include:

- product master data for product codes, variants, formulas, brands, categories, and manufacturing information
- document repositories for certificates, supporting evidence, internal documents, and product information file attachments
- quality systems for analytical evidence, microbiology information, safety records, or complaint follow-up
- marketing asset or artwork workflows for claim and public material review
- reporting platforms for regulatory dashboards, status reports, and management review
- email or notification systems for request, review, approval, rejection, and delegation alerts
- identity or organization data for user roles, reviewer groups, delegation, and approval authority

The recommended approach is to begin with lifecycle visibility and controlled evidence. Deeper integration can be added after ownership, status definitions, and reporting requirements are stable.

Related Blueprint Opportunities

This platform can become the umbrella for several focused blueprints:

- Product Information File Management System for dossier section control, raw material evidence, safety reports, and completion tracking.
- Post-Market Surveillance Management System for product findings, recommendations, audit dates, and next follow-up cycles.
- Consumer Safety & Cosmetovigilance Workflow for complaint and safety case review, approval, release, closure, and reporting.
- Marketing Claim & Regulatory Review System for public material, claim evidence, risk assessment, and approval routing.
- Regulatory Submission Tracking Platform for authority submissions, response tracking, deadlines, and evidence history.
- Controlled Document Management System for regulatory procedures, supporting files, controlled documents, and periodic review.

These related workflows can be implemented as separate phases or as modules within one regulatory affairs platform.

Conclusion

Product registration is part of a broader regulatory lifecycle. A product record may connect to variants, dossier evidence, certificates, product information files, claims, post-market surveillance, safety cases, expiry status, and management reporting. When these processes are managed separately, teams lose visibility and spend too much effort reconciling status and evidence.

The Product Registration & Regulatory Affairs Platform Blueprint provides a structured approach for controlling the lifecycle. It connects product approval, regulatory review, document evidence, claim review, product information file readiness, post-market surveillance, consumer safety cases, delegation, and reporting into a single governance model.

The expected outcome is stronger regulatory visibility, clearer ownership, better document readiness, improved audit evidence, and more reliable management control.

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.

Areas of focus:

- Regulatory Workflow
- Compliance Documentation
- Approval Governance
- Enterprise Reporting

Liberty Jaya works with organizations that need practical systems for real business processes. For product registration and regulatory affairs, the work starts by understanding the product lifecycle, document evidence, approval responsibilities, regulatory status, surveillance requirements, and reporting needs before defining the digital workflow.

Call To Action

Need a product registration and regulatory affairs workflow adapted to your organization?

Liberty Jaya can help:

- review the current regulatory lifecycle
- 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 regulatory affairs digitalization requirements.

