Updating Your Regulatory Information Management Capability? It Could Pay to Get Hands-on

Letting business-savvy techies play around with a new RIM system ahead of the proposed implementation could save Life Sciences companies a fortune, says Romuald Braun, Managing Partner at MAIN5, warning against hasty vendor selection and contracting.

Everyone is time-poor now. So, when Life Sciences companies are looking to formalise or refresh their regulatory information management (RIM) capability, it is tempting to default to the leading brand. After all, if peer companies have already done the research to arrive at this choice, why reinvent the wheel?

Yet, a lack of rigour in the requirements definition and vendor selection process could invite considerable risk and additional cost, if something important has been overlooked. As the EU IDMP grace period gives way to a hard mandate for data standards compliance, and as digital transformation ambitions expand beyond the Regulatory remit to encompass Quality, Safety & Clinical processes, it's more important than ever that companies do their research when approaching RIM vendor selection and contracting. An overly generic request for proposal (RFP), or 'safe' shortlist made up of what everyone else seems to be using, is a risky starting point.

The Growing Expectations for RIM

Deploying a formal, optimised system or platform for regulatory information management is a given now for all Life Sciences companies, irrespective of their size and focus. Regulators expect this and, as data rather than static documents evolves to become the default means of submitting, exchanging and maintaining regulated product and process information, it follows that the systems for managing and keeping track of everything must be sophisticated and reliable.

In the 2020s, a strong, modern RIM platform should equip a company to:

- Fulfil all of the differing and continuously evolving health authority requirements internationally.
- Effortlessly and reliably track the status of products, their licences and current marketing authorisation applications.
- Maintain a single, authoritative version of regulated product/process/licence truth that is accessible centrally and locally by the people who need it.
- Support future ambitions for process transformation, for instance beyond the scope of Regulatory Affairs – potentially encompassing adjacent functions such as Quality, Safety and Clinical operations – through integrated system capabilities and readily exchangeable data.

Although individual events such as a company merger or acquisition, or EU IDMP compliance, may trigger the decision to invest in a new RIM capability, it's important not to progress this decision without considering the broader associated opportunity – e.g. to address internal data control challenges; transform internal visibility and decision-making; and ultimately re-imagine processes so that they are more efficient and support the business strategy more directly.

All these considerations should feed into the RIM selection process, which requires that all of the various business (as well as technical) stakeholders are consulted early on for feedback about their requirements and current process pain points. Thought should be given not only to what the company and its functional teams want and need to be able to do, but also to scenarios they wish to avoid in future. These might include:

- Incurring delays/business interruption and new cost as new features and capabilities have to be added to the system later, e.g. in response to a change or update to regulatory requirements in one or more markets.
- Future problems with system or data incompatibility if the company later tries to improve the connection and information flow with other departments or part of the global organisation; or following a business merger resulting in system consolidation.
- Issues arising from a change to the software vendor's circumstances, ownership or strategic focus (e.g. what will happen to your data, and how you'll extract it/get it back).

Assessing the Available Options, Using a Formal Structure

A structured, holistic approach to vendor selection is the best way to ensure that nothing is left to chance in the choice of a new system – from its long-term strategic fit, and lasting deliverability for all target users, to the fulfilment of procurement requirements around cost/value for money, sustainability and so on.

Taking a structured approach (e.g. applying an agreed vendor selection methodology) will make it possible to score each option/each long-listed vendor across the full range of criteria, in a meaningful and comparable way.

This should span:

- Expressed user requirements and priorities.
- The strategic/wider digital transformation roadmap perspective (e.g. a move away from isolated best-of-breed solutions towards a unified platform approach to application rollout and data sharing); and
- Any technical/IT considerations, such as system architecture specifications (e.g. cloud-hosted or cloud-ready, and compatibility/integration potential with adjacent legacy systems).

Raising Awareness, Fostering Inclusion

While no single solution will tick every box, following this formalised vendor selection approach will ensure that each RIM proposition and supplier is considered from every angle. This means that any trade-offs (e.g. in specific user features that may be sacrificed for a more holistic platform serving multiple departments) can be duly considered, communicated properly and agreed pragmatically – an essential pillar of effective change management.

Starting with a standardised approach (to establishing user requirements, for instance) is a great way to get teams thinking about what is most important. That could be across a series of common or desired use

cases. In a Regulatory context, these might include variations management in marketing authorisation; IDMP-specific processes; and investigation of new drugs in key target markets.

Thinking through each scenario will help focus teams on what they need from a new system – before they make their choice.

Tailored Demos & Hands-on Experimentation

There's no substitute for seeing a new system in action. Ideally, this should happen via a bespoke demo applied to routine use cases and familiar scenarios – better still, using the company's own data (e.g. via a demo 'sandbox' environment).

It is in the vendor's interest for target users to understand the system's potential in their own setting and routine context. Requesting and securing this will enable a more confident and better-informed decision. If the demo can also reflect processes as they might evolve in the future (e.g. as Regulatory is blended more seamlessly with Quality and Safety, if this is a strategic aim), so much the better.

A good pain-saving tip is to let business-savvy technical enthusiasts within the company play around with capabilities to see what they can do, something that is easily provided for today via the cloud. This active user involvement is much more illuminating than watching a pre-set vendor demo and will drive home an understanding of what's really important when specifying and choosing a new platform.

Payback: The Benefits of Early Scrutiny

Investing the time in a proper needs assessment is a powerful way to get everyone on board and manage expectations, which in turn will cement user acceptance and ease change management. The risk otherwise is being saddled with a solution that doesn't fit the bill and which no one uses (a failed rollout), or which incurs a six/seven-figure cost and lengthy additional timescale to put right.

Or it could be that striving to fulfil all the immediate user requirements results in a fully featured, single-application system, yet curbs the potential for cross-organisational process transformation. From ordering regulatory information to catering for broader Quality, Safety and Clinical processes in the future, it's important to look five-ten years ahead when assessing a RIM vendor and solution. Otherwise, it could take two years to implement the initial solution, only to find it needs replacing again a further two years down the line.

A further aspect of a solid vendor selection process is to perform supplier due diligence/background checks – looking into their financial stability, their existing client base and customer satisfaction ratings, and their longer-term product roadmap, for instance.

Performing all of this work up front is not only a good risk management strategy; it will also provide solid justification for the vendor/system decision if unforeseen issues arise later.

Contracting for Success

Using a formal methodology in vendor scoring and selection can help in the negotiation and contracting process too, by drawing attention to what is essential versus less important. It's also a means of ensuring that additional considerations (e.g. data preparations/migration, and issue resolution, and potential future data transition requirements) are factored into the contract and pricing.

Remember that data-related work is rarely a one-time event, so it will be important to specify, scope and assign ongoing processes – and relative accountability – around data (data governance).

Indeed, the success of any project requires that internal teams also allocate sufficient time and resources to its effective delivery. A good contract should protect the interest of both parties.

Be prepared – and pragmatic.

A final, but important, point in assessing potential suppliers is to consider what they will be like to work with on a day-to-day basis. Every company has its own culture, set of beliefs, and way of working, and a good match will help ensure a harmonious relationship and optimum outcome.

Not everything can be controlled, but being precise about what's needed, and well prepared for every eventuality, can go a long way in ensuring a project's successful delivery.

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