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Building the business case for better Regulatory Information Management

3 key considerations

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It's that time of year when many life sciences organisations will be reviewing their regulatory information management (RIM) capabilities. This means they'll be determining what they need to see them through not just the next wave of mandatory submission and reporting requirements (eg under EMA's implementation of ISO IDMP) - but also a future in which digital process efficiency is the new normal.

? So what should some of the key considerations be when surveying what's on the market, and what does a robust and futureproof RIM capability look like in 2021 and beyond?

At a recent DIA event, a senior Regulatory executive from a global pharma R&D company retraced the decision process it had been though, explaining its RIM ambitions.

Defining the bigger picture

From the outset, the company has been keen to deliver something with strategic business benefits beyond streamlined global submissions management.

In translating its goal into key system requirements, the team posed three critical questions:

1. In relation to efficiency: how do we use our resources to bring products to market faster and maintain existing products with less effort?
2. Linked to discovery: how do we create that environment for essential information 'discovery'?
3. In terms of data: how do we reduce human transcription, intervention and rework?

The company's strategic goals indicated the need for an intelligent, unified content and process management platform – with the scope to allow teams across a global business to connect with the documents, data and insights they need to accelerate and optimise the work they do.

The initial ROI was calculated on the basis of reduced IT cost and complexity, linked to having:

- Fewer systems
- Fewer hand-offs
- Less complexity in the end-to-end process

But the scope for improved outcomes extends much further. This called for the following next-level considerations as part of the RIM RFP process.

Goal 1

Process efficiency & automation

Bringing products to market faster and maintaining existing products with less effort - moving away from separate labelling processes, etc - and shaping universal best practice.

Here, look to establish:

- Global submission process standardisation;
- A collaborative global approach to submissions;
- Total traceability & information; and
- Universal access.

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Goal 2

RIM-based discovery

Fostering an environment for essential information discovery - giving users faster and greater visibility to credible at-a-glance information about what's registered, and where.

To this end, start by determining what questions users typically ask of any existing RIM set-up, or of their colleagues. For instance: *Is this currently approved? Am I using the right information? Was this submitted locally? What did the HA say? Have we answered this before?*

The new system should be able to get to these answers consistently and reliably within a click or two, and show how the dots are joined. This requires the ability to create relationships between documents, data and other content sources (eg email trails) so that users can quickly build a picture of 'how we got there'.

Look for capabilities that help to establish:

- Current Approved Power
- 'Where Used' Discovery
- 'Smart' Submission Generation

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Goal 3

Improved data, content, and dossier management

Reducing human transcription, intervention and rework. This will require improvements in data, document and dossier-management processes - through the deployment of optimal RIM system functionality and automation.

Priorities here should include:

- Process clean-up & understanding
- Data clean-up & understanding
- Construction of a 'web' of related regulatory information
- Support for re-use and visibility
- Templates & process standardisation

A unified approach

Generis CARA Life Sciences platform – with its rich content creation tools and, crucially, its positioning as a unified platform - supports all of these capabilities, whether the ambition is to implement everything immediately or incrementally over time.

CARA supports interconnection of all global Regulatory activity, enabling reliable end-to-end data sharing and real-time status visibility.

Because it's a platform you can keep adding to as a business (it's easy to build new applications on top of it), the investment paves the way to link in more functions, processes and content to support additional use cases and business benefits over time.

If your own vision is to run Regulatory Operations in a smarter way, supported by richer knowledge about processes and their performance, these are the kinds of considerations to include as part of any RIM-based RFP.

Let's have a conversation about your RIM needs

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