Insight Brief

A BLUEPRINT FOR OPTIMIZING RIM SYSTEM DEPLOYMENT

How an agile approach can drive change management, increase user buy-in, reduce risk and ensure added value

JENS-OLAF VANGGAARD, Director, Global Regulatory and Safety Solutions

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INTRODUCTION

As the number of regulations keep increasing and becoming more and more data-driven, the concept of Regulatory Information Management (RIM) keeps evolving and becoming more comprehensive, but also more complex. Driven by these changes, the pharmaceutical and MedTech industries are looking to transform the way they manage regulatory information from a siloed, legacy-driven approach to a comprehensive, end-to-end approach where business processes, information and data seamlessly flow across functional and organizational boundaries.

As the regulatory landscape and client requirements change, so do the offerings of regulatory technology vendors, with the majority now either working on or offering end-to-end (E2E) RIM platforms to support this evolution. The E2E model is built on the same assumptions that have successfully driven Enterprise Resource Planning (ERP) system adoption over the last 25 years, namely that a pre-integrated, modular platform will deliver significantly lower risk, increase cost-efficiency, and provide a consistently better user experience. However, it is still early days for E2E RIM, with low maturity within the industry.

End-to-end systems can offer a more seamless regulatory management experience; however, some customers will find the customization and adoption journey to be more complex than initially anticipated, especially if there are unique process requirements. This may be frustrating for users who are accustomed to well-established workflows and can make user adoption a tougher sell.

To mitigate these issues and accelerate acceptance of any new RIM solution, we encourage companies to take a “blueprint approach” to their platform roll out.

THE BLUEPRINT APPROACH TO EARLY DEPLOYMENT

In a traditional system roll-out, companies work with vendors to predefine detailed requirements based on the old ways of doing things. Then, they customize the platform to follow those workflows and roll it out in pilots to validate proof of concept. This process can take months, and often results in customizations that aren't optimal for the system.

A MORE AGILE, USER-DRIVEN APPROACH

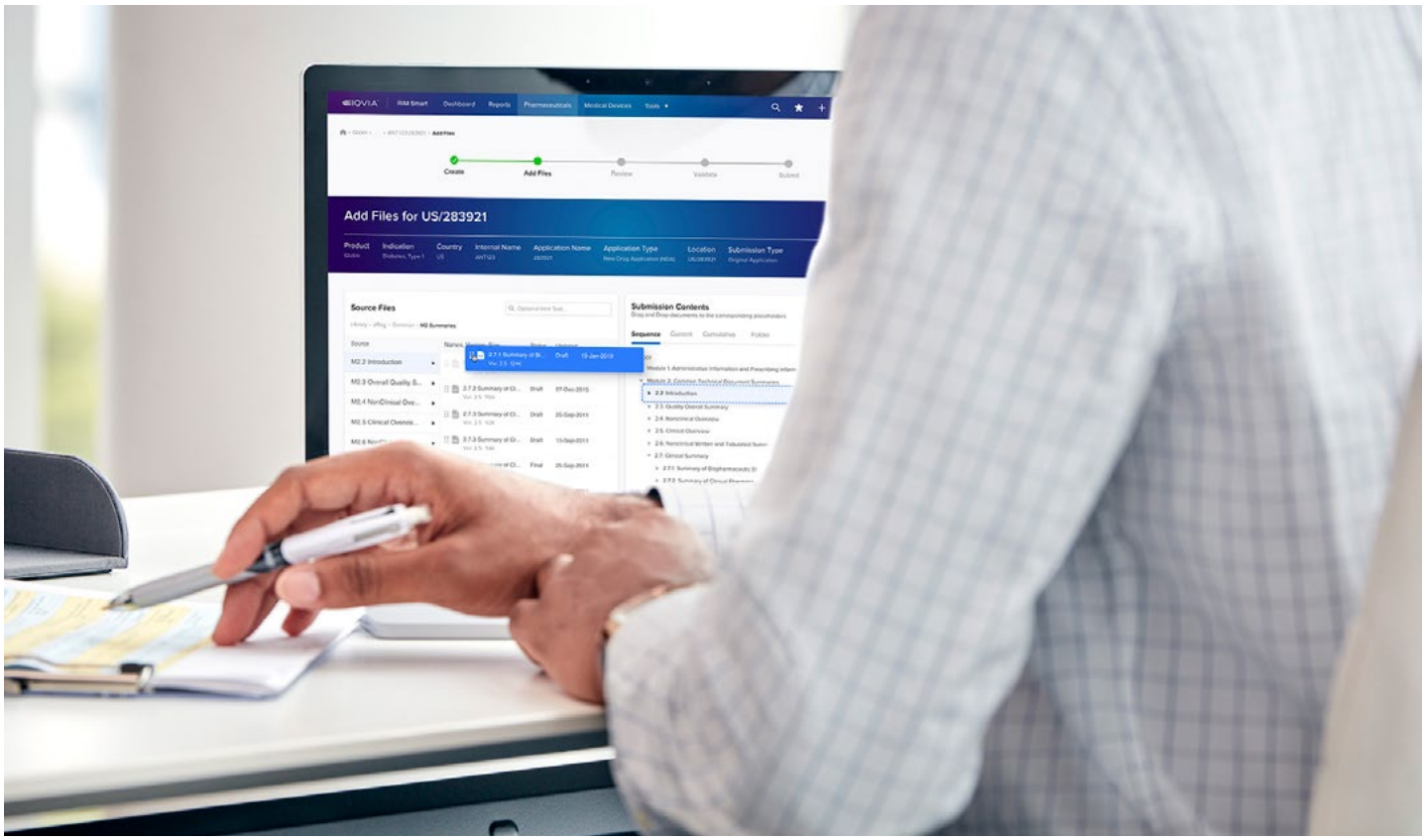
With the blueprint method, once a company chooses a RIM platform, they work with the vendor to define only the high-level requirements and business processes the platform must accommodate during the initial phase. This provides the blueprint, or broad outline, of what the platform must do. Otherwise, they leave it in its generic form for this phase of the project, which gets rolled out simultaneously to all users.

Although, this may sound counter-intuitive, it delivers two key advantages.

1. SPEED TO DEPLOYMENT:

The blueprint approach gets the platform up and running as quickly as possible which is vital to maintaining ongoing regulatory compliance. Regulatory reporting cannot be delayed while a new RIM system is implemented, so getting the basic RIM technology operational is key to keeping these critical tasks moving forward.

When companies wait to fully customize the platform before rolling it out, they can lose months of performance optimization and still may not get the full usability they want.



2. PROCESS OPTIMIZATION:

This is where the real, long-term benefits of taking a blueprint approach emerge. When companies deploy a RIM solution, their gut instinct is to translate all their existing workflows and tasks exactly as they are currently into the new system. While this approach feels more comfortable, it is short-sighted and will ultimately stifle the full value of the RIM solution. Deploying a RIM platform provides users with an opportunity to optimize their processes, gain efficiencies, and reduce time spent on non-value-adding tasks while reducing the risk of errors. To make the most of this value proposition, companies need to rethink their regulatory information management processes and how they can be improved by applying this new technology.

By rolling out the platform without customizations during the initial deployment phase, compliance staff have time to complete training on the new platform and then to explore the system. This allows them to figure out how the existing features work and to think through how they could be further tweaked to optimize performance. This kind of insight helps promote the behavioral changes necessary to make the most of the RIM platform -- because users can't just revert to the old way of doing things. It also ensures that any customizations made during later deployment phases, or additional capabilities added to the core platform, will be adopted by the core user base because they came from their feedback. This gives them ownership over the ultimate workflow, which helps optimize performance improvement.

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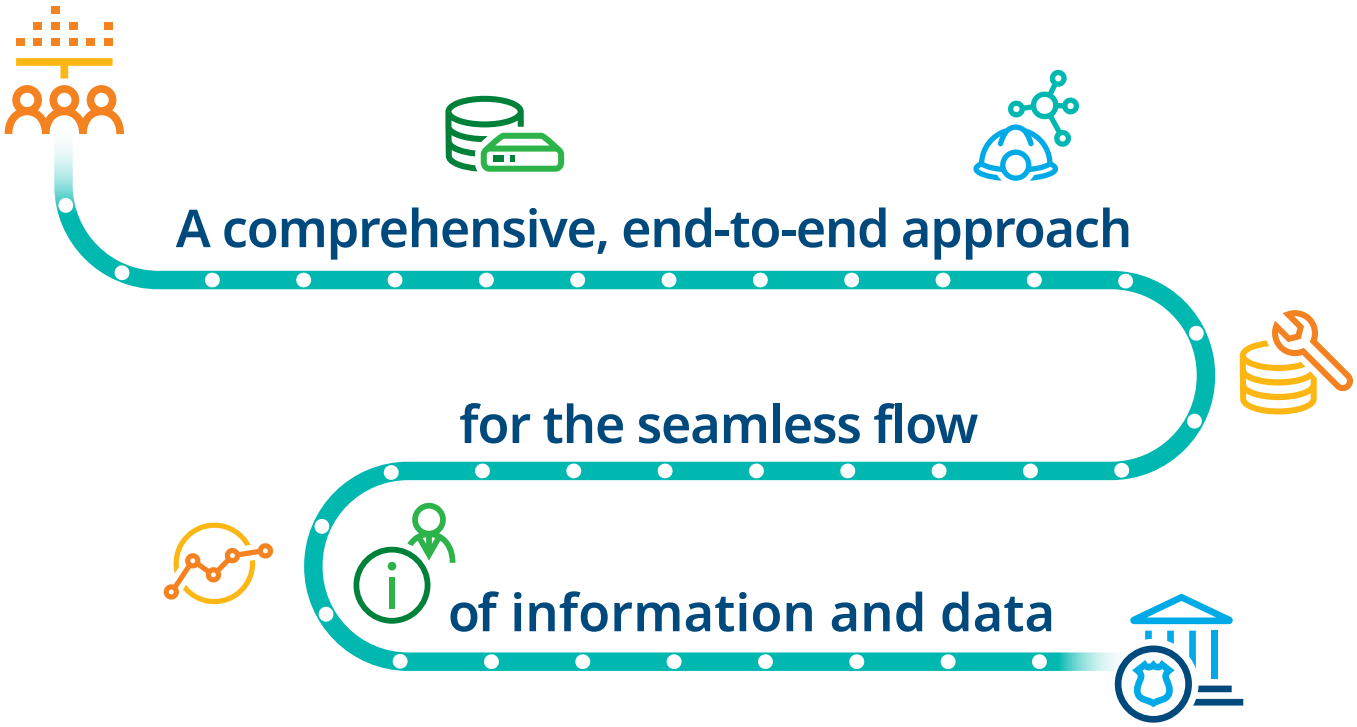

CONCLUSION

Change management is often one of the most important (and overlooked) features of any new technology deployment, and RIM systems are no exception. Taking a blueprint approach creates an environment that encourages change and generates buy-in for the new solution – without force-feeding it to users. When you provide them with a generic solution and invite them to see what works, what's missing, and what they might do differently, they engage with the technology in a more organic way.

A blueprint approach is a low risk way to empower end users and make sure the final iteration of the RIM platform delivers the most value for everyone involved.

To learn more about how IQVIA can assist your company with optimizing deployment of a RIM system using the blueprint method, contact us at: iqvia.com/rimsmart.

ABOUT THE AUTHOR

JENS-OLAF VANGGAARD
Director, Global Regulatory
and Safety Solutions

Jens-Olaf Vanggaard is the lead of IQVIA's Regulatory Solutions practice and has more than 10 years of experience providing advisory and project implementation services within Clinical Development and Regulatory Affairs. Jens-Olaf has strong domain expertise within Regulatory Information Management (RIM), IDMP, Data Governance and Master Data Management from a Regulatory Affairs and Pharmacovigilance perspective.

Mr. Vanggaard received his M.Sc. in Business Administration and Computer Sciences from Copenhagen Business School.

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iqvia.com/rimsmart

CONTACT US

iqvia.com/contactus

LOCATION

4820 Emperor Boulevard
Durham, NC 27703
United States