A Guide to MedTech RIM Maturity for a Successful Modernization Strategy

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Introduction

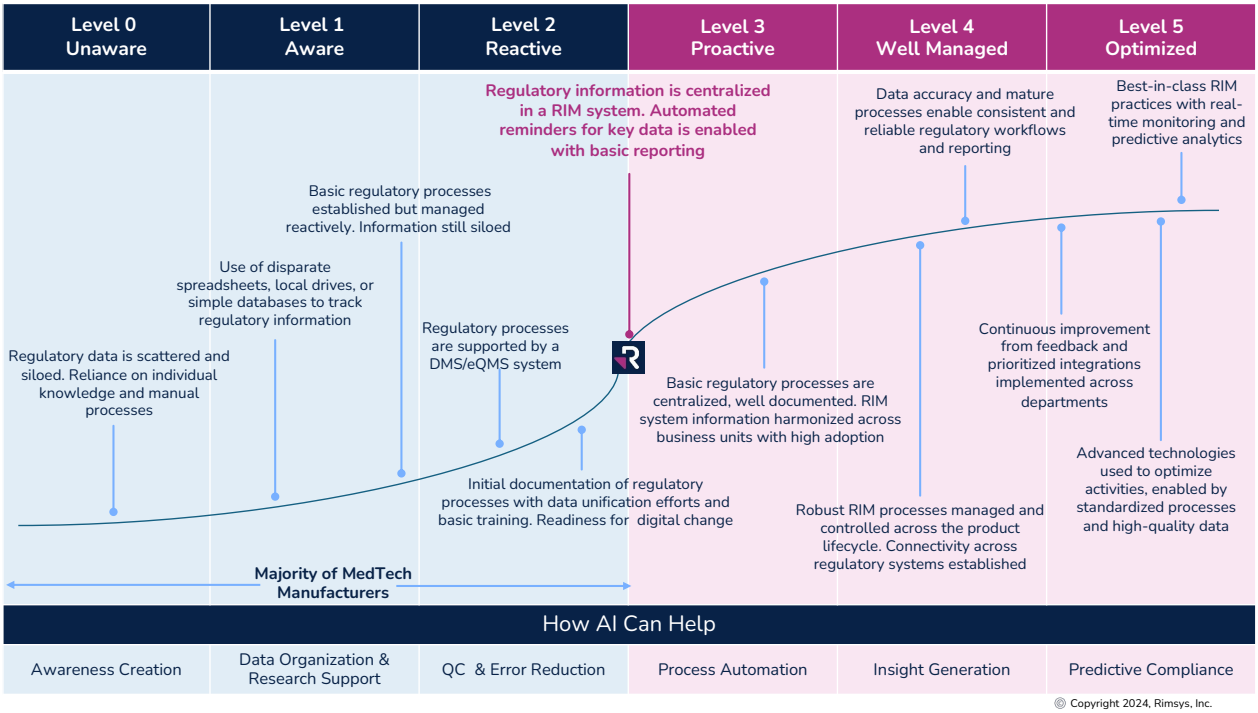
MedTech regulatory affairs teams are at an inflection point. An evolving regulatory landscape is adding increased complexity to regulatory affairs as new regulations come online and existing requirements change. Additionally, health authorities are adopting their own requirements to improve transparency and increase efficiency such as post-market and UDI regulations. Frequent regulatory change coupled with varying regulatory requirements across global markets is creating a large amount of data for MedTech regulatory affairs teams to organize, manage, and derive actionable insights from.

Additionally, regulatory affairs teams are being tasked to execute projects faster with a fixed team size. Not only are many regulatory affairs teams operating leanly, but employee turnover is making it difficult to maintain continuity between projects and processes. According to the 2024 RAPS Global Regulatory Affairs Professionals Workforce Report, the number of medical device regulatory affairs professionals who are "open to work" on LinkedIn rose by 9% in Europe and North America from 2021 to 2024. These challenges are being layered with an abundance of data and driving the need for better regulatory management, which includes the harmonization and digitization of regulatory information. Traditional manual, siloed approaches to regulatory information management (RIM) are creating risks that can't be ignored, including audit findings, missed renewals, time-to-market delays, revenue impacts, and worst of all, having to pull life-changing medical technologies from the market.

Regulatory affairs teams that have refined, digitized processes in place to manage their information are able to reduce compliance risks, operate more efficiently, and build sustainable advantages amidst an increase in competitive pressure. The Gens and Associates 2024 World Class Regulatory Information Management Study White Paper similarly noted a correlation between mature organizational alignment and business gains: "Simply put, the stronger an organization is with regard to its organizational components coupled with mature and standard processes—the more value is received from technology investment and therefore higher business benefits." Getting to a place of optimal regulatory efficiency requires a deep understanding of an organization's regulatory information management (RIM) maturity. However, assessing RIM maturity can often be a complex process. Regulatory affairs teams need to have an understanding of where their regulatory information is stored and how it is managed across the business before they can fully leverage the benefits of digitization, automation, and advanced technologies.

Approaching RIM digitization can seem daunting, but the RIM Maturity Model is designed to help MedTech companies understand how mature their current regulatory processes are, provide a clear set of incremental milestones to help them mature, and set a successful modernization strategy. In this executive guide, we'll discuss each level of the RIM Maturity Model, the attributes of each, and what MedTech teams can do to advance at each level of the journey, including the incorporation of AI.

The RIM Maturity Model at a Glance



Even though each RIM Maturity Level has distinct attributes, there are two main subsets:

- Levels 0-2
- and Levels 3-5

Organizations at Levels 0-2 have minimal or no formal regulatory processes in place. Regulatory information is often managed reactively and stored in disparate systems. Some regulatory information may not even be formally documented at all. Most MedTech companies currently fall within Levels 0-2.

In Level 3, we see an inflection point. Organizations at this stage and beyond have a RIM system in place to centrally store regulatory information and manage internal processes. It is nearly impossible to advance beyond Level 3 without a RIM system, as they promote information centralization and organization that set the foundation to standardize processes, integrations, and advanced technology utilization.

A Look at Each RIM Maturity Level

In this section, we'll take a look at each RIM Maturity Level in more detail to help MedTech regulatory affairs teams assess their own level of maturity, understand potential risks at each stage, and identify steps needed to advance to the next milestone. We'll also provide some insights on how MedTech regulatory teams can leverage AI to help them work more efficiently at each level.

Level 0 – Unaware

Organizations at this level are at the lowest level of maturity. They have no centralized repository for regulatory information. It's not uncommon to see information scattered between multiple, disparate sources with no unification in place. Regulatory information may still live in local file sites and may not be digitized at all.

Additionally, regulatory management processes are not standardized. Information management varies by individual within the regulatory team, opening up the risk for knowledge gaps should turnover occur. Organizations at this level are at an increased risk of audit findings and non-compliances as there is no way to easily track regulatory activities and projects across team members.

How AI Can Help at this Level: Awareness Creation

- Automated knowledge discovery
- AI-driven alerts for regulatory changes
- Data cleansing and consolidation

Level 1 – Aware

Organizations at this stage have some awareness that regulatory processes need to be established for effective information management. However, their processes are not yet sophisticated. While adopting some digital tools to manage regulatory information, Level 1 organizations are largely using disparate file sharing sites, local drives, or simple spreadsheets.

More mature companies within Level 1 have basic regulatory processes established, but they're managing them reactively. There are no processes in place to proactively track and manage regulatory activities, and as such, these organizations are still at an increased risk of non-compliances. While some processes are established, information is still widely decentralized.

How AI Can Help at this Level: Data Organization and Research Support

- Natural Language Processing for document classification and tagging
- AI-powered data integration
- Automated data entry and validation

Level 2 – Reactive

By Level 2, organizations have realized that they need an integrated digital solution to help them manage regulatory information. At this level, RIM activities usually take place in a repurposed platform such as a document management system or eQMS since these systems are traditionally implemented before a RIM platform. While regulatory management is still reactive, there is an effort to unify data and document processes. However, regulatory information is not fully centralized and harmonized across office locations and business units.

At this level, there is often a deeper realization that a more sophisticated solution is needed to manage regulatory information and processes across the business. Sometimes this realization comes as the result of previous audit findings or non-compliances. As regulatory affairs teams advance through Level 2, they are starting to plan for and implement a regulatory information management (RIM) system. To get to Level 3 in RIM maturity, adopting a dedicated, medtech-focused RIM platform is imperative in order to fully harmonize regulatory information, leverage purpose-built automations, and layer in advanced technologies.

How AI Can Help at this Level: Quality Control and Error Reduction

- AI-based data validation and quality
- Predictive risk assessment models and tagging
- Process optimization through machine learning

Level 3 - Proactive

By Level 3, regulatory teams have implemented a RIM system to help them manage and organize regulatory information. At this level, information is centralized in the RIM platform. Furthermore, organizations have begun taking a proactive approach to regulatory information management. This typically involves automated notifications to track regulatory activities, including registration expirations and renewals, upcoming task reminders, standards changes, and approvals. With information now centralized, regulatory affairs teams are also able to track regulatory correspondence and lessons learned to date in the RIM platform for increased visibility among all stakeholders. Basic reporting capabilities are established but are not fully measured or optimized yet.

Organizations on the breach of approaching Level 4 have their basic regulatory processes well documented. RIM system information is also generally harmonized between business units with high user adoption rates. However, there may still be inconsistencies in the RIM system data, unclear performance metrics, and regulatory workflows that still need to be established or refined.

How AI Can Help at this Level: Process Automation

- Data ingestion and import
- AI-driven smart reminder systems
- AI-enhanced document management

Level 4 – Well Managed

Organizations at this level have their regulatory processes standardized in a RIM system, with controlled processes across the product lifecycle. This standardization enables them to have sophisticated performance metrics in place to track, measure, and optimize in order to build additional efficiency gains. For instance, regulatory affairs teams now have the clear ability to report on time-to-market metrics based on their specific product lines and countries. RIM system data is accurate and reliable. It is also identified as the source of truth for all regulatory information and processes.

At this level, most organizations have been able to establish basic connectivity with other key systems such as PLM, eQMS, and ERP to enable greater visibility across the business and proactivity. With clearly established regulatory workflows and standardized processes across all relevant business units, MedTech teams at this level often aim to expand their integrations and utilize advanced technologies such as AI and predictive analytics to put best-in-class processes in place.

How AI Can Help at this Level: Insight Generation

- AI-powered data analytics for performance monitoring
- AI-enhanced interconnectivity across systems
- Automated audit trail analysis

Level 5 – Optimized

With well-managed processes and performance metrics already established, Level 5 organizations are focused on continuous improvement through user feedback and performance metrics. Their RIM system is fully integrated across all relevant departments to ensure complete regulatory visibility for the organization.

With applicable integrations and unification fully instituted, they're able to leverage additional AI advancements to optimize their daily activities and ensure continuous data quality. At the highest level, organizations have best-in-class RIM practices established while being able to utilize real-time monitoring and predictive analytics to drive more informed decision-making across the business and build stronger competitive advantages. This includes realizing significant time-to-market gains that increase measurable ROI.

How AI Can Help at this Level: Predictive Compliance

- AI-driven predictive compliance model
- Continuous learning systems
- Advanced AI for submission management

Using AI to Establish Greater RIM Maturity

Advancements in artificial intelligence are helping MedTech regulatory affairs teams become more efficient, but AI has also prompted many questions about using it safely and thoughtfully in a highly regulated industry. While AI can help RA teams see efficiency gains at each level of the RIM Maturity Model, there are considerations MedTech companies should make before incorporating it into their processes.

- **Make sure you have a necessary data foundation established at each level**

  It's important to set proper expectations about the use of AI at each level. Without a strong foundation in place at each, AI cannot be used to its full potential. For instance, an AI-driven predictive compliance model is not going to be effective without getting data centralized and integrated workflows established in a RIM first. Focusing on the data harmonization, centralization, and process management in each level is critical to reaching a higher level of maturity, and a perceived AI shortcut will not suffice long term.

- **Take time to get a data governance plan in place**

  AI will not be an effective research and data collection tool without reliable source data. Take time to make a data governance plan to outline your organization's use cases and identify a consistent, repeatable process for training the AI. It's also important to ensure that there are processes in place to check source data periodically and that the regulatory team is trained on how to use it effectively. They should be aware if their data is being used in any capacity to train a model and which model the AI is using to generate insights.

- **AI cannot replace the regulatory affairs function**

  While AI can aid in research and data collection, it will not replace the regulatory affairs function. Regulatory affairs professionals are critical to effective regulatory reviews, approvals, and forecasting. AI can help MedTech RA teams get on a path to RIM maturity and advancement, but it is unable to add logical reasoning and strategic decision-making to regulatory processes.

Planning Your Organization's Next Steps in RIM Maturity

Achieving the highest level of RIM maturity takes time. Setting proper expectations and plans at each level are critical for advancement and maximizing benefits at each. Whether your team is just starting to digitize and unify its regulatory processes, in the middle of a RIM system implementation, or looking to optimize its RIM system workflows, Rimsys can help you achieve regulatory management efficiency. Contact us to set up a free RIM maturity strategy session.

About Rimsys

Rimsys is improving global health by accelerating delivery and increasing availability of life-changing medical technologies. Rimsys Regulatory Information Management (RIM) software digitizes and automates regulatory activities, helping medtech regulatory affairs teams to plan more effectively, execute more quickly, and confidently ensure global regulatory compliance. Rimsys is designed around medtech workflows and supports a full breadth of regulatory activities including registrations, submissions, UDI, essential principles, and standards management in a single, integrated platform. For more information, visit www.rimsys.io.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