The Year Ahead for Life Sciences Regulatory Operations

Amplexor asked some of its closest partners for their views on the most important developments in Life Sciences regulatory operations in 2022, and for their predictions for 2023. Renato Rjavec of Amplexor Life Sciences shares their input.

Of the most prominent issues facing Regulatory functions, Steve Gens sensed renewed urgency around improving global ways of working, particularly around reducing the time for market approvals.

Gens & Associates, which has been tracking RIM-related improvement activity closely, has observed increased application of modern technology and digitisation focused on improved ways of working and process enhancement (change control, label management, regulatory intelligence) at an end-to-end level.

There is general agreement now that the shift away from inconsistent manual, document-oriented processes towards agreed use of standards-based data will be pivotal to transforming key processes. Remco Munnik noted that, up to now, Regulatory has always been the "spider in the web" within a pharmaceutical company – collecting all of the relevant information for submission of the registration: Clinical, CMC, administrative data, etc – then compiling a valid eCTD by the submission deadline. In future, all of this will be data driven, he said – requiring a different approach to managing everything and ensuring its quality.

Kelly Hnat observed that the current advance toward structured data and new submission paradigms would have benefits for Regulatory, and across the enterprise, as the value of clear, accurate and complete data representations of registered medicinal products is tapped.

Resourcing to Meet Condensed Timeframes

The potential for transformed processes may be considerable, but the industry faces ongoing challenges in getting to where it would ideally like to be. Tris Nockles highlighted the challenges for organisations in assembling the right resources to meet increasingly condensed timeframes for submissions.

"Finding people with the right skills to work in Regulatory, which has been problematic historically, seems to have become a more difficult and lengthy pursuit in recent years," she said, noting that it can take 6–12 months to onboard mid-level and senior staff these days. "On top of that, technology is under-delivering in many cases," she added. "It's not uncommon for companies to augment their RIM capabilities with more friendly technologies to capture and feed data in, or look to flexible resourcing to enter data on behalf of their Regulatory staff."

With the twin challenge of speed of delivery in a highly competitive job market, Tris said, companies will need to consider new and innovative ways of filling the staffing void, whether through flexible resourcing (outsourcing/offshoring) and technology and automation to enable routine operational work, or adjusted talent strategies that value technology-savvy newcomers in the workforce.

Evolving Organisational Structures

Other considerations as companies extend their ambitions are the need for more formal organisational change, as the growing flow of standardised data paves the way for new process fluidity across functional boundaries.

As Steve Gens put it, "Companies that are modernising RIM now are focused on evolving the regulatory operation organisation – driven by the data sciences and advanced technology including robotic process automation, structured content generation, and connectivity to other critical functions such as Quality, Manufacturing, Safety, and Clinical.

"We are in the early stages of the 'data connectivity' period, he said. This in turn requires a clear focus and excellence around cross-functional data governance, he explained. It is where the promise of cross-functional business analytics, real-time information visualisation, and advanced technology will play out. "What we're witnessing is the birth of the data science era," he summarised.

Becoming Data-driven

With EMA's direction toward agile development now, pharmaceutical companies too must become agile - in terms of adapting their own processes and systems, Remco added. "The biggest challenge ahead is for companies to become more data-driven organisations, and to adapt complex processes and transform the content from large volumes of legacy documents into more dynamic, reusable data," he said.

Ultimately the challenge ahead is a business process one, though. Kelly urged change in the way Regulatory product teams work with technology to facilitate this.

To get to where they want to be, companies now need to develop a clear digitisation strategy in conjunction with other functions such as R&D and Manufacturing, Steve said. That's in addition to improved information exchange at a local affiliate or "last mile" level, where further innovation is required. These two factors, if addressed appropriately, promise to greatly enhance both the efficiency and effectiveness of the Regulatory organisation.

Above all, companies need to reset their strategy now, adapting as they go, so that they can deliver more data-driven ways of working without the scale of the opportunity, and the associated challenge, becoming too daunting.

Business Processes Trump Technology

In 2023, companies need to become better at central, regional, and local affiliate collaboration and information management, Steve said. "Lost opportunities persist when it comes to improving how real-time regulatory information is available globally, to support day-to-day operational tasks across different markets," he warned.

On top of that there is substantial untapped scope to strategically improve the 'time to patient' for new products – especially in the smaller markets around the globe. Improved regulatory intelligence sharing; global dossier management excellence; and the central organisation working more seamlessly with the local affiliate will be critical success factors going forward.

Kelly highlighted that the key to success will ultimately always be manifested through business process and organisational culture: "Top-performing organisations excel at the process and organisational work, along with strong implementation execution. These strengths can overcome the weaknesses with almost any software platform... but the opposite is never true." Clearly, organisations should be careful not to rely too heavily on technology and tools to solve their problems.

Steve Gens

Steve Gens, Managing Partner, Gens & Associates, a boutique Life Science benchmarking and advisory firm specialising in operational performance improvement, benchmarking, World Class RIM℠, and organisational transition for the regulatory domain – including closer integration with clinical, commercial, safety, quality, and health authorities.

Remco Munnik

Remco Munnik, Associate Director, Iperion – a Deloitte business, a subject matter expert in RIM, eCTD, xEVMPD and ISO IDMP.

Kelly Hnat

Kelly Hnat, founder and Principal of K2 Consulting (k2rim.com), a Regulatory Information Management and IDMP expert and active participant in the EMA SPOR Task Force.

Tris Nockles

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Renato Rjavec

Renato Rjavec is Director of Product Management at Amplexor Life Sciences. Amplexor helps organisations that are developing pharmaceutical drugs, medical devices, and biotechnology to launch products and break into new markets quickly using innovative end-to-end regulatory and quality management solutions. Its solutions and services expedite the management of highly-structured data and the creation and delivery of consistent, compliant global content. Amplexor's services include technology consultancy, implementation, and management services.

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