Three Success Criteria for a Unified Regulatory Solution

Veeva ASPHALION

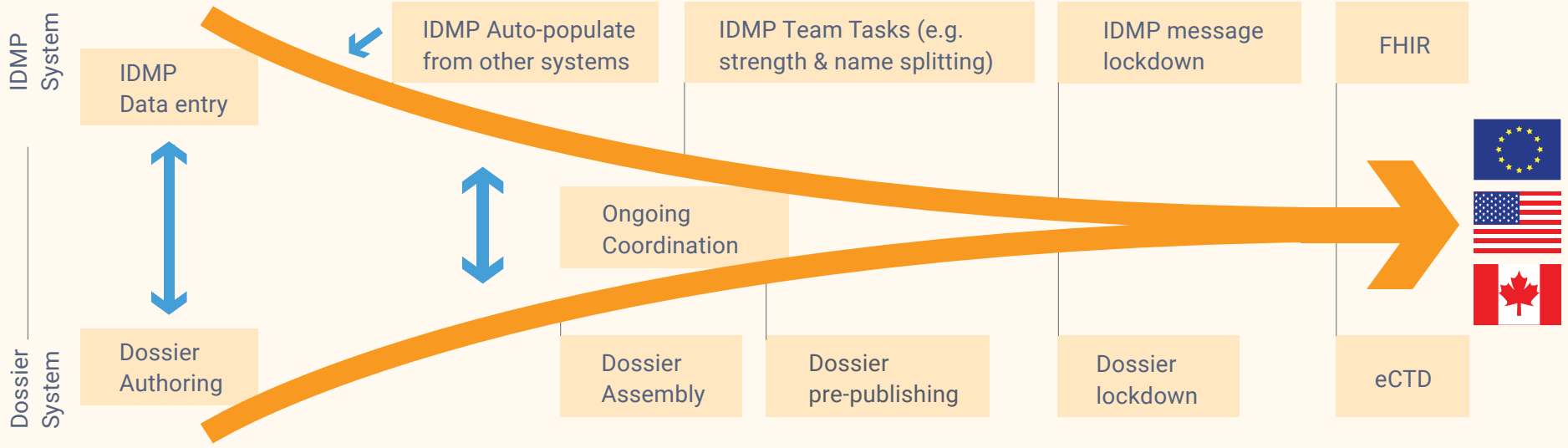
INTRODUCTION:

Three Success Criteria for a Unified Regulatory Solution

The transition from siloed systems to a unified regulatory information management (RIM) platform that fully supports end-to-end business processes is underway. This white paper examines the business drivers behind this shift and three factors that are critical to maximizing the benefits of a unified RIM solution.

Current Challenges

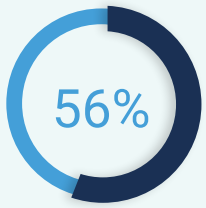
Planning, tracking, and organizing regulatory submissions in an efficient and cost-effective way requires intense coordination. This is especially true when managing products across multiple markets. Unfortunately, many life sciences companies struggle with standalone point applications like outdated document management systems, which can't keep up with today's changing regulatory environment. Gaps between applications limit visibility and force regulatory teams to rely on manual processes to share information and coordinate tasks. Upcoming IDMP requirements compound this challenge. By early 2022, companies will need to capture more data from more sources when applying for a marketing authorization in Europe. Managing dossiers and IDMP data in different, disconnected systems will make it difficult for cross-functional teams to bring together required information in a timely and error-free way.



Move to Unified RIM

These impending changes have driven life sciences companies to rethink how they capture and manage regulatory data and documentation. Preparing for IDMP can provide the perfect opportunity to increase efficiency and collaboration by transforming how information is organized and leveraged across global teams.

Many leading organizations are adopting unified RIM solutions to drive greater compliance, operational excellence, speed to market, and reduced costs. The 2020 World Class RIM Survey published by Gens & Associates found that 56% of survey respondents said they are highly likely to use a single platform solution for most of their RIM capabilities, while others said that they'll investigate that approach over the next few years [1]. Furthermore, 80% of top performing pharmaceutical companies shared that a RIM system will be the primary component of their upcoming IDMP / SPOR solutions.



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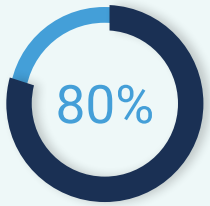

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Three Critical Success Factors for Unified RIM

Maximizing the business value of unified RIM requires the right technology platform and an expert implementation partner. Companies should consider the following success factors before kicking off an IDMP project or selecting a new RIM platform.

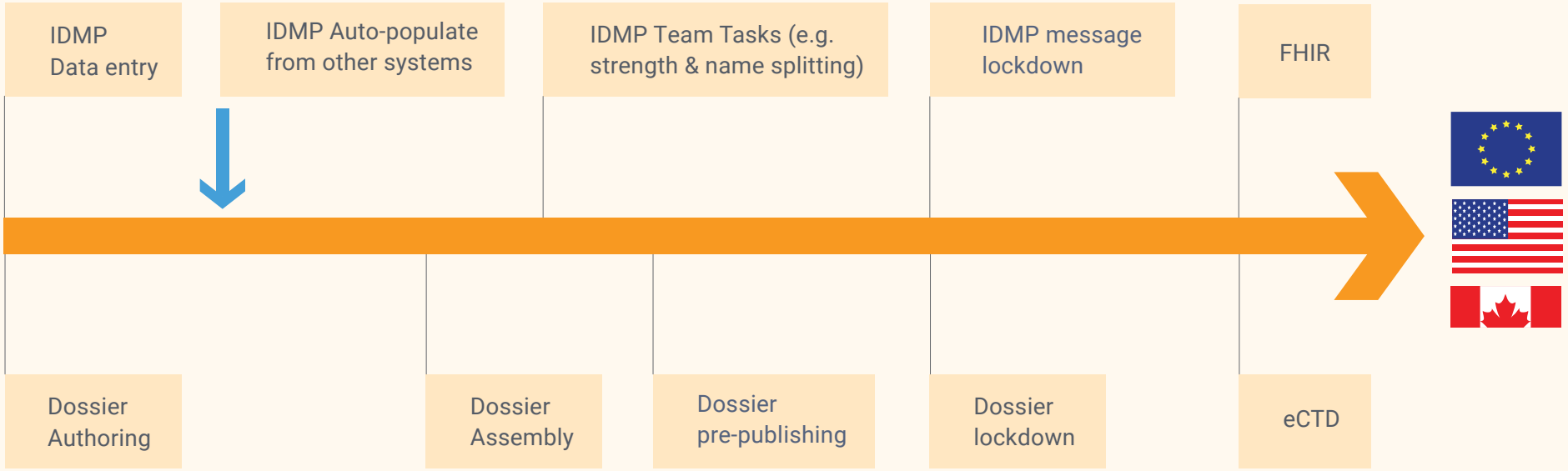
1. Source: Gens & Associates, 2020 World Class RIM Survey, Spring 2020. Top Performing companies are those with a Strong Performance or World Class rating and include small, mid-tier, and large pharmaceutical firms.

SUCCESS FACTOR 1:

One Platform for Documents and Data

Reduce manual effort and the risk of errors

Consider a unified RIM solution that can store, sync, and track submission documents along with product and registration data all in one platform. This not only simplifies the IT landscape but also eliminates information gaps and manual hand-offs, which hinder collaboration and raise the risk of incomplete or inaccurate regulatory submissions. By working with a single, shared source of information, teams can accelerate the assembly and finalization of submission packages.



Be sure that the RIM solution also provides a complete view into product registration information -- whether that be data, documents or published output -- regardless of departmental ownership. Users should be able to exchange information with global Health Authorities and generate real-time, customizable dashboards to facilitate decision making.

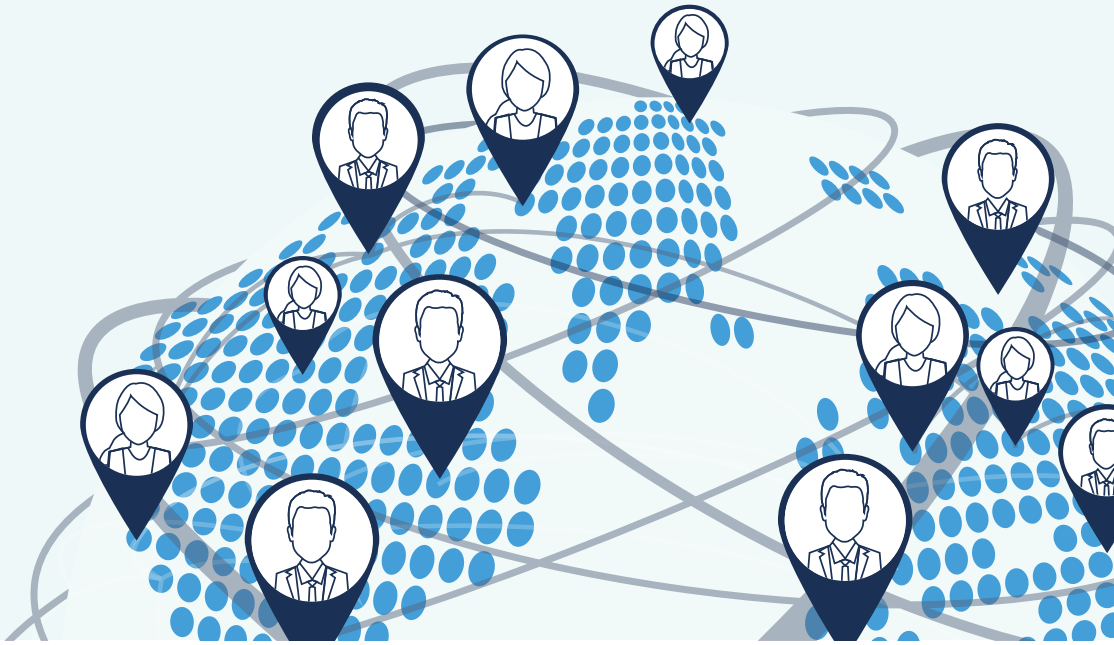
SUCCESS FACTOR 2:

Global Accessibility to Documents and Data

Support headquarters and local affiliates

The ideal RIM solution should provide your teams with the information they need, no matter where they are located. For example, GlaxoSmithKline (GSK) decided to replace a number of aging regulatory applications with a single RIM solution to support country operations and interactions with local health authorities across the organization. This global accessibility will help GSK integrate teams in different countries, streamline how they work, and improve the completeness and timeliness of documents and data.

> "By putting everybody onto a unified RIM platform, and that platform becoming everybody's primary tool, I am really optimistic that this will drive a step change in the overall quality of our data."
>
> Stephen Cook, Regulatory and Systems Program Lead, GSK



SUCCESS FACTOR 3:

Implementation Partner with RIM and IDMP Expertise

Benefit from best practices and proven experience

To realize the full benefits of a unified RIM solution, it's important to choose a skilled partner that can support every step from technology selection to implementation. Look for capabilities that span project management, business analysis, implementation, data migration, validation, and training. Partners should have knowledge of EMA centralized procedures as well as local regulations to help companies meet various compliance requirements. They should also be sensitive to an organization's unique business culture and be able to speak a common language for seamless communication.

CASE STUDY

Partner delivers RIM solution to replace homegrown database

A leading pharmaceutical company outgrew an internal registration tracking tool when its product line doubled in five years. The custom database lacked process capabilities and was hard to maintain and integrate with other systems. As a result, regulatory teams had a tough time staying current on product approvals.

The company engaged a full-service implementation partner to deliver a new RIM solution. To maximize the system's impact, the partner collected and prioritized user requirements by analyzing the processes of multiple regulatory teams. In addition, the partner authored new SOPs, validated regulatory processes before go-live, and trained users on the software. The result is a widely adopted modern RIM system that supports the customer's diverse business model and product portfolio.

Conclusion

Forward-looking life sciences companies are embracing IDMP as the impetus to replace aging, standalone IT systems with one unified RIM solution. Many organizations are moving toward modern platforms that manage both documents and data and provide shared regulatory capabilities for headquarters and affiliates. A unified RIM suite enables greater efficiency, data quality, and preparedness for upcoming regulations, but selecting the right technology provider and implementation partner is critical to success.

Veeva

Veeva Systems, Inc. is the leader in cloud-based software for the global life sciences industry. Veeva has over 200 live Vault RIM customers and has helped them streamline global regulatory processes on a single, cloud-based platform. This enables companies to improve visibility, data quality, and efficiency.

ASPHALION

Asphalion is an international scientific and regulatory affairs consultancy with offices in Barcelona, Madrid, Amsterdam, Munich, and London. The company supports the selection and implementation of a unified RIM solution to help meet IDMP requirements and optimize regulatory processes.