Regulatory Information Management (RIM)

Buyer's Guide for MedTech Companies

Rimsys®

Contents

Digital Transformation for Medtech

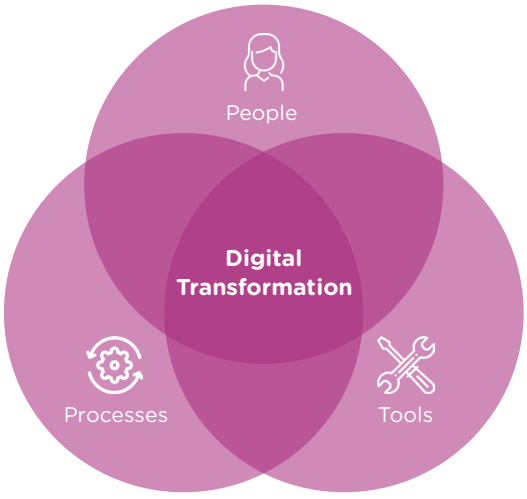
Digital transformation for medtech

Welcome to the Regulatory Information Management (RIM) buyer's guide for medtech. This eBook is designed to be a reference for regulatory affairs (RA) teams in the medtech industry who are beginning to explore digital tools to improve productivity and effectiveness. We appreciate that many of these solutions as well as the general topic of digitization are new to a lot of teams. In our recent survey of RAPS Convergence attendees in 2021, only 11% of respondents said they currently use a RIM system, and 33% had no knowledge of RIM systems at all.

For a lot of teams regulatory activities are still largely manual: run through paper-based processes or spreadsheets. Growing regulatory complexity around the world is pushing teams towards the limits of these processes. The implementation of the EU MDR regulations in May 2021 (to be followed by the IVDR in 2022) has brought new general safety and performance (GSPR), unique device identification (UDI), and post market surveillance requirements. Analysts have estimated that these expanded regulations will result in up to 50% of medical devices and 76% of in vitro diagnostics being removed from the market. With many markets following the EU's lead: essential principles requirements in Australia, UDI in China, etc, RA teams simply don't have the bandwidth to maintain compliance using traditional approaches.

The good news: a RIM system can help. RIM systems centralize and manage regulatory information, and automate regulatory activities—reducing the manual work associated with traditional processes, and improving confidence in regulatory compliance. Much like CRM for sales teams, ERP for finance, and eQMS for QA teams, RIM systems serve as a central system of record for RA teams. They help to inform and better manage nearly every aspect of regulatory affairs from regulatory intelligence gathering to product submissions to expiration management and GSPR maintenance.

The bad news (or at least something important to understand): Like any other system of record, a RIM implementation is more than just the addition of a new tool, it's a fundamental digital transformation for the RA team. It changes how work gets done, and impacts job roles and responsibilities. 70% of digital transformation efforts fail. Without senior leadership support, and a focused change management process, teams will struggle to effectively implement and realize value from a RIM investment.



Successful RIM implementation is about more than digital tools

This buyer's guide provides a detailed exploration of RIM systems, and critical capabilities to consider when evaluating vendors' offerings. More fundamentally, it will help you understand if a RIM system could benefit your organization, and how to run a successful acquisition and implementation process that ensures you actually realize those benefits.

What is Regulatory Information Management (RIM)?

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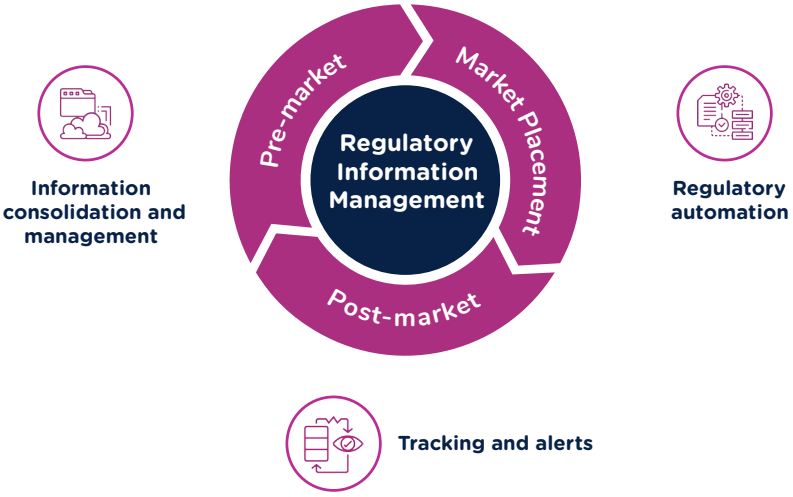
Regulatory Information Management refers to a category of software solutions that are designed to support and streamline the activities of regulatory affairs teams. They are a fundamentally new category of software, and generally replace manual (sometimes paper-based) processes rather than other software. RIM systems first emerged in support of pharmaceutical regulatory activities, but in recent years several new medtech-focused solutions have hit the market. While regulatory functions are certainly similar between pharma and medtech, the distinct regulatory regimes, and unique processes associated with medtech regulatory compliance, make pharma-focused solutions difficult to use for medtech RA teams.



Core RIM system functions

RIM systems provide 3 core functions:

- **Information consolidation and management:** At its heart, regulatory affairs is about information: market requirements and regulations, product specifications, performance and safety, labeling, selling status. All of this data is highly relevant to RA teams, and is traditionally scattered across the organization. This is why RA professionals spend up to 50% of their time simply looking for information. RIM systems centralize and organize all of this information making it much more accessible, and consistent across regulatory activities.
- **Automation:** RIM systems leverage the information they manage to provide a layer of automation around core regulatory processes like market submissions, registration management, regulatory and standards research, and essential principles maintenance. They provide digital interfaces for these functions, the ability to auto-populate data across them, and workflows for collaboration and approvals with full audit logs and revision history.
- **Tracking and alerts:** RIM systems help RA teams monitor and measure submissions, selling status for different products and regions, and changes in relevant standards and regulations. These automations monitor a much wider range of data than can be done manually, and they help RA teams identify and respond to potential compliance risks, before they impact revenue.

As a system of record, RIM systems are partially defined by their breadth of capabilities. There are adjacent tools, like document management solutions for example, that can perform some of the information curation capabilities of a RIM, but they don't marry that with the relevant workflow automations. There are also point solutions on the market that address very specific aspects of regulatory affairs such as submissions assembly and UDI management. Subsequent sections of this eBook detail all of the key capabilities that are typically associated with RIM systems, and help you understand if they would be relevant or valuable for your team.

Will your organization benefit from a RIM Platform?

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A RIM system can provide significant value to both regulatory affairs teams and medtech companies at large, but they aren't a good fit for every team. As we discussed in the previous section, a RIM system is a multi-functional system of record that encompasses a wide array of regulatory functions. Depending on the needs (and size) of your team, some of the adjacent or point solutions might be a better fit.

One way to evaluate the potential value of a RIM is to look at regulatory complexity. For a lot of companies complexity is driven by having a large number of regulated (usually Class II or Class III) products, or operations in a large number of market regions. However, complexity can mean different things to different organizations. For early-stage companies, complexity comes with trying to figure out how to get novel products to market for the first time. For established companies complexity is associated with keeping track of the regulatory status for a large, global product portfolio.

Well-staffed RA teams with good (even if they are manual) processes can handle more product / market complexity than teams that are chronically overworked. So how can you determine if a RIM system is a good fit for your organization? Here are five key signs to look for:

1. **Your team is missing things.** Perhaps it's expired registrations, new regulatory rules, standards changes. Things that can potentially (negatively) impact the selling status of a product are happening without your awareness. Rather than proactively preparing for changes, your team is regularly reacting, and scrambling to prevent revenue risk.

2. **You're struggling to pass audits.** Whether they're internal, contracted (such as MDSAP) or conducted by regulatory authorities, have recent audits resulted in less than ideal results? If your team is working on remediation for a corrective and preventive action (CAPA) letter, or other nonconformities, it may be time to look for a more comprehensive solution.

3. **You can't accurately forecast.** There's always a certain amount of uncertainty in the expected time to complete regulatory activities, as they're dependent on responses/feedback from regulatory authorities. However, if your team struggles to provide even approximate estimates for market clearance, or other regulatory approvals, you likely don't have processes in place that deal well with complexity.

4. **You're resource constrained.** RA teams are always busy, however if you find yourself constantly behind, overworked, and unable to keep up with requests, a RIM system may be helpful. Another sign is the extent to which your organization relies on 3rd-party consultants to get work done. If you're constantly outsourcing work, investing in technology may prove to be a more cost effective solution.

5. **You have knowledge silos.** Individual team members will always have areas of expertise. However, if key information about markets, regulatory requirements, or the status of products or regulatory submissions is only known to specific employees, then the team is carrying a certain amount of risk. RA professionals typically remain in their roles for less than 3 years. What happens to that critical knowledge when someone leaves your organization?

If these pains resonate with you, or if you're specifically seeing these signs regularly in your team, then read on. The issues described in this section typically mean that teams have too much administrative/ manual work, and likely can't access or share relevant information easily—two fundamental issues that a RIM system can address. In this situation, RIM systems can significantly increase RA team productivity, add more predictability to RA activities, and reduce revenue risk from noncompliance. The next section details some of the specific capabilities associated with RIM systems that you can use to evaluate different solutions.

Key RIM capabilities for medtech

Key RIM capabilities for medtech

Before diving into detailed RIM capabilities, it's important to highlight one critical capability that all medtech companies should be looking for in a solution—medtech relevancy. As we discussed earlier, the first RIM systems were designed for pharmaceutical RA teams. Many of these same solutions are positioned today as medtech offerings, but their capabilities to support the industry can vary significantly. Many solutions require significant customization to effectively support medtech-specific RA activities, or simply can't support them well at all.

> *For medical device companies, consider vendors that are best aligned to needs specific to medical device regulatory needs, as most vendors began with a focus on pharmaceuticals. View modern low-code platforms as a means to accelerate integrations with solutions like QMS with PLM, registrations tracking or product information management systems.*
>
> Market Guide for Life Science Regulatory Information Management Solutions Gartner

Before spending significant time evaluating a solution, RA teams should first ascertain that the solution provides good support for medtech. Regulations, and regulatory processes are different for medical devices, in vitro diagnostics, and combination devices. Vendors should be able to clearly demonstrate how their solution can adequately support these needs out-of-the box. If not, the solution likely isn't worth investing the time to evaluate.

Key capability #1 - product and registration management

Handling product and registration data is perhaps the most fundamental capability of a RIM system. For some vendors, this is the sum total of the capabilities they provide. Products are the central component of RA activities, and solutions need to be able to store and/or access detailed product information while keeping track of registrations and selling status across countries. While this is a near universal functionality within RIM systems, there are nuances to how it is implemented that teams should pay attention to:

- **Product families and hierarchies.** There are typically multiple levels of packaging and SKUs associated with product families. Evaluators should explore how a vendor's approach aligns with how their product portfolio is organized and whether the hierarchies/relationships can be easily customized.
- **Ease of importing information.** If you're like most organizations, you aren't approaching a RIM implementation with a blank slate. You have a product portfolio and your products are registered in multiple markets. How quickly you can realize value from a RIM depends on how quickly you can get all of the relevant information about your regulatory activities into the system. Evaluators should understand what options a vendor has to assist with this initial step—integrations, bulk uploads and/or professional service offerings.
- **Supported product information.** There is naturally some variation in how vendors store base-level product information. Knowing that products are the core piece of regulations, having as much detail as possible within the RIM system is best. Evaluators should check that all of the product and manufacturing information they need to reference can be stored in the solution. Also, all product history and changes are tracked.
- **Active management of selling status.** Most RIM systems will provide visibility into current registrations to the RA team. Not all of them provide mechanisms for the RA team to communicate that status and/or ensure that sales and marketing activities are fully aligned with market clearance. Therefore, an important function is the ability to connect with ERP/CRM systems to manage product selling status in the tools that go-to-market teams use.

Key capability #2 - submissions

Assembling regulatory submissions is an important and time-consuming portion of RA work. Submission dossiers require the assembly of a large array of information from different departments and systems, as well as cross-team collaboration, approvals, and communication with health authorities. RIM systems can provide a lot of support for submissions, from government templates and guidance, to organizing information, to generating final submissions. Some key submission features to explore include:

- **Pre-built government templates.** Most solutions provide submission templates for common regulatory applications like the FDA 510(k), and EU STED. However you should make sure that the vendor supports the specific applications and markets in which you do business, or, at minimum, allows teams to create or customize templates for their own needs.
- **Information integration.** Regulatory applications require a lot of supporting information from product details to evidence of product safety and performance. Most tools can upload and store this information, but in many cases it's preferable to set up integrations with PLM and eQMS systems to access the data directly. Understanding the types of integrations supported (to which systems), and specific integration features (what information can be accessed/shared) should be an important component of any RIM system evaluation.
- **In-tool authoring.** In addition to assembling dossiers, does the tool allow you to directly author submission elements that correspond to a 510(k), PMA, STED, Supplement, Technical File, or Additional information request (descriptions, cover letters, comparisons, etc.)? This can be a helpful feature, rather than having to shift back and forth between office or word processing software, and the regulatory submission. Authoring within the RIM system also provides greater visibility into revision history and version control.
- **Content reuse.** Regulatory submissions involve a lot of repetition, both within and across applications. This is both time-consuming and an opportunity to generate errors or inconsistencies (for example, if the indications for use for a device aren't consistent). Look for vendors that have found a way to reduce this burden, either through the reuse of structured content snippets or previous submissions.
- **Regulatory authority correspondence.** Many submission processes typically involve multiple steps (and sometimes iterations) with regulatory authorities. The correspondence and feedback at each step is vital information, so it's worth exploring whether a vendor has an intuitive way to store this information alongside the submission project.
- **Workflow management and approvals.** Submissions are typically a collaborative affair. They're led by RA professionals, but often insight and content from QA and product teams is needed. Most also go through levels of approval before they are submitted. There are ways in which RIM systems can streamline some of the workflow elements associated with submissions. Look for features such as task assignment, and shared notes, as well as the ability to route items for approval. Make sure that the vendor captures approvals in a way that's 21 CFR Part 11 compliant.
- **Submission packages.** Once a submission's complete, it needs to be pulled together in an integrated regulatory submission. Most solutions provide this capability, but the final product can vary. Some vendors will auto-generate content like a table of contents or appendices based on the submission content which can be helpful. Tools that allow you to preview the finished submission before exporting can be helpful as well so that you don't have to complete multiple iterations. You'll also want to make sure that the final format is compatible with the submission requirements for the markets you wish to reach (i.e. eCopy for the FDA).

Key capability #3 - Essential principles and standards management

Compiling and maintaining technical file documents are a significant burden on RA teams, especially because they have to respond to the regulatory authorities within each region, any time there is a change to the standards or essential principles within the technical file. This process can take weeks to complete, depending upon how many technical files need to be updated and what changes within each one. RIM systems that support the following features can significantly ease the challenge of complying with these regulations.

- **Standards curation and association.** The core function of the technical file is the ability to associate relevant industry standards and essential principle files to products and product families. Evaluators should look for vendors that provide a lot of flexibility in how to set up these associations, the ability to curate a library of applicable standards, and integrate the design document files from eQMS and other enterprise systems.
- **Standards monitoring and alerts.** Much like regulatory monitoring this feature looks at relevant industry standards, and alerts you when they're updated, withdrawn or superseded. The same alerting mechanism can alert you when linked evidence documents are updated as well.
- **Bulk updating.** This simple feature can be one of the most useful to teams that have to maintain a large number of technical files. Small changes like a standard getting superseded can trigger hours of work as teams hunt through the tables to identify every place where that standard is referenced, and update it to the new version. Bulk updating can fully automate this work—easily populating minor updates across all of your technical file documentation.

Key capability #4 - UDI and label management

UDI and labeling are often managed separately from other regulatory activities, so depending on the structure of your organization, this may or may not rise to the level of a critical capability. However, as more and more regions adopt UDI requirements, managing this information for each region within a RIM system, rather than transferring or manually updating this information in another system can be very beneficial. Some specific UDI features to look for include:

- **"Universal" UDI structure.** While each market has unique UDI requirements, much of the required data is the same. RIM systems can provide a "universal" view of UDI data where that information can be stored in a centralized record that is auto-populated to country-specific records.
- **Auto population and updating.** One of the key advantages to a "universal" data structure, and managing UDI data alongside other regulatory records is that a lot of the data is duplicative and can be derived from product records. RIM systems can take advantage of this proximity to automatically update UDI information for multiple countries when product or top-level UDI details change.
- **Regional support.** As more UDI requirements come online (China, South Korea, etc.) evaluators should make sure that the UDI data in prospective RIM systems conforms to the specific requirements for each region, and can support emerging regions as they come online.
- **Basic UDI-DI support.** The EU MDR/IVDR regulations introduced a new level UDI code, called a Basic UDI-DI or BUDI. Rather than being associated with an individual product, the BUDI is a category or product-level identifier that is used across the EUDAMED database. Though the BUDI doesn't have to be included on the product label, it's an important part of the UDI record for the EU. Look for vendors that have a data structure that can support UDI association at this level.
- **Electronic submission.** UDI regulations encompass both the device labeling (UDI code itself) and all of the product metadata which is stored in public health authority databases like the GUDID and EUDAMED. Where these databases accept electronic submissions, it's helpful if the RIM system can directly package and send compliant information.

Key capability #5 - project management

RIM systems are first and foremost a data platform—helping to collect and manage a wide range of relevant information for RA teams. However, as a core system of record, they also provide capabilities to manage a lot of the work that surrounds the information. Activities that require collaboration and/or documented approvals across a series of tasks, can often be better managed within a RIM system. Projects can include planning for new product introductions, manufacturing location changes, impact assessments of product or regulation changes, or standards change assessments.

As a result, evaluators should look for robust project management and workflow capabilities in any RIM system. These can include:

- **Project requests and backlog.** The ability for RA and other teams across the organization to submit and manage project requests. Most RA teams have a continuous backlog of work, and keeping track of requests as they come in is important to ensure that nothing is lost, and projects can be prioritized appropriately.
- **Impact assessments and surveys.** An important aspect of many regulatory projects is understanding the impact of proposed changes. Whether it's a change in standards, regulations, or in a product's design, materials, or manufacturing, all of these can have an impact on licenses or market clearance. Regulatory information management tools that have comprehensive data structure (usually centered around products rather than submissions/registrations) can automatically identify and flag the products or registrations that may be impacted by a project plan. Some can also survey registration or country owners to capture their assessments of a project's impact.
- **Tasks and owners.** While sub-tasks and assigned owners are standard features for project management software, having these capabilities within a RIM system allows them to be specifically aligned with regulatory activities. For example, requesting a declaration of conformity from QA teams as part of a 510(k) application. These features make it easier to work collaboratively on submissions and other regulatory projects.
- **Project history and approval records.** As a regulated industry, medtech teams naturally want to keep a full record of all activities and approvals as it relates to a good quality management system. Within specific project management capabilities, evaluators should understand how project details, communications, milestones, and most importantly approvals are recorded and retained within the RIM system.

Key capability #6 - reporting and dashboards

One of the major benefits of RIM systems is that they provide a layer of measurability to RA projects. Because RIM systems store relevant data and project details, they can help teams understand and better estimate the time required for new submissions and other activities. It's therefore an important RIM capability that teams be able to access and build reports that align with their roles and business goals within the system. Some key reporting features to look for include:

- **A mix of useful pre-built, and customizable reports.** RA teams aren't data scientists. RIM systems should provide relevant summary reports out of the box, alongside custom reporting features that allow teams to build specific views if needed.
- **The ability to drill into details.** Summary reports are helpful, but the ability to drill into specific products, registrations, or standards from those reports significantly increases their usefulness. If you have 15 products registered in Australia, which specific SKUs are they? When do those registrations expire? What standards are included in associated technical files? Reporting features should be able to answer these questions.

- **User-configurable dashboards.** RA team members have specialized areas of focus, whether that's specific regions, functions like regulatory intelligence, or alignments with specific teams and/or partners. As a result, the RIM information that's most relevant to them will vary. Look for systems that allow users to customize their default/dashboard view in the tool to feature the things that matter most to them.

Key capability #7 - compliance, security, and privacy

A vendor's specific data security policies, and certifications will likely be covered as part of any acquisition process by your IT or security team. However, it's important to understand the basic requirements that all vendors will be subject to, and not spend too much time evaluating solutions that won't meet the baseline for a highly regulated industry like medtech. At minimum any RIM provider should have:

- ISO-27001 certification
- SOC-2 Type 2 certification
- Processes and workflows (especially approvals) that are 21 CFR, Part 11 compliant
- Data retention, access, and privacy policies that are in alignment with GDPR regulations

In addition, look for good, granular levels of user control and permissions. You will likely have different classes of users accessing the system—including people outside your organization such as in-country representatives and distributors. RIM systems should allow you to provision these users with the right (limited) amount of access. Also, it's likely that your organization has a preferred SSO solution such as Okta or Microsoft Azure Active Directory. You'll want to make sure that a RIM vendor can support user authentication through these services.

RIM aquisition and implementation

RIM acquisition and implementation

Evaluating vendor capabilities is an important component of any RIM acquisition, and teams should have a clear sense of the specific needs they have before embarking on any analysis. However, identifying a solution that matches your needs is only one part of a successful acquisition and rollout. There are a number of additional considerations that an RA team should address early in the process alongside the vetting of potential solutions.

Business case

RIM systems for medtech are relatively new, and as a result, if you're running an evaluation, you likey aren't looking to replace an incumbent vendor, but to make a net new software purchase. In these scenarios it's rare for RA teams to have a specific, allocated budget for a RIM system. This means that you will need to assemble a business case for what will be an incremental investment. Doing this ahead of time will prevent challenges as you try to bring a vendor on board.

Business cases aren't complicated to put together, but they do require an extra layer of analysis. It's not enough to identify the pains that a potential solution could solve, you'll need to quantify the expected business benefits. So for example, automating activities via a RIM system means less manual, administrative work for your team, but it probably also means the company needs to spend less on external consultants. A couple areas to look at when building a business case include:

- Time savings for regulatory work and the financial impact of greater productivity
- Revenue gained from faster, or at least more predictable time to market for new products
- Reduction in costs associated with remediating nonconformities

For more business case guidance, and a template that you can use to build out a business case, see our Building a business case for a RIM system guide.

Internal stakeholders

While the RIM system is a software solution designed specifically for the RA team, there is likely a broader set of stakeholders within your organization that needs to be part of any RIM acquisition project. Engaging them early in the process will prevent later roadblocks, and can help you navigate some of the potential challenges associated with a significant software acquisition. It's likely that the following organizations will need to become involved with your project:

- **IT.** Your IT team are the software experts within your organization, and will be a helpful resource as you evaluate solutions. While, after reading this guide, you may have a good sense of the capabilities that are most important to you, your IT team will understand security requirements, implementation, and how a RIM system would integrate with the rest of your organization's software stack. They're your internal experts on software acquisition, and will likely need to sign-off on any new purchase.
- **Procurement.** IT teams are experts in technology, and procurement teams are experts in purchasing. In most companies, any purchase will go through the procurement team, and will need to follow established company processes. Typically designed to save the company money, these processes can be time consuming—especially if you're working with a vendor who has no prior business with the company. Bringing procurement teams into the discussion earlier can jumpstart some of these processes and ensure you're collecting the information they need to complete a purchase.

- **Other department users.** RA teams will be the primary users of a RIM system, but other departments that participate in regulatory activities (such as QA teams) may spend time using the system as well. Making sure they're aware of the RIM project, and have an opportunity to preview the system before it's implemented will help to ensure full adoption.

Each of the stakeholders can play an important role in the evaluation, acquisition, and implementation of a RIM system. While you don't want to have too many individuals involved in the project, understanding which teams can contribute to, and have influence over the project outcomes is important. Best practice is to map out the list of stakeholders, and have a plan at what point in the project you will bring them in.

Change management

It's not unusual for RA teams to be struggling at the time they embark on a RIM search. As we discussed earlier in this guide, the growing complexity of global regulations is making traditional approaches to regulatory processes simply untenable for a lot of teams. Naturally, there's an inclination to believe that once a tool's in place these problems will go away.

This is certainly a possible outcome, but teams need to recognize that the introduction of a RIM system represents a broader organizational change. If team members don't change the way they work, don't adopt the tool, and don't make the commitment to a successful implementation, then they won't realize value from the solution. This is a standard change management need, but one that teams should consider as part of a RIM acquisition.

Automation in any organization can be disruptive and potentially frightening to team members. To mitigate some of these challenges, RA teams should:

- **Ensure they have leadership support.** Change management is something that happens from the top down. Team members need to perceive that leadership supports the change, and that it's part of a strategic organizational plan.
- **Communicate early and often.** Don't surprise team members with a new system all at once. Explain the "why" behind the RIM product, keep team members in the loop throughout the process, and invite them to participate in demos or trials of prospective solutions. This goes both for RA team members as well as some of the broader stakeholders discussed in the previous section.
- **Have a plan for implementation.** RIM systems are designed to better organize and manage all regulatory information, which means that in order to be useful, they need to ingest a lot of data across the organization. Many vendors provide implementation services that can help with this, but there will still be a commitment from RA team members. This means that there will be a slight increase in workload before the benefits of the RIM system are fully realized. Planning for this, identifying the roles and responsibilities of team members, and getting commitment ahead of time can prevent delays and ensure a successful implementation.

The organizational impact of adding a tool like a RIM system shouldn't be overlooked. Value comes from adoption, and organizations that are prepared and supportive of the changes are much more likely to fully implement and adopt a new RIM system. This preparation should be a key component of any RIM system project.

Three steps to get started

Three steps to get started

This guide presents a lot of information, and for many RA teams, it's likely tempting to jump in and begin researching solutions. While selecting the best RIM system for your team is undoubtedly important, there are some important initial steps that you should take first to lay the groundwork for a successful project.

Step 1 - assess your organization

Before going too far down the path of looking at RIM systems, it's important to understand if a RIM system will be beneficial to your organization in the first place. Medtech companies often see significant regulatory process improvements that lead to greater productivity, less reliance on outsourcing, and faster time to market for new products, but a RIM system isn't a fit for every organization.

Look at the common pain points outlined in the 3rd section of this guide, share them with your team, and see if they accurately describe your current state. Look at your current processes. How well do they allow you to manage your backlog of work? How much time do you spend looking for information? Answering these questions will give you a clearer picture of the benefits you could get from a RIM system, and will provide the basis of the business case for investment.

Step 2 - loop in leadership

Acquiring a RIM system is a big project. It doesn't just impact the RA team. IT and procurement teams will be involved as will adjacent departments who will use and integrate their tools with the system. Without leadership support (RA and/or operations leadership) it will be difficult to effectively bring together all of these stakeholders.

The other important consideration is the impact of a RIM system on the team from an organizational change perspective. As we've discussed in this guide, teams shouldn't assume that a RIM system will be automatically fully adopted. Having leadership support for the project, and having your leadership team driving communications around it will do a lot to make sure that the organization is prepared for change. It will also help you prioritize the specific work needed for the initial RIM implementation.

Step 3 - identify stakeholders

As we've discussed throughout this guide, there is likely a pretty broad set of stakeholders that will need to be involved with a RIM acquisition. Nothing will derail a project more quickly than a late entrance by a key stakeholder who has heretofore been in the dark about the project. Before embarking on any project, you should take the time to identify the key stakeholders who will need to be involved. This likely includes leadership (both RA as well as operations/IT leaders) IT, procurement, and other departments who will be using the RIM system.

This doesn't mean that everybody who will be involved in the project should be engaged immediately. It means that you are more likely to have a smooth, on-time, and ultimately successful project if you take the time to identify the important stakeholders ahead of time, and plan for when you will bring them into the project process.

Appendix: Vendor evaluation worksheet

Appendix: Vendor evaluation worksheet

This worksheet brings together the key capabilities discussed in this guide in a quick checklist you can use as you begin to evaluate RIM solutions. The worksheet is also available in an editable, digital form as an Excel spreadsheet.

Vendor:					
RIM Offering:					
Feature	**Future Support**	**Full Support**	**Partial Support**	**No Support**	**Notes**
Product registrations					
Supports individual SKU-level data, and organizes information around products					
Supports product families/hierarchies that are customizable					
Bulk or API upload of existing product and registration information					
All necessary product and manufacturing information is supported					
Excel export of (bulk or individual) registration records					
All changes to product or registration data are logged/reviewable					
Global selling status can be tracked/managed					
Selling status can be integrated to and controlled within ERP/CRM systems					
Regulatory submissions					
Provides a framework or pre-built templates for regulatory forms (510(k), STED, etc.)					
Allows submission templates to be fully customized (structure, numbering, fields, etc.)					
Flexible options for document/evidence collection (uploads, links, PLM/eQMS integration)					
Content can be easily re-used across submissions (either through structured snippets, variables, or submission cloning)					
Direct authoring is supported in-tool					
Can store and track health authority correspondence					

Provides workflow management and (21 CFR Part 11-compliant) approvals					
Submission-ready PDF/document export					
Provides a searchable archive of published submissions					
Essential principles and standards management					
Provides pre-built (EU MDR/IVDR, Australia TGA) and customizable essential principles templates					
Can setup relevant standards library and associate with products/GSPRs/essential principles					
Monitors for standards changes and alerts when there is a potential product impact					
Bulk updates are supported for GSPR/essential principles maintenance					
UDI					
"Universal" UDI data model provides top-level management for common UDI fields					
Compliant UDI data storage for relevant countries/regions					
Populates/updates UDI data from product, registration, and certificate records					
Supports category-level Basic UDI-DI records for EUDAMED					
Electronic UDI submissions to health authority databases (GUDID, EUDAMED, etc)					
Project management					
Project request functionality and backlog management					
Automated impact assessment and survey capabilities for project scoping/impact.					
Ability to assign and track project tasks					
Project history, changes, and approvals are tracked and auditable					

Reporting and dashboards					
Provides both pre-built and custom reporting options					
Users can easily drill into summary reports for more information					
Dashboard views can be customized for different users					
Security and privacy					
Solution is ISO 27001 compliant					
Solution is SOC 2 compliant					
Processes and workflows (approvals) are 21 CFR Part 11 compliant					
Data retention, access, and privacy policies are in alignment with GDPR regulations					
Supports different user types and permission sets					
Provides user authentication via SSO					

About Rimsys

Rimsys is bringing regulatory order to the medtech industry. The Rimsys Regulatory Information Management (RIM) platform digitizes and automates regulatory activities, freeing teams from inefficient administrative work, and helping them confidently establish and secure global regulatory compliance. Unlike complex spreadsheets or expensive consultants, Rimsys centralizes all regulatory information, automates submission processes, and monitors relevant expirations, standards, and global regulations. Overburdened regulatory affairs teams struggle to keep pace with the increasingly complex global landscape. Rimsys streamlines all regulatory activities in an integrated platform, helping MedTech companies get to market more quickly and reduce risk of non-compliance, product recalls, and unexpected expirations.

For more information about Rimsys or to get a free demo of our platform, please visit rimsys.io


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