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BUSINESS PROCESS DIGITALIZATION

Regulatory Submission Tracking Platform Blueprint

A proposed digital workflow for managing multi-country regulatory submissions, document evidence, authority responses, deadlines, commitments, and closure

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Business Process Digitalization

Submission Tracking · Authority Response · Deadlines · Commitments

Executive Summary

Regulatory submission work is often larger than a single product registration activity. Organizations may need to manage submissions across multiple countries, authorities, product categories, business units, distributors, importers, manufacturing sites, claims, artwork changes, variation requests, license renewals, notification updates, post-approval commitments, and authority queries. Each submission may have its own document package, reviewer responsibilities, submission route, authority response, deadline, commitment, and approval evidence.

When submission volume is low, Regulatory Affairs teams can often manage this work through spreadsheets, email, calendar reminders, shared folders, and manual follow-up. As the organization grows, this approach becomes difficult to control. A submission may be prepared by one team, reviewed by another, submitted by a local representative, queried by an authority, answered by technical or quality teams, and then closed with an approval letter or rejection evidence. If these steps are tracked separately, management may not know which submissions are pending, which authority responses are overdue, which commitments are unresolved, which countries are blocked, or which evidence supports the final decision.

The business risk is not only missed deadlines. Weak submission control can affect launch timing, market access, renewal continuity, regulatory commitments, distributor coordination, management reporting, and audit readiness. Teams may spend significant time reconciling trackers, checking folder contents, asking for response status, and preparing manual summaries. When a regulator, distributor, customer, or management team asks for the history of a submission, the organization may need to reconstruct the decision trail from several sources.

The Regulatory Submission Tracking Platform Blueprint describes a practical digital workflow for controlling submission records, document readiness, internal review, authority submission, response tracking, query resolution, approval or rejection evidence, commitments, deadlines, and management reporting. This blueprint is intentionally broader than product registration tracking and narrower than a full regulatory affairs platform. Its focus is submission governance across authorities, countries, products, and regulatory workstreams.

Liberty Jaya approaches regulatory submission tracking as a business process digitalization challenge. The objective is to convert submission obligations, document requirements, ownership rules, authority interactions, deadline controls, and reporting needs into a governed workflow. Technology supports the process, but the core value comes from clearer accountability, stronger evidence history, and better regulatory visibility.

Business Context

Regulatory submissions connect internal preparation with external authority decisions. The exact submission type depends on the organization and industry. It may include product registration, variation, renewal, notification, import approval, license update, labeling submission, claim support, dossier amendment, certificate request, commitment response, or country-specific regulatory filing.

Several stakeholders are typically involved:

- Regulatory Affairs teams who own submission planning, document readiness, authority communication, and final evidence.
- Quality Assurance or technical teams who provide certificates, specifications, safety evidence, manufacturing documents, or review comments.
- Marketing or product teams who provide launch plans, claim context, artwork, product information, or business priority.
- Supply Chain or Operations teams who depend on submission status for launch, import, production, or distribution planning.
- Local affiliates, distributors, importers, or representatives who may submit to local authorities and provide status updates.
- Management teams who need visibility of submission workload, blocked markets, delayed approvals, and unresolved commitments.
- Auditors or compliance reviewers who need reliable submission history and evidence retention.

The process usually begins when a submission need is identified. The regulatory team defines scope, country, authority, product or document context, timeline, and owner. Required documents are collected and reviewed. The submission is sent to the relevant authority or representative. Authority responses, queries, commitments, approvals, rejections, and renewals must be tracked until closure.

Because submission activities often span several months and several parties, the organization needs more than a list of dates. It needs a controlled record of what was submitted, when, by whom, which evidence was used, which response was received, and what remains open.

Typical Business Challenges

Organizations often experience submission tracking problems as unclear status, missed follow-up, or manual reporting workload. Common challenges include:

- Submission records are tracked separately by country, product, authority, distributor, or department.
- Document packages are stored in shared folders without clear readiness status or review evidence.
- Internal review and approval before submission is informal or handled through email.
- Authority submission date, reference number, receipt evidence, and submitted package are not consistently captured.
- Authority queries are received through different channels and may not be assigned to clear owners.
- Query deadlines and response commitments are tracked manually.
- Approval, rejection, or additional information evidence is stored outside the submission record.
- Post-approval commitments are forgotten after the main approval is received.
- Launch, import, renewal, or market access plans are affected because submission status is not visible to other teams.
- Management reports require manual consolidation from spreadsheets, emails, local representatives, and file folders.
- Historical submission records are hard to search when similar filings or authority questions arise later.

These challenges are usually caused by fragmented control. Regulatory teams may be actively following up, but the process does not give all stakeholders a reliable view of status, ownership, evidence, and deadlines.

Regulatory & Governance Drivers

Regulatory submission requirements vary by country, authority, product category, industry, and submission type. This white paper does not provide legal advice or regulatory interpretation. Each organization should confirm applicable requirements with qualified regulatory personnel and current official guidance.

From a governance perspective, submission tracking usually needs to support these principles:

- Submission scope, authority, country, product, and owner should be clearly defined.
- Required evidence should be complete and reviewed before submission.
- Submitted document packages should be retained with submission reference information.
- Authority queries and deadlines should be visible and assigned.
- Responses should be documented with evidence and decision history.
- Approvals, rejections, withdrawals, or closures should be supported by retained authority evidence.
- Commitments after submission or approval should be monitored until completion.
- Management should be able to monitor pending, overdue, approved, rejected, queried, and closed submissions.
- Historical submission records should support future filings, audits, and management review.

Regulatory governance is not only about submitting documents. It is about controlling the relationship between requirements, evidence, authority communication, decisions, and business impact.

Proposed Process Workflow

The Regulatory Submission Tracking Platform Blueprint follows a controlled submission lifecycle. The workflow should be adapted to each organization, but the following baseline provides practical control points.

Step 1: Register Submission Need

The process begins when a submission need is identified. The requester or regulatory owner creates a submission record with country, authority, submission type, product or document scope, business purpose, target date, responsible owner, priority, and related business activity.

The output is a registered submission record with clear owner and initial status.

Step 2: Define Requirements and Checklist

Regulatory Affairs defines the required document checklist, authority requirements, internal review needs, local representative responsibilities, expected timeline, and submission route. Checklist rules may vary by country, authority, product category, or submission type.

The output is a structured submission preparation plan.

Step 3: Collect and Review Evidence

Document owners upload or provide required evidence. Regulatory Affairs and other reviewers check completeness, version, consistency, and suitability for the intended submission. Missing or incorrect documents are returned for correction before submission.

The output is a submission package that is ready for internal approval or authority filing.

Step 4: Approve Submission Readiness

Where required, internal stakeholders approve the submission package before it is sent. Approval may involve Regulatory Affairs, Quality Assurance, technical teams, department heads, or management depending on risk and company policy.

The output is a readiness decision with approval evidence.

Step 5: Submit to Authority or Representative

The submission is sent to the relevant authority, portal, distributor, importer, or local representative. The record captures submission date, submission reference, submitted package, submitter, channel, and initial status.

The output is a submitted record with traceable filing evidence.

Step 6: Track Authority Response

The regulatory team monitors authority response status. Responses may include receipt confirmation, query, request for additional information, deficiency letter, approval, rejection, withdrawal, renewal request, or pending review.

The output is a response log with current authority status.

Step 7: Resolve Queries and Commitments

Queries are assigned to responsible owners with due dates. Responses are prepared, reviewed, approved where required, and submitted with supporting evidence. Post-approval commitments are tracked until closed.

The output is controlled query and commitment follow-up.

Step 8: Record Outcome

When the final outcome is received, the submission record is updated with approval date, rejection reason, approval number, certificate, letter, validity period, conditions, or closure evidence. If the submission is withdrawn or rejected, the reason should be retained for learning and reporting.

The output is a controlled submission outcome record.

Step 9: Monitor Deadlines and Renewals

The workflow monitors response deadlines, commitment dates, renewal dates, validity periods, and aging. Owners receive alerts before deadlines become overdue.

The output is better deadline control and fewer missed commitments.

Step 10: Report and Review

Management and process owners review submission volume, status by country, authority response aging, overdue queries, approval cycle time, rejection reasons, commitment status, and blocked launches or markets.

The output is stronger regulatory visibility and business planning support.

Proposed System Modules

The following modules describe business capabilities that support regulatory submission tracking. They should be adapted to the organization’s regulatory model and reporting needs.

Submission Register

The Submission Register is the central repository for regulatory submissions. It records submission type, country, authority, product or document scope, owner, target date, priority, current status, and outcome.

Expected controls include unique numbering, mandatory classification, owner assignment, status history, and search by country, authority, product, type, or period.

Requirement and Checklist Matrix

Requirement and Checklist Matrix defines required documents and preparation steps by country, authority, submission type, product category, or internal policy.

Expected controls include checklist version, mandatory documents, document owner, due date, readiness status, and review responsibility.

Document Evidence

Document Evidence stores the documents, certificates, forms, letters, technical evidence, product information, labels, artwork, or supporting files used for the submission.

Expected controls include upload category, version, owner, review status, replacement history, and linkage to the submitted package.

Review and Readiness Approval

Review and Readiness Approval manages internal review before submission. It helps ensure that the organization does not submit incomplete or unapproved packages.

Expected controls include reviewer assignment, decision capture, comments, return for correction, due dates, and approval timestamp.

Authority Tracker

Authority Tracker records submission date, reference number, channel, authority, local representative, receipt evidence, and current authority status.

Expected controls include submission reference, submitted package, status updates, response dates, authority notes, and supporting files.

Response Log

Response Log captures authority queries, deficiency letters, additional information requests, approvals, rejections, withdrawals, and other responses.

Expected controls include response type, received date, owner, due date, evidence, status, and resolution history.

Query and Commitment Management

Query and Commitment Management tracks required responses and post-submission or post-approval commitments. It ensures that commitments remain visible after the main submission milestone.

Expected controls include assigned owner, response deadline, commitment due date, response package, approval requirement, and closure evidence.

Deadline Control

Deadline Control monitors target dates, authority deadlines, query response dates, commitment dates, validity periods, and renewal dates.

Expected controls include alert thresholds, overdue indicators, escalation recipients, aging analysis, and management visibility.

Outcome Evidence

Outcome Evidence stores final approval letters, certificates, rejection letters, authority decisions, conditions, validity information, and closure notes.

Expected controls include outcome type, approval number, approval date, validity period, conditions, file attachment, and related commitment tracking.

Management Dashboard and Reporting

Management Dashboard and Reporting gives Regulatory Affairs and management visibility of submission workload and risk. Reports may show submissions by country, authority, status, owner, deadline, query aging, approval cycle time, rejection reason, and commitment status.

Expected controls include filterable dashboards, export-ready summaries, consistent definitions, and role-based visibility.

Example User Journey

Multi-Country Authority Query Follow-Up

A company is preparing several regulatory submissions for the same product family across different countries. Each country has different document expectations, local representative involvement, and authority response timing. In the previous process, the regulatory team used one spreadsheet for submission dates, separate folders for documents, and email to track authority queries. Management often asked for status, but the team needed time to reconcile information from different owners.

Using the Regulatory Submission Tracking Platform Blueprint, Regulatory Affairs creates submission records for each country and authority. Each record captures product scope, submission type, target date, owner, local representative, and required checklist. The checklist differs by country, but the dashboard gives management one consolidated view.

Document owners upload required evidence. Quality Assurance provides manufacturing certificates, the technical team provides supporting product information, and the local representative confirms country-specific forms. Regulatory Affairs reviews the package and returns one document because the version does not match the intended submission. After correction, the submission package is approved internally.

The local representative submits the package and uploads the submission receipt. The authority later issues a query requesting additional clarification. The query is logged with received date, response deadline, responsible owner, and required evidence. Regulatory Affairs assigns the technical team to prepare the response and Quality Assurance to review supporting evidence.

The response package is completed, reviewed, and submitted before the deadline. The response log shows the original query, assigned owners, response evidence, resubmission date, and current authority status. Two weeks later, approval is received with a condition requiring a post-approval document update within a defined period. The approval letter is uploaded, and the condition becomes a tracked commitment.

At management review, leaders can see which countries are submitted, queried, approved, delayed, or waiting for local representative action. The team can also see outstanding commitments and authority

response aging. The submission process becomes visible and governed rather than dependent on manual reconciliation.

Expected Benefits

Operational Benefits

- Clear visibility of submission status by country, authority, product, owner, and deadline.
- Reduced manual follow-up for missing documents, authority responses, and query owners.
- Better coordination between Regulatory Affairs, QA, technical teams, local representatives, and management.
- Faster retrieval of submitted packages, response history, and outcome evidence.
- Improved planning support for launch, import, renewal, and market access activities.

Governance Benefits

- Stronger document readiness control before submission.
- Traceable authority response and query resolution history.
- Better control over post-submission and post-approval commitments.
- More reliable evidence retention for audit and management review.
- Reduced risk of missed deadlines or unresolved authority requests.

Management Benefits

- Dashboard visibility of pending submissions, overdue queries, authority response aging, and blocked markets.
- Better insight into rejection reasons, recurring queries, and country-level bottlenecks.
- More reliable regulatory reporting without manual tracker consolidation.
- Stronger accountability for submission ownership and commitments.

Customization Considerations

Every organization manages regulatory submissions differently. A practical implementation should match the organization’s countries, product categories, authority relationships, local representative model, and reporting needs. Areas commonly requiring customization include:

- Submission types and status definitions.
- Country and authority-specific checklist requirements.
- Document readiness and internal approval rules.
- Local representative, importer, distributor, or affiliate responsibilities.
- Query response deadlines and escalation rules.
- Commitment tracking after approval or submission.
- Outcome evidence categories such as approval, rejection, renewal, withdrawal, or conditional approval.
- Integration with product registration, document control, SKI, import documentation, artwork, claim review, or regulatory master data workflows.
- Dashboards by country, authority, product, owner, business unit, deadline, and status.

The blueprint should be treated as a process design starting point. Implementation should begin by mapping current submission types, identifying handoff points, defining evidence requirements, and agreeing which deadlines and commitments management needs to see.

Integration Opportunities

Regulatory submission tracking often connects to adjacent regulatory and compliance workflows. Potential integration points include:

- Product registration systems for product, dossier, approval, renewal, and registration evidence.
- Document control systems for controlled certificates, letters, templates, labels, and supporting documents.
- SKI or import approval workflows for import-related submissions and authority evidence.
- Artwork and claim review workflows when submission depends on approved labels, claims, or public materials.
- Product information file or dossier systems for source evidence and section readiness.
- Management reporting dashboards for launch readiness, market access status, and regulatory workload.

Integration should be based on business traceability. The organization should be able to see which evidence supported a submission, which authority response was received, and which business activity depends on the outcome.

Implementation Approach

A successful submission tracking implementation should begin with process clarity before system configuration. Recommended activities include:

1. Inventory submission types, countries, authorities, local representatives, documents, and current trackers.
2. Identify recurring gaps such as unclear status, missed deadlines, duplicate documents, and manual report workload.
3. Define target submission lifecycle statuses from preparation to closure.
4. Standardize checklist rules, owner responsibilities, query categories, deadlines, and outcome evidence.
5. Configure submission register, document evidence, readiness approval, authority tracker, response log, commitment management, and dashboards.
6. Pilot with selected submission types or countries before expanding the model.
7. Review reporting quality and refine status definitions, escalation rules, and commitment tracking.

This approach keeps the implementation focused on regulatory control and business visibility rather than merely digitizing a spreadsheet.

Conclusion

Regulatory submission tracking is a cross-functional governance process. When managed manually, it can create unclear ownership, missed deadlines, scattered evidence, weak authority response control, and slow management reporting. When managed as a digital workflow, it gives Regulatory Affairs and management a clearer view of document readiness, submission status, authority responses, commitments, and outcomes.

The Regulatory Submission Tracking Platform Blueprint provides a practical framework for managing submissions across countries, authorities, products, documents, queries, deadlines, and commitments. It helps organizations move from fragmented tracking toward controlled regulatory visibility and stronger evidence history.

Liberty Jaya can help organizations adapt this blueprint to their regulatory process, country model, document standards, approval governance, reporting needs, and implementation roadmap.

Contact

Liberty Jaya helps organizations transform business processes, regulatory requirements, compliance workflows, approvals, documents, and reporting into digital systems.

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