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Insight Brief

IS YOUR REGULATORY INFORMATION MANAGEMENT PROCESS PUTTING YOUR COMPANY AT RISK?

Boost your compliance performance through RIM

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INTRODUCTION

It now takes roughly $2.5 billion and more than 10 years to bring a new drug to market[1]. Over the course of that journey, biopharma companies face many obstacles and risks including managing their ongoing interactions with regulatory agencies.

Communication with regulatory authorities begins as soon as researchers identify a potential use for a new drug or device. From that point on, every interaction with an agency is critical and, in some regions, must be documented and made available during any inspections.

If an agency requests specific information or action, that request becomes a commitment that the company must complete and document. Effective interaction plays a vital role in initial market approval and is mandated to continue throughout the product's lifecycle to maintain compliance.

With the increasing numbers of products across a growing number of markets against a backdrop of diverse, changing requirements, the regulatory complexity for a company can be mind-boggling.

The required level of compliance is best supported when organizations have a regulatory information management (RIM) system in place that can capture compliance-related data from multiple business units and organize it for easy access and review. However, lacking this level of regulatory data management sophistication, many companies are putting themselves at risk.

>2000

new or modified regulations released by the FDA alone since 1998[2]

It costs

~$2.5 billion

to research and develop a new product[1]

53%

of global life sciences CEOs **consider industry regulations a top disruptive business trend**[3]

New therapies take more than

10 years

to reach the market[1]

AVOID ERRORS, DELAYS, LOSSES

In small and even some mid-sized biopharma organizations, compliance-related data is often captured in spreadsheets and through shared files that may only be accessible by one or a few individuals. This creates situations where data can be lost or mishandled, giving rise to information gaps that may not be discovered until the data is requested by regulators as a condition of achieving or maintaining approval. In some cases, companies may not realize the need to maintain this data until they attempt to file an application for marketing approval or receive an inspection. Such errors can set an organization back months as it attempts to capture or recreate regulatory data after the fact, significantly delaying the approval process. This may result in financial loss to the company and most importantly, needless delay in providing patients with life-saving drugs.

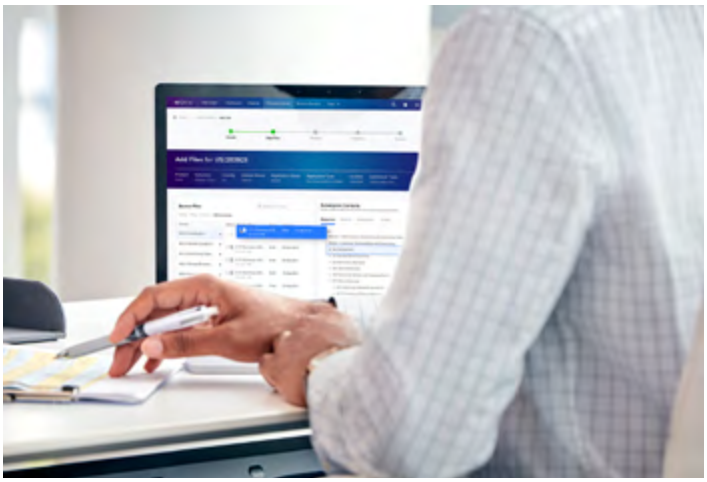
Some companies have implemented point solutions that capture data within functional departments; however, these systems rarely interact, creating silos that make data hard to access and increasing the possibility of errors or incomplete data sets.

Although these concerns may seem small in the broader scheme of drug development, when companies lack uniform access to regulatory data through a single solution, it can lead to expensive crises.

The required level of compliance is best supported when organizations have a regulatory information management (RIM) system in place that can capture compliance-related data from multiple business units and organize it for easy access and review.

When regulators request information, companies must be able to compile data into reports from multiple systems or spreadsheets within tight timelines. If they can't do this efficiently, or the individuals who control the data aren't available, they risk missing regulatory deadlines. This can lead to loss of compliance, delayed approval, lost opportunity and even outright fines – which all come with a hefty price tag.

These risks are particularly critical for products sold in Europe, where regulatory agencies require companies to maintain all records for compliance purposes and conduct audits to verify that data systems are up-to-date.



THE VALUE OF RIM: COST & PERFORMANCE

A centralized RIM platform solves these problems by bringing clarity and uniformity to the regulatory data management process. Along with automating paperwork, RIM systems provide regulatory planning and resource management tools, correspondence tracking, and custom dashboards that let leaders across the organization monitor progress and track relevant metrics. Comprehensive RIM systems, such as IQVIA's RIM Smart, also include submission viewing, validation and publishing, registration tracking, and other features. Biopharma companies gain much greater insight into their regulatory programs, avoiding bottlenecks and mitigating risks before they lead to mistakes and costly delays. These reporting and tracking capabilities also make it easier to stay ahead of annual filings, optimizing the resources needed to keep those obligations on time and within budget.

Many companies see significant time and cost savings as soon as a RIM system is deployed. At IQVIA, we recently worked with a fast-growing biotech company that had two marketed products in the U.S. and others in the pipeline. Its leaders had previously relied on outsourcing, off-the-shelf products, and spreadsheets to manage compliance data and reporting, which required manual organization of seven separate tracking hierarchies of products, indications, countries and clinical trials.

> ***With comprehensive RIM systems, biopharma companies gain much greater insight into their regulatory programs, avoiding bottlenecks and mitigating risks before they lead to mistakes and costly delays.***

Once they deployed our cloud-based RIM system they saw immediate benefits. In the first six months, they experienced significant cost savings through the elimination of multiple development, validation and production application servers. They succeeded in cutting thousands of dollars in monthly support costs and lowering rates for submissions compared to previous service provider partnerships. They also eliminated redundant tasks and reduced on-boarding timelines for new regulatory staff from one week to one day. Additionally, they saw improvements in knowledge management and talent development across their teams.

COMPREHENSIVE RIM SYSTEM BENEFITS

Faster response times

Reduction of repetitive, manual data entry

Elimination of redundant systems

Real-time access to relevant regulatory data for your entire team

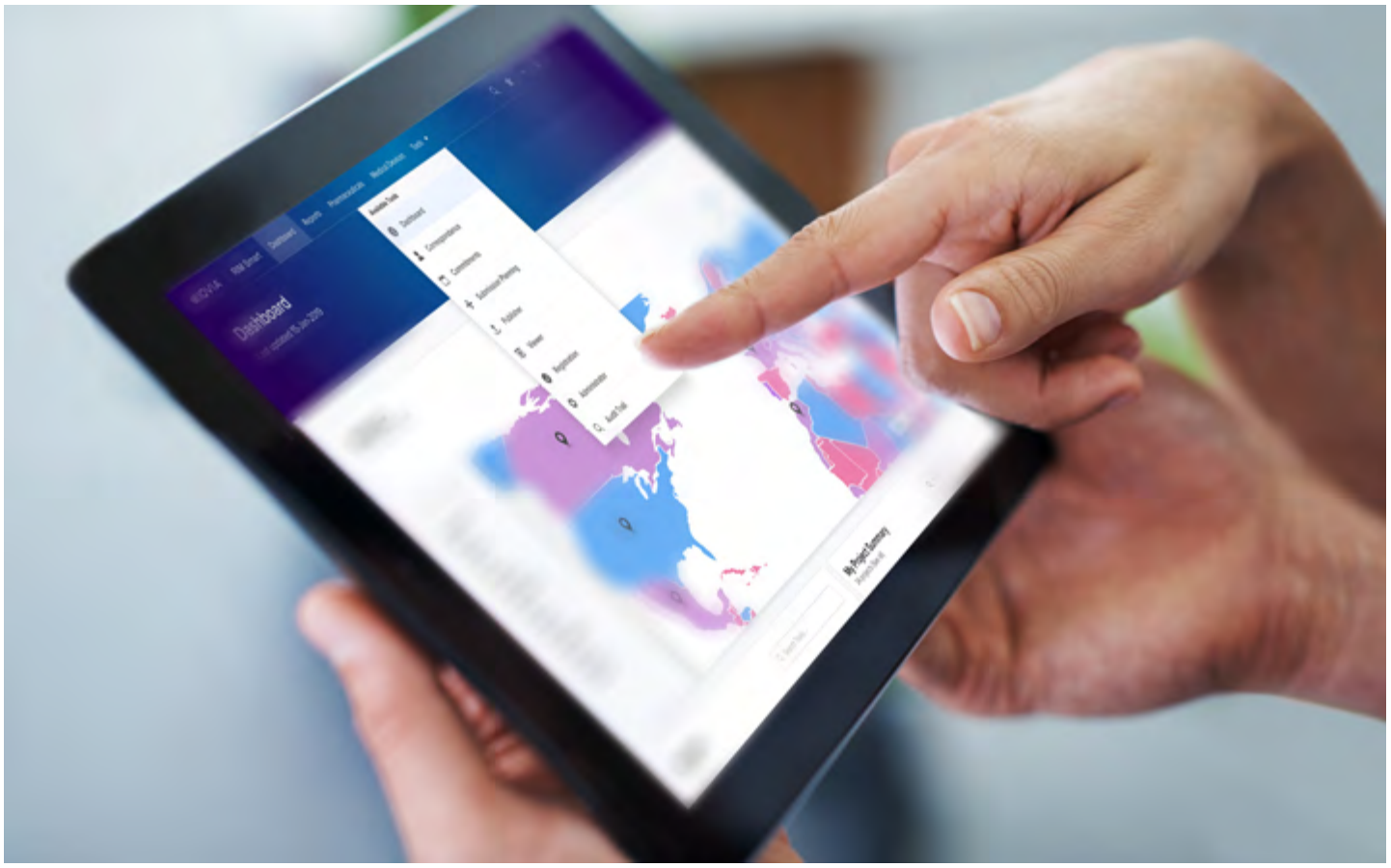
Rapid, accurate management of all correspondence & commitments

Simple, easy 24 x 7 x 365 global access

CONCLUSION

Immediate measurable benefits result when companies transition to RIM solutions. In an industry as heavily regulated as life sciences, it is vital that everything a company does is documented and provable via data captured in a common data system. These interfaces do more than automate laborious tasks. They ensure consistency and quality in every regulatory exchange from first discovery through end of market life.

To learn more about how IQVIA can assist your company with regulatory compliance—including our regulatory information management system – visit us at: iqvia.com/rimsmart



ABOUT THE AUTHOR

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Innovator, Technologist, Entrepreneur, Domain Expert with 25+ years' experience in the Life Sciences industry. Shy has been assisting companies of all sizes with design, development and implementation of solutions and processes.

With his team, Shy developed and deployed the very first publishing solution for eCTD in early 2000. Since 2012 he and his team have been focusing on the new state of the art cloud-based RIM solution. He is also the architect of many PDF tools that are widely used for publishing PDF files for regulatory submissions around the world.

Shy has an MPH (Epidemiology and Biostatics) degree from Boston University and an MA (Social Sciences) degree from Bangalore University. Prior to IQVIA, Shy was founder, president and CEO of two successful ventures: ACUTA founded in 2012 and acquired by IQVIA in 2018; Datafarm founded in 2007 and acquired by Liquent in 2010.

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