

Affiliates Want a Substantially Increased Role in Transforming Global RIM, Finds a Major New Global Study

New research has confirmed that in-country Life Sciences company affiliates feel unrepresented in the pursuit of streamlined regulatory information management on a global scale. In the light of this, central organisations must determine how to increase participation in efforts to improve global RIM design, to maximise efficiency for everyone and to drive a tangible return from now-sizeable RIM investments. Steve Gens of Gens & Associates analyses the findings.

Regulatory excellence in Life Sciences companies depends on a combination of process optimisation, effective global systems, high data quality, and enhanced affiliate collaboration. One weak link in that chain could risk compromising all the other efforts and investment. Yet, in too many cases, highly manual processes, specific local market requirements, and inconsistent use of tools have left a gap in global information visibility for pharma organisations of all sizes.

This oversight is adding risk to key regulatory processes and undermining the potential return on investment in regulatory information management systems (RIM) – the subject of extensive spending over the last 15 years across the industry.

The role of affiliates, and their contribution to RIM success (or not), has been the subject of important new research we have just published at Gens & Associates. It is the most comprehensive available study performed to date, which explores the evolving role and importance of local affiliates, in efforts to make global regulatory processes more dynamic consistent and effective through optimised systems and tools. Such processes include submission forecasting and planning; product registration management; health authority interactions and commitment management; local label management; submission content management, and archiving; regulatory intelligence management; and promotional material management.

Progress is Evident, but More Work is Needed
Our latest research includes detailed feedback from 320 local offices/affiliates

representing 94 countries. The affiliates represented 20 sponsor companies, most of which yielded between 10 to 25 affiliates of varying size and geographic location to participate in the research.

Although this is the first time, we have investigated the affiliate perspective in such detail, we have been charting various aspects of affiliate operations in managing regulatory information as part of our World Class RIM study program for around a decade.

This has enabled us to compare the current findings with a baseline, and we have determined that companies are now roughly halfway to achieving a strong level of operating performance from a local affiliate perspective. For example, many companies are striving to reduce the time from first market to last market regulatory submission by 50% (cutting 9–12 months from this critical cycle).

As things stand, 52% of the time spent by affiliates on managing their regulatory processes continues to involve use of local and regional tools, in addition to or instead of global, authoritative systems. The remaining 48% of time is now used in centrally designated platforms which is encouraging, and represents a significant improvement on the 13% reporting the same back in 2015. Clearly, there is still work to be done to further streamline operations.

As long as affiliates continue to default to manual processes, spreadsheets, and local file shares to manage their information and documents, there will be inefficiencies both locally and centrally. That's as work is duplicated, and as manual verification steps are performed to locate definitive, authoritative content or insights. This time-consuming work is not adding any value, and those resources could be used much more constructively if affiliates were better served by RIM systems and processes.

Breaks in the Chain

Even when new system capabilities have been extended to local affiliates, the benefits aren't always being felt, the research reveals. In the current study, almost a third

of affiliates say recent system and process investments have failed to improve their situation. In other words, they continue to struggle with their ability to use global RIM systems and efficiently manage regulatory information for both local and global consumption. This confirms our suspicion that affiliates do not feel well served by the IT systems and processes dictated by central operations, because they were not the target user group when those facilities were being designed.

One of the most striking findings is that smaller affiliates feel most acutely overlooked when it comes to inclusion in terms of system and process optimisation being tailored to their needs. Most companies request local affiliate participation from the larger affiliates as they are more likely to have the resources to support global initiatives. This brings “bias” to the local affiliate needs as often the small offices have individual resources doing both regulatory, quality and safety activities. If such concerns were addressed, they would be able to comply with internal global RIM expectations set by the central organisation more easily and efficiently.

Closing the Circle to Achieve RIM's ROI

Based on our estimates, Life Sciences companies have collectively spent some \$1.9 billion over the last five years on global RIM modernisation at a system and process level. Yet up to now they have not achieved the desired 360° transformation. What's needed is the next leap in delivering end-to-end regulatory information management from a cross-functional standpoint. But this will require that more affiliate feedback is incorporated as part of new enhancements – both to vendors' software and more critically, to internal processes.

The study asked “what one investment would affiliates like to see improved about regulatory information management”; they most commonly responded they wanted greater simplicity. This reflects the view that there are still too many steps to locate information or complete tasks, as the top three “simplification” themes were better integrated systems, improve system usability / training, and simplify processes / role



clarity. The current complexity impacts common daily tasks but has a much greater impact in critical processes such as label compliance, tailoring core submission packages, and managing variations.

A Proposed Solution to the Affiliate Challenge

Formalising feedback loops to ensure affiliates have a way to voice ideas for solutions, or help identify affiliate specific inefficiencies, is an effective way to build up and support affiliate engagement. Meanwhile, when new system or process changes are introduced, affiliates share a common issue, that the training often isn't specific enough to the affiliates circumstances or requirements, so this needs to be addressed too.

Also, a lot of time is being spent on data and content verification and it is here again that central organisations could step in and make a positive difference, to the benefit of all parties. This is because, without a definitive source, and without full transparency globally, there is a risk that the wrong information will be used. Striving for a single, and effective, authoritative source of truth remains a core goal for most regulatory

organisations, to maximise the ROI of global RIM investments.

Although, when we scored companies on their global RIM capability including affiliate contribution, only one company qualified as a 'strong' performer. What was interesting to the research team is that 16 of the 20 companies' performance scores were very close, which implies most companies share the same challenges and opportunities. Progress is being made; however, we are not at a stage where a definitive 'best practice' is emerging for affiliate inclusion.

Communication is the Key in Making Affiliates Feel Heard

For software and service providers, as well as for central regulatory teams, the message is to be more proactively inclusive in bringing affiliates into feedback loops, and into future system development.

This should also involve discerning the differences in the needs of very small affiliate teams (e.g., with under 5 people), and larger in-country teams. Conducting a 'day in the life of' fact-finding activity would go a long way here. Optimised processes and solutions could then be adapted intelligently, so that

only the relevant fields are presented to the local affiliates.

Improving engagement with affiliates requires structured communication and transparency. Where affiliate requests cannot be accommodated, for instance, it is a good idea to communicate the reasons back to affected users to validate their input. This also enforces the feedback loop for all parties.

A white paper on the wider theme will be published next year.



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