



KALYPSO

THE IMPERATIVE OF BETTER REGULATORY INFORMATION MANAGEMENT

By Dave Hadfield, John Hubert and Malika Virk

Medical device companies face an extraordinary set of challenges today

Complex and constantly changing regulatory compliance, growing product quality requirements, and the evolving landscape of digital technologies are both an opportunity and a challenge for medical device companies seeking to compete and innovate.

To navigate this environment, companies must find ways to maximize return on investment by manufacturing products as efficiently and cost-effectively as possible. To serve global markets, they must produce products that comply with global regulations, adhere to each country's submission process, and meet growing customer needs - and they must do all this in a timely manner.



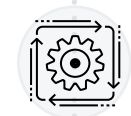
Not an easy task at all, especially when so many companies suffer from these common issues:



1. Regulatory groups are involved too-little and too-late in the product development process



2. Siloed systems for product-related information



3. Unsalable products due to delayed compliance renewals and changing country regulations

The Value of a Regulatory Information Management System

Regulatory Information Management (RIM) systems are centralized and adaptable, allowing companies to manage information for new and existing products before, throughout and following the product design and registration processes.

Instead of managing regulatory data sporadically throughout many different systems, information is consolidated in one, flexible system so that companies can easily manage and track the entirety of their regulatory data.

By organizing and pooling both structured and unstructured data into one system, companies can cut time out of the product registration process and expedite time to market. RIM systems shift the focus from a document-driven to a data-driven approach, enabling a new level of precision in executing regulatory responsibilities.



The Evolution of RIM

Regulatory information management systems are not new, but they have evolved to incorporate new data-driven technologies that more effectively connect data throughout the lifecycle of a product, and to better support the global requirements of medical device companies.

Here's a quick look at the evolution of RIM:

1st GENERATION

The original RIM systems supported regulatory submission processes in one key way - by pooling documentation from different systems into one package. 1st generation tools offer no integration or reciprocity, and data collection is completely manual.

2nd GENERATION

In later years, the scope of data management expanded to enhance document-based submissions on a regional basis. 2nd generation RIM systems compile a defined set of additional data including packaging information, market authorizations, manufacturer information and clinical data.

RIM Today

3rd GENERATION

Today's systems offer a comprehensive, global and connected master data management system. 3rd generation systems function on a global (not regional) basis, and they focus on more than just packaging information for submissions - they track complete registration information from the very initial stage of product development. About 85-90% of the data that is needed for a regulatory submission for any given country is captured concurrently, so by time the product is manufactured, most of the required registration data is already packaged. Instead of focusing on documentation, RIM systems today enable a holistic view and single source of truth for data, making data-driven regulatory submissions an easy output of this process.

The Imperative of RIM

Many companies have adjusted to changing regulations either without a RIM system or with a first or second generation system. So why bother considering the third generation? In short, many companies are better positioned to successfully implement a more advanced regulatory information management system because of shifts in the way of thinking about regulation and the advancement of technology in today's digital world.

SHIFT IN THOUGHT PROCESS AND TRENDS

Regulation used to be the primary concern of only a small number of people in a medical device organization. Now, regulation is an increasing focal point for C-Suite executives, cementing its place as both an opportunity and challenge for the entire company. Many executives are looking for new ways to innovate the registration process to maximize efficiency.

GROWTH OF TECHNOLOGY IN A DIGITAL WORLD

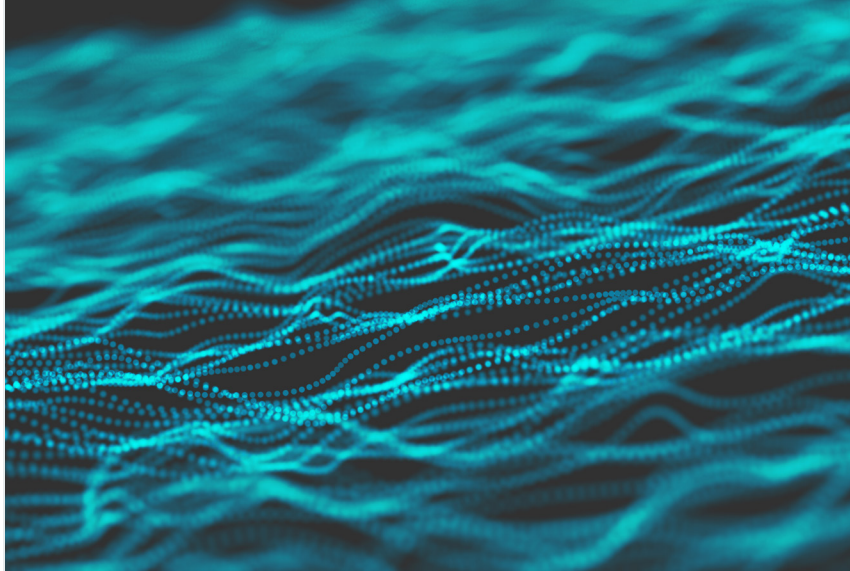
Technology in the medical industry has evolved exponentially over the past several years. These advancements are not limited to the medical device itself - data systems have also evolved dramatically, resulting in a world of connected data. Systems are starting to provide real-time updates on market and regulation changes. By quickly identifying and analyzing these updates, companies can rapidly adjust their submission data. These new technologies far surpass previous data management system capabilities and they are structured to be upgraded in the future as technology continues to advance.

The Benefits of RIM

RIM systems should be considered a strategic asset, and therefore a strategic investment.

While implementing RIM is a significant effort, the benefits far surpass the costs. RIM enables faster time to market through innovative registration strategies and more effective submissions development processes.

- Faster time to market
- Expedited international sales and controlled distribution with connected data
- Reduced implementation risk
- More informed decisions with updated data
- An adaptable, user friendly platform
- Better compliance and regulation tracking



The introduction and adoption of RIM can position medical device companies for transformative growth. Those that embrace this transformation wholeheartedly will leverage new technologies to accelerate the process of bringing products to market.

In doing so, they will position themselves closer to customers than ever before, which will prove to be a significant source of value in the medical industry in the coming years.

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We help life sciences companies innovate to improve patients' lives

The pace of change in the life sciences industry is both exciting and extraordinary. Major market forces such as intensifying regulatory scrutiny, growing product quality demands, emerging digital technologies and evolving healthcare models are causing core paradigm shifts in business strategies and processes alike.

This environment opens up opportunities for life sciences companies to better serve more people around the world with increasingly innovative and affordable diagnostics, treatments, combination devices and cures.

Whether it's regulatory information management, quality and compliance, PLM, digital transformation, connected health and products, or core business innovation, we're here to help you drive results.

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