The Promise of Enterprise RIM – What's Slowing the Innovation Potential?

By Steve Gens and John Cogan

Executive Summary

Regulatory Information Management (RIM) is one of the highest priority investment areas in Life Sciences R&D today, driven by the need to greatly improve the efficiency of regulatory globally, currently averaging 43% across 18 RIM capabilities[1], and manage regulatory information as a true enterprise asset. The convergence of updated suites of tools, either from single organizations or through partnerships and alliances, the maturing of technologies for process and task automation, and a real focus on Regulatory Operating Models to reduce the cost and improve the efficiency of Regulatory Lifecycle Management has provided a truly interesting time for RIMs potential. In addition, artificial intelligence (AI) is being explored and will add an additional value dimension, although pragmatic use cases have yet to fully materialize.

In this paper, we will examine why – even now – this RIM transformation narrative still remains all too familiar with discussions still focussed on cloud vs on-premise, suites vs best of breed and capability-oriented discussions about documents, registrations, publishing, labelling and archiving. These feel like only incremental improvements from where we were 20+ years ago, where ICH standards work led to the standardization of e-submissions (eCTD) in many markets.

We contend the way we think about RIM is fundamentally outdated and is significantly damaging our ability to fully advance the Regulatory Affairs function. In this paper, we will examine a multitude of contributing factors and propose some new approaches, as the potential business benefit is significant! You may not agree with some of our points and that is fine, as our goal, first and foremost, is to stimulate the conversation to move Regulatory Affairs to the next level. We would, however, ask that as you read this paper, think about this: How would Amazon do RIM in their complex ecosystem?

Background – how did we get here, what's holding us back

Over 25 years ago, we began to examine ways to make Regulatory Affairs more efficient by establishing a function called Regulatory Operations and investing in technologies like Documentum and CoreDossier to move away from the traditional paper-based approach to Regulatory submissions. We had come out of the 1980's and early 90's where typewriters and tippex were as common as computers, and "all hands-on deck" was used to compile paper submissions and load them into trucks. Fast-forward to a world where modern smart phones have more computing power than NASA had when sending a man to the moon, and where we are networked way beyond LANs and WANs with 4G/5G connectivity. We have more computing power and storage than we'll ever need.

When our industry first tackled RIM, we rightly focussed on the core areas that had the highest impact, namely moving the creation of documents from paper to electronic, investing in publishing tools to dramatically shorten the time to get submissions out the door and in registration databases to track what products were registered where and manage renewals and commitments. Business cases were simple, reduce the time to agency submission by multiple months and budgets were

[1] 2018 Gens and Associates World Class RIM: Connections to Supply Release, Product Change and QMS survey of 70 companies

approved quickly. Indeed, this approach had success. We talked about doing new drug applications in waves, with different countries being in each wave, and we rapidly moved to global, simultaneous submissions. While this was the first stage of regulatory innovation (1995 – 2010), it stalled for many years as emerging agency standards were cancelled (e.g. remember the PIM initiative) and dominance of a small group of software providers had little incentive to innovate. Regardless, today every medicinal product is either registered in every desired market, or can be registered there in very short order. This success has given us another growing challenge: maintaining these global registrations (Lifecycle Management), which consumes ~70%+ of all regulatory resources today with the growing volume and complexity. More on this later.

Whether by accident or design, this initial "system"- or "capability" based approach to Regulatory technology has defined our view of how to approach this topic. The vendor community has aligned in this way having several different orientations, i.e. documents (EDMS), data (Registration Tracking) or an application (Publishing). Only in recent years has the recognition emerged that an end-to-end, process-orientated view of Regulatory may be required, with documents and data being artefacts in those processes rather than the central-point of them. Certainly, the emergence of RIM suites & best-of-breed alliances is moving the ball forward in this process thinking approach, and is also bringing much needed master data management to RIM, driven in part by regulation such as SPL and IDMP.

The burden of Regulatory Lifecycle Management, despite the rather un-sexy nature of the work, is also contributing to this process-based thinking, particularly as organizations transform their operating models to blend resources on-shore, off-shore and near-shore either insourced or outsourced. However, labour arbitrage either internal or external, remains the dominant thinking in operating model transformation, with the opportunity to standardize, streamline and measure regulatory processes receiving only secondary attention. Lifecycle management activities such as CMC and labelling changes consume huge levels of resource, and are obvious candidates to start and drive this cross-functional process thinking. Despite all of the activities in this space, there is still little to no discussion about process definition or standards, such as resource management or user experience – a hint as to the areas we will explore later.

We should also briefly address a few other factors that may be holding us back, because these factors contribute to the culture in which Regulatory Affairs and the wider R&D organisation operates. We are not going to focus on these any further, but in brief:

- **Gross profit margin vs the propensity to innovate**: Thinking about highly innovative industries with low margins / dynamic market forces (consumer products, oil & gas etc.), it could be proposed that the propensity to innovate is inversely proportional to gross profit margins. When margins are small but volumes are high, the benefits of a few percentage points can dramatically impact the bottom line. Biopharma, on the other hand, has enormous gross profit margins, with benefits of a few percent getting dismissed as not worth the effort. The Biopharma industry can afford to be inefficient, however, with the current patient uproar over prescription drug prices in many markets, this era may be ending with the needed reduction of product prices globally!
- **Validation, QA, risk aversion**: This brings us to another observation; our large gross-profit margins have allowed us the luxury of building a whole industry around validation, quality assurance and risk aversion. We contend that these functions are vastly over-engineered (they cross the practicality line) and are significant constraints on technology innovation in Life Sciences. 21 CFR Part 11 has a lot to answer for, but that was 20 years ago. It's time to

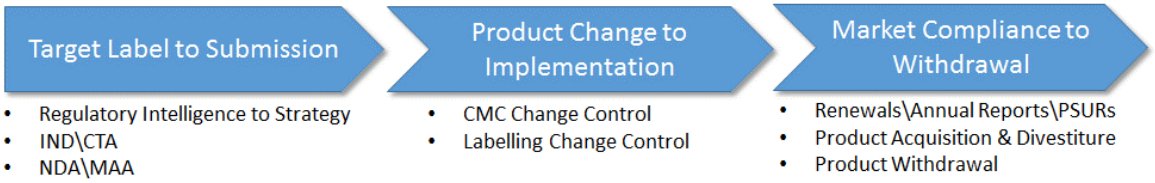
move on despite what all the entrenched vested interests may tell us. If you don't believe this, try having a discussion about agile development methodologies in R&D!

- **Perfect is the enemy of good**: The cultural mindset for most in regulatory is one of perfection - "It needs to be perfect before going to the health authority". Regulatory staff are the gate keepers and this mind-set is required, but can get in the way of innovation and continuous improvement. Other functions have a mindset of constant improvement such as manufacturing (how do we reduce waste and cycle times on the manufacturing line daily) and sales (improve the product launch process before the next launch) that support innovative "outcomes". For regulatory, in our experience, there are many innovative "aspirations" and "concepts", but the struggle is with the details and outcomes. While the increasing pace of technology options (RIM platforms and value-added tools such as AI) are getting the attention, it is the hard work of end-to-end process improvement, role modification and moving decision-rights lower in the organization where most regulatory organizations struggle. Experimentation with "good results" moves the performance dial while awaiting the perfect solution leads to "treading water".

An alternative future (what would Amazon do?)

Regulatory Affairs is the execution of processes in order to get new products to the global market and then to keep them there. Why is it not as simple as this? Going a little further, what exactly are these processes and where do they start and finish? There is a growing narrative in lifecycle management to define these processes in more depth (CMC change, labelling, renewals, etc.), with many organizations embracing some level of process review as part of RIM transformation or modernization initiatives. However, most of what we see today is a limited approach that may deliver "incremental value". To explore this, let us look beyond Regulatory and R&D into other parts of the organization.

It is reasonable to say that in many parts of the organization, ERP systems are all pervasive, whether this is in Finance, HR or Supply Chain. What is remarkable about ERP is the total focus on process above all else. You will hear terms like "order to cash", "procure to pay", "record to report" and "hire to retire" as the all-encompassing definitions of how these systems operate. Multiple sub-processes hang from these high-level processes, but as a rule, these processes are accepted as standard and their definitions are well understood. Now compare this with Regulatory, where there is no industry-wide definition of Regulatory processes. If you are in any doubt about that, ask five of your regulatory colleagues how long it takes to do a Type IB variation in the EU, for example. Each of them will assume different start points for what is in scope, and therefore give wildly different responses. Could Regulatory Affairs be simplified in this ERP way? Could we agree on these three high level processes to cover everything we do?



A number of sub-process would no doubt flow down from these, but we suggested these should also be limited to a handful or less.

Apart from having defined and agreed on standard processes cross functionally; the other benefits of a process-orientation are more profound. We would consider master-data as a fundamental "leg on the table" – systems participating in the end-to-end process need the same lexicon. This conversation that was heightened with IDMP assessment is still not mainstream, let alone in a production environment. We would also focus on managing the process end to end; this would include managing the resources required to execute the process, process ownership as an organization strategy, clear measurements of the process from end-to-end to identify improvement opportunities and a technology approach that moved these process through our organization in a digital way, rather than each step requiring an email to the next person and a record made in an offline excel tracker. We would also ensure that the user interface / experience was optimised to ensure maximum performance from all actors in the process, especially those that are infrequent users (e.g. may use the system once a month) who typically account for 80% of the population.

Finally, have you thought about what Amazon would do? Firstly, the whole offering would be focused on the consumers rather than the participants. Those functions directly relying on the outputs of Regulatory processes (e.g. health authorities, supply chain, business leadership) would be at the center of the system design. All participants in the process would have an optimized user experience, regardless of their role or geographical location. The process would be underpinned by a single, common set of master data, and all activities would be managed within the system. It would be possible for business leadership to see the performance of the process in real-time (like your Amazon order), to make decisions about demand management, unit costs and resource optimization. This view of RIM is very different from the current conversations about capabilities like document management, registration management publishing or archiving. These capabilities are merely building blocks to deliver the processes to the consumers. This is why we see RIM entering a new phase where enterprise connectivity and information throughput are key principles[2]. Amazon connectivity to thousands of third parties with information throughput is a critical success factor to what we enjoy today: only a few clicks from your search to the order confirmation!

Considering all of this in the context of Regulatory Affairs, the time is now to embrace a new paradigm of end-to-end process thinking, master data as a critical corporate asset, agile continuous improvement and rapid experimentation. Otherwise this might be as good as it gets – disconnected information and manual data quality reviews that kill productivity. As an industry (sponsors, consultants and vendors), we have an opportunity to collectively change the game by a modest shift in thinking, orientation and embracing calculated risks.

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[2] 2018 World Class RIM Whitepaper: Fall Edition (www.gens-associates.com)

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