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People, Process, Tools. Optimized.

RIM for Medical Devices: It's Time to Dump the Spreadsheets!

Yet another medical device design change has hit your desk for regulatory assessment. You read the email but just can't get to it due to all the other Regulatory responsibilities you have. By the time you pick up the reminder voicemail, the design change has slipped your mind and you have to search for that "heads up" email from R&D. As you dig into the change order, you realize that this one will be a beast. You know even before consulting your spreadsheets that this change will affect multiple country registrations as well as manufacturing facilities.

It's possible to implement a database that will be your single source of truth for all your medical device information.

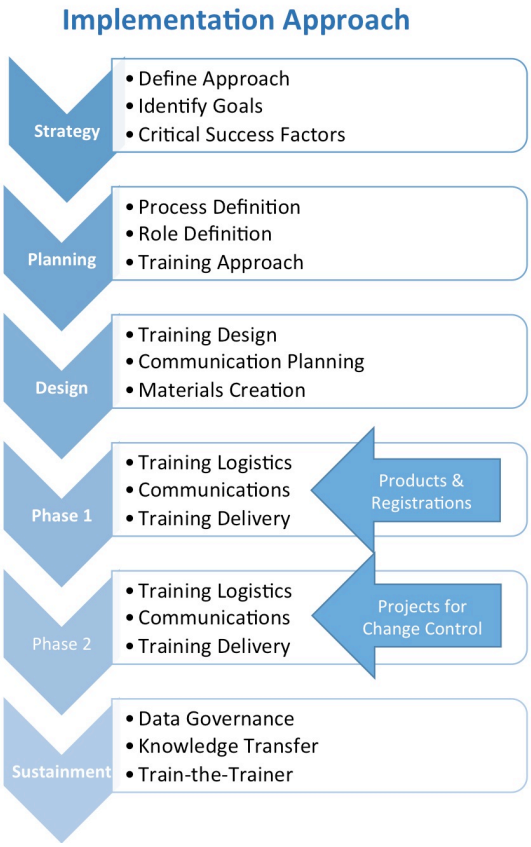
The spreadsheet you faithfully maintain to track where the product is registered, and in which facilities it's manufactured, is probably current but… are you sure? You know you have a lot of work ahead of you; emails to send to colleagues around the world and endless follow-up. Your only hope is that you stay organized and that your affiliate/partners might put the evaluation of this change on the top of their long list of priorities… and that is just the first step!

If this sounds like you on any given day, you need to stop the madness! Put down the spreadsheet and look towards a regulatory information management (RIM) system for tracking your medical device activities. The Pharma industry has been implementing and evolving RIM solutions for years, but few medical device companies have made the same transition. Luckily, the path has been paved and there is no better time to drive towards process improvement and efficiency gains. Why not beat the clock on the new medical device regulations that are coming? The U.S. may now be tracking unique device identifiers (UDI), but that is just the beginning of ever-increasing demands by health authorities for medical device information.

RIM success starts with knowing your regulatory processes. Once you have a clear definition of the role regulatory plays in the lifecycle management of your products, then it's possible to implement a database that will be your single source of truth for all your medical device information. A global system that has all products linked to their related registration(s) and full integration with the end-to-end regulatory change process means you will not only gain efficiency but also visibility into the regulatory activities of your entire country, region, company and portfolio!

Imagine the time savings you would realize if you could search the RIM product catalog to find your device (or family of devices) with all of its key characteristics and direct links to the related global registrations, facilities, certifications, declarations of conformity and UDI details. Yes, this is possible and in this new reality, every time a product change order is initiated, the RIM solution would track it as a project—allowing the regulatory change owner to identify the applicable team members, tasks, and timelines.

The RIM solution would also auto-generate a list of countries with current registrations so each country could be assigned a task to assess the local impact and document results/outcomes. Automatic notifications are built in so every project participant is alerted when a task is assigned or completed. Progress is monitored and once the local assessments are completed, a report is generated summarizing the global results. If a country determines that the change will require a license amendment or a new registration, those activities can become sub-projects that fall under the parent Change Order, allowing the entire effort to be monitored holistically.



RAO Solutions has applied their regulatory expertise to successfully implement a RIM solution for a global medical device company. The system incorporates both Registration Tracking and Lifecycle Management.

This RIM solution was implemented in two phases in order to first establish the medical device product and registration database and subsequently add project functionality to enable support of the product lifecycle (see diagram). Our approach to the project was divided into stages, allowing the team to coordinate implementation activities with the technical deployment team.

The ultimate result was a smooth launch with high levels of participation in training and adoption. The results have been truly transformational; the client was thrilled with the implementation and commented on how with the increased access to data and their

streamlined process, they expected to significantly increase the efficiency and ease the compliance burden of global change control throughout the organization.

It is time to stop relying on spreadsheets that are cumbersome and difficult to maintain. It is time to stop the missed handoffs and miscommunications that historically delay medical device changes. It is time to implement a RIM system.

For more information on implementing a RIM solution at your company, visit our website at:

RAO Solutions
www.raosolutions.net

About the Author

Andrea Kozak, Partner at RAO Solutions *has 18 years of experience helping Life Science companies solve their Regulatory challenges, staying on time and on budget. As a Director of Regulatory Information Management (RIM), Andrea implemented strategic initiatives for Global Regulatory Affairs including global process harmonization and cross-functional system implementations. Andrea's experience also includes Program/Project Management and global implementation of Electronic Document Management and Publishing Systems.*