# Five Regulatory Tracking Spreadsheets it is Time to Retire

It's always crunch time for regulatory operations. Whether you're managing plans and documents for an upcoming IND or producing routine product variations, there are a thousand moving parts. With so much complexity, it's no wonder that teams have developed Excel tracking tools to keep things straight.

**A once helpful tool quickly becomes a burden:**

- Document linking is manual
- Status updates are manual
- Shared copies are disconnected and rapidly become out-of-date
- Terminology, naming, and what to track often vary by product or region
- Hours are spent correcting data-entry mistakes
- Entries can be accidentally overly written

In maintaining an ever-growing number of trackers, team members are frustrated and waste time that could be spent on more productive work. Because whether working in Microsoft Project, Access, or Excel, static trackers are inherently ill-suited to the dynamic nature of regulatory work.

## Make Tracking a Byproduct of a Well Managed Process

While Excel may have been the best tool available in years past, RIM technologies have advanced significantly and can now integrate tracking with submission components, health authority commitments, and product registrations.

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# Beyond Trackers: Managing the Complete Submission Process

Today's RIM systems can provide a single source of truth for regulatory by unifying workflow and tracking capabilities with content and data management. Data and related documents are entered once, and made available to authorized individuals throughout the company by way of tasks, reports, and at-a-glance overviews. The unified tracking can report on multiple dimensions of a process, e.g. tasks, commitments, and planned submissions. Workflow-driven processes drive status changes and are tracked automatically as an output of the RIM system.

**The right RIM system can mitigate many of the limitations inherent in static trackers:**

- Auto-linking to related documents
- Real-time tracking of activity or document updates
- Single authoritative source shared by all parties
- Standardized terminology, naming, and tracking variables enforced
- Data inheritance and auto-fill rules minimize data entry
- Version control for data entries as well as documents

*My mantra is '**Automatic tracking, live reporting, connected content.**' It's a big paradigm shift, but once people see tracking as an organic part of the process, they quickly get on-board.*

*Each stakeholder has a link to real-time self-service tracking reports. It would now be hard to return to the archaic trackers of old."*

– Craig Gassman, Associate Director, Regulatory Operations
Karyopharm Therapeutics, Inc.

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Here are the top five offenders for most regulatory operations teams.

1

## Submissions Planning Tracker

**What It Is:** Outlines planned submissions and required reporting with owners and due dates, by product and country.

**Why It's Time to Retire:** Critical due dates are kept on a shared drive, vulnerable to data entry mistakes. If submissions become delinquent, or weren't added to the sheet, the organization can be out of compliance.

2

## Submission Content Plan

**What It Is:** Lists documents to include within a submission, organized appropriately by submission type and country. Plan includes document owner, expected dates, content status, publishing readiness, and more.

**Why It's Time to Retire:** It is rarely up to date, tedious to maintain and difficult to track. Must support multiple team members working in parallel, which introduces version control issues.

3

## Publishing Readiness Tracker

**What It Is:** Tracks which documents have been approved for publishing, which documents are still missing and when they are expected.

**Why It's Time to Retire:** Is time consuming to update and to create manual document links. Provides no visibility into overall status nor insights for process improvement.

4

## History of Submissions by Product

**What It Is:** Lists applications per product and submissions per application. Should include sequence numbers and brief descriptions. Often used by teams to find the right volume to pull from the records room.

**Why It's Time to Retire:** Inaccuracies lead to hours spent searching through a heavily air conditioned records room. If owned by one person, risk losing record when he or she leaves the company.

5

## Correspondence Tracker

**What It Is:** Chronicles all emails, phone calls, and faxes between company and health authorities, including conversation notes. Often leads to resulting commitments.

**Why It's Time to Retire:** Typically siloed with no link to related submissions and commitments. Duplicate data entry and manual linking between correspondence, commitments, and submission planning trackers.

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If you are ready to move beyond static trackers, look for the following capabilities when evaluating prospective RIM applications:

- Can manage all documents and data related to the target business process
- Provides direct access for relevant parties with easily-managed access control permissions
- Orchestrates processes with pre-defined workflows and lifecycle states
- Connects related tasks, activities, data and documents
- Automatically generates real-time tracking reports
- Can update fields directly within an Excel-like interface
- Can calculate performance metrics based on a combination of document, activity, and workflow data
- Provides interactive dashboards for process owners and executives

## Closing Thought

Traditional systems only track segments of the process they manage. Consolidating multiple systems on a single platform will allow you to track and analyze the entire process. Submission content plans, submission components, and their trackers are all interrelated. By unifying them within a business system, regulatory operations can provide real-time information to support data-driven decisions and operate more efficiently. A unified RIM suite provides the visibility that you need to respond quickly when opportunities or changes arise.

## Take the Next Step

Contact us at **veeva.com/contact-us** or download the **Veeva Vault RIM product brief** today.

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