14 Reasons to Unify Regulatory Information Management with PLM

by Sajesh Murali and Nate Reisch

Medical device companies have many unique challenges, including rapid growth by acquisition. As product portfolios expand, they must efficiently manage information on new and existing products, all while considering stringent regulatory requirements and global distribution challenges.

In many cases, these manufacturers don't know every place where products are registered or need to be registered. They also struggle to provide international affiliates or divisions with all the information they need to register products.

When regulatory and product development information are not aligned, there are numerous financial and quality impacts, including loss of international sales, increased regulatory risk like recall notices or unauthorized shipments, and a strain on resources due to the manual effort required to collect information to support the regulation needs.

But it doesn't have to be like this. By aligning regulatory information management (RIM) with product lifecycle management (PLM) systems, companies can gain significant benefits, reduce regulatory risk and improve international sales.

A Quick Refresher on PLM and RIM

PLM, at its core, is more than just a software system or solution. It's a set of unified business processes that interconnect all of a product's data from the time of conception until obsolescence. The benefits of a global PLM solution, driven by leading practices, are numerous and well-documented. Importantly for this discussion: with a PLM system in place, the foundation for RIM system is already laid.

RIM, at its core, is a unified process of handling product development data that is required to register a product that complies with regulations of every country or region where it will be sold.

From strong governance to high data quality, a global PLM system provides visibility across the entire product lifecycle. When connected to a RIM system, companies gain visibility to the regulatory ecosystem in the same way.

14 Benefits of Unifying PLM and RIM

1. Consolidate Systems
In general, it's a well-understood leading practice to consolidate data between systems. Benefits include lower cost of ownership, easier transfer of information across business processes, and common user experiences.

2. Reuse Product Master Data
Leverage a single source of truth for all product data - from early design throughout the lifecycle - for easy re-use in design dossiers and submission packages.

3. Increase International Sales
Register products in more international markets, with greater speed and less effort. Easily maintain registration status and expiration notices on an ongoing basis.

4. Improve Regulatory Support of Business Planning
Gain global visibility to registration information (status, plans, etc.) to help the business drive decisions and to support better collaboration and alignment between business and regulatory planning.

5. Streamline Submission Package Management
Enable easier creation and management of submission packages (510k, tech file, etc.) with all the data integrated in one place. It's easier to maintain technical files and international submission packages even as product data changes, because it's directly linked to the master source.

6. Reduce Manual/Duplicate Effort
Reduce time spent finding and communicating registration information across many different functions. Reduce redundant efforts between countries, ensuring proper communication and availability of the right information at the right time. For example, clinical trials performed for one country may be shared with another country for reuse.

7. Reduce Unauthorized Shipping
Integrate registration within the design, commercialization, and distribution processes. This reduces the risks and regulatory penalties that occur when products are shipped to countries where they are not registered, or where the registration is not active.

8. Improve Planning and Communication
Limit the number of review cycles and changes to improve global submission planning and communications across different functions.

9. Share Country Requirements during Product Development
Enable design teams to understand and plan to meet all the different country requirements during the product development process.

10. Notify of Country Requirement Changes
Notify design teams of country requirement changes that might impact products. Help plan the changes accordingly to reduce delays in renewals and time back to market.

11. Plan for Product Obsolescence
Enable better obsolescence planning by taking related registration information into account and ensuring there are no active products in the field at remote locations.

12. Faster Regulatory Affairs Resource Planning
Achieve more accurate and faster planning by giving regulatory affairs groups full visibility to upcoming registration activities.

13. Enable International Change Notifications
Enable more efficient and integrated processes for notifying international teams of design changes by broadcasting a message to all countries.

14. Change Impact Assessment
Give design teams full visibility to assess if and how a design change will impact compliance. With an integrated change process, international regulatory affairs groups are notified and engaged earlier.

Which Comes First - PLM or RIM?

First, your starting point doesn't greatly affect the expected outcomes or benefits. Companies can start with RIM or PLM and still expect similar results.

However, implementing a RIM system *alone* will not deliver transformational results. Companies must also address organizational (people), statistical (data), and procedural (process) dimensions to fully realize the potential of a comprehensive regulatory information management solution.

It's also important to not think about RIM and PLM as individual functional areas, business process, or systems. Break down the old school, siloed school of thought. Approach both regulatory and product lifecycle information management from a holistic perspective focusing on the interactions between the two and the areas where they have traditionally broken down.

Getting Started: Key Questions and Guidance

Do your organization's current RIM and PLM processes use an integrated approach to sharing information or a "throw it over the wall" approach, where the two groups don't collaborate or interact during the commercialization phase of the product lifecycle?
Most companies still operate with a "throw it over the wall" approach, which wastes time when people must re-find or re-create information that already exists. By collaborating at the right time and with the right data, time-to-market and regulatory filing errors can be drastically reduced.

Does your company currently use common and consistent roles between RIM and PLM processes?
Functional areas should not have largely standalone functions that have no connection or place in the greater organization. Roles and skill sets should be consistent across the organization. The greatest improvements to innovation results often come from cross-collaboration with employees working outside of their standard, boxed-in ways of thinking.

Is your organization ready to fully integrate RIM and PLM into a single system?
Depending on your organization's current maturity level and strategy related to mergers and acquisitions, now may not be the right time to invest in a single platform for all functions. But companies can gain benefits and reduce costs by first defining integrated people and process strategies *prior* to fully integrating the systems. And when the time is right, the integration will be faster and cheaper with this pre-work complete.

Final Thoughts

Today's regulatory submission process is complex, but with integrated PLM and RIM solutions, companies can implement inter-connected processes and share information through product development and all the way to the distribution cycle. Companies that do this well focus not only on the systems and data in the merging of these processes, but also on managing people and change.

And all the effort is worth it. Embracing this transformation and embedding safety and compliance into every step of the medial device innovation process, will ultimately lead to better results for patients.

More Reading

eBook: Imperative of Better RIM
Download this eBook to learn about the evolution, imperative and benefits of RIM

Streamlining your EU MDR Compliance Journey

Accel for Regulatory Information Management (RIM)

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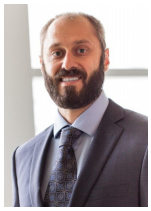
What's your view? Add your question or comment

About the Authors

Sajesh Murali

sajesh.murali@kalypso.com

Sajesh lives in Austin with his loving wife and is a die-hard gamer drawn to anything high tech. Superbikes are his passion and in his free time he loves to cook and catch up with his books.



Nate Reisch

nate.reisch@kalypso.com

Nate is an experienced product lifecycle management (PLM) Business Process and Solution Architect with an in-depth understanding of best practices in core PLM concepts.