IQVIA TECHNOLOGIES

White Paper

Digital Transformation of Regulatory Affairs

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Introduction

Global Regulatory Affairs (RA) teams have made tremendous strides in moving from the broom cupboard to the boardroom in many companies, however, in some organizations, they still struggle to be seen as a professional market-access function.

RA professionals can often be viewed as part of an administrative function that is engaged in transactional document activities with global regulatory agencies. The result of this is that, when it comes to product development activities, they are pulled in late to project discussions, have to retrospectively create a global regulatory strategy rather than optimize a global approach from the beginning of a development project's infancy, and often need to engage in accelerated remediation activities and close out gaps that could create delays in global submission and registration approvals. When RA teams are viewed as a necessary evil, rather than a respected, strategic, market access function, an organization is introducing risk into their design and development projects that can create significant delays to market launch times, revenue generation, and patient access to healthcare solutions.

An evolution of perception and execution is needed within organizations if they are to maximize the talent available within their global RA teams.

The global regulatory environment has changed at a faster pace than many organizations' global RA operations. Global RA professionals are managing an increased number of regulated markets, with increasing local variation, ever-evolving requirements, and a reduced room for error in global RA operations. The volume of information global RA teams track, from registration approval data, to correspondence and commitments with global regulatory agencies, to labeling changes and product lifecycle management activities that can affect a submission's status, has become harder to manage with legacy ways of working that often use spreadsheets, SharePoint sites and emails blended with legacy technological systems. The benefits of global RA professionals leveraging AI and end-to-end automation are no longer side conversations. Their value in a range of use cases including, but not limited to, submission authoring support, submission content review, change detection and impact analysis, and submission operations is being actively discussed in many RA forums. Yet many organizations are still asking their global RA teams to work across disconnected systems including spreadsheets, emails, shared drives, and local trackers.

The uncomfortable truth is that if RA is working in such a manner then much of their time is being invested in transactional activities, reconciling data, and holding together disparate systems rather than being focused on professional RA activities that support innovation, commercialization and patient impact activities. The global RA function has to move from document coordination to decision support, and it does not have the luxury of waiting as any delays impact patient access to healthcare solutions.

Legacy RA operations need an evolution

Global RA teams often define success with submission approval rates, the reduction in questions and queries from global agencies, and the timeliness and predictability of global registration approvals. Behind each of these success criteria is a team of RA professionals who connect disparate systems, curate information to meet local requirements, and engage with global regulators to ensure the company maintains a credible presence throughout the submission process. This work is still absolutely critical; however, the evolution to empowering teams with end-to-end, AI-enabled Regulatory Information Management (RIM) solutions removes much of the transactional, administrative burden and opens up global RA teams to spend more time on professional, scientific, engaged activities that drive optimized registration approval times and improved market access.

These next generation RIM solutions support global RA professionals in navigating changing regulator and health authority expectations. When local requirements change, the ability to rapidly identify the change, understand its regulatory impact, and determine which existing registrations and in-flight submissions are affected provides a significant strategic and operational advantage. The shift from document-based processes to structured data is accelerating automation while creating the trusted foundation required for the efficient, controlled, and compliant use of AI in healthcare's GxP environment. Regulatory intelligence is becoming increasingly strategic and is closely linked to effective RIM solutions. This technological evolution has the potential to transform not only global RA teams, but also a company's approach to design, development, and innovation, creating significant opportunities to improve commercial performance and operational execution.

In effect, the adoption of digital, AI-enabled RIM solutions, coupled with a shift toward recognizing global RA teams as critical contributors to innovation, is elevating more RA professionals from the broom cupboard to the boardroom as trusted strategic advisors.

However, for companies that claim to be modernizing global regulatory activities when all they have done is deploy a new system while leaving their operating model unchanged, that is not transformation.

If RA teams still have to reconcile registration data and submission content across disparate systems, manually upload registration status to company ERP and PLM systems, and email spreadsheets around to operational and marketing teams to answer basic questions around what products are available in which countries for sale, the core operating model has not changed. True transformation occurs when companies center around the core deliverable of timely market access of healthcare solutions in all target markets, align operational processes and teams accordingly, and accelerate professional activities through deploying end-to-end, digital RIM capabilities that ensure RA teams have a deeper pivot from transactional to strategic, scientific activities.

The value of the global RA evolution

Legacy, analogue operating models do not hold up well under current regulatory pressure. Bringing global RA teams to the table late in an innovation project has significant risk. Country-specific regulations and product-specific requirements may be overlooked, and that is particularly acute in countries that require standalone technical, toxicological and/or clinical activities, or where thresholds in global standards are tighter in the local country transposition. Missing these nuances and variations can result in the need for product redesign, generate unforeseen remediation costs and delay market access. That has a direct impact on a company's ability to generate revenue and a patient cohort's access to healthcare solutions.

RA should not be the function that gets involved last. One of the biggest opportunities for change that drives significant value is to engage global RA teams early in innovation projects to support the setting of a global regulatory strategy. These RA teams would influence market launch sequencing and labeling strategy through the identification of requirements and predicates, define evidence expectations in global submission content, identify change control impacts and necessary implementation activities, and explain what is actually feasible in each market. These teams provide insights that influence launch sequencing, evidence generation, market prioritization, and regulatory risk management long before a submission is assembled.

In too many companies, RA is still treated like a function that reviews decisions after the innovation project timeline is already set. Turning this around is key and involves operational changes such as:

Clearly identifying target countries for product launches so that country specific regulations can be included in the original design, and so that local technical, toxicology and clinical activities can be built into project costs and times.

Involving global RA teams in manufacturing, formulation, packaging, and labeling changes before decisions are finalized, so the impact on existing registrations, implementation timelines, and remediation costs can be quantified.

Reducing the costly and timely impact of remediation activity from including RA teams in innovation projects so as to avoid surprises of identifying gaps to local requirements during importations.

These key changes require a pivot in organizational culture and an evolution in how global RA teams are viewed. Technology certainly matters; however, a successful transformation from legacy regulatory operations into next generation technology requires a shift in mindset if the full benefits of AI-enabled, digital RIM solutions are to be realized.

Modern RA teams are navigating a very different level of complexity than they were five years ago. Core regulatory judgment is still the foundation of the role, supported with the need to explain with clarity a consistent viewpoint, backed by science, in a regulatory submission. That does not change and is critical to the RA role. But now this must be paired with data literacy, stronger analytical thinking, comfort with digital platforms, and a practical understanding of where AI helps, where it fails, and what still needs human review if these teams are going to take advantage of the latest RIM technologies.

This is where some organizations may get exposed.

They are investing in RIM platforms without investing sufficiently in workforce capability, digital literacy, and operational change management. They are talking about AI-enabled RIM systems without establishing the foundations required to use them responsibly, including data governance and AI governance that are fit for purpose in a GxP environment. They are expecting strategic input from teams that are still spending too much time on transactional activities driven by legacy ways of working, such as status chasing, content reconciliation, and administrative clean-up.

That is not a technology problem. That is a business operation problem.

If organizational leaders want a more strategic RA seat at the table, they must build global RA teams that can operate like strategic advisors. That means better use of data, better interpretation of risk, stronger cross-functional influence, and better judgment in a world where not every answer comes from a document.

AI is not the future story. It is the maturity test

Many organizations still talk about AI as though it is a future decision. For Regulatory Affairs, it is already here. AI is being applied across activities such as content authoring, requirements monitoring, change detection, document comparison, and submission preparation. The question is no longer whether AI will be used, but where it creates value and how it can be governed responsibly within a GxP environment.

The real maturity test is not access to AI technology. It is whether organizations have the data quality, governance, operating processes, and workforce capability required to use it effectively. Organizations that deploy AI on top of fragmented data and inconsistent processes are unlikely to realize its full value.

AI does not replace regulatory expertise, accountability, or judgment. The most effective model is RA professionals supported by stronger data, smarter automation, and modern RIM capabilities.

The document mindset is holding the function back

Too many RA teams continue to organize work around documents first and data second. In a digital environment, that approach is increasingly limiting. A team can be efficient at managing documents yet still lack visibility into registration status, regulatory commitments, change impacts, and market readiness across a global portfolio.

The foundation of a modern regulatory function is trusted data. Product registrations, submission history, market status, labeling relationships, commitments, deadlines, and dependencies should be connected, visible, and actionable. When that foundation is weak, regulatory teams spend more time reconciling information than generating insight.

The future of RA is data-driven and strategically engaged. Organizations that combine strong data foundations with AI-enabled RIM capabilities will be better positioned to improve decision-making, accelerate market access, and support the delivery of safe and effective healthcare solutions worldwide.

Positioning global RA as a strategic differentiator

If you are leading regulatory transformation, the next question is not what technology to implement. It is what role you want RA to play within the business. The organizations gaining the greatest value from RA are not simply processing submissions more efficiently; they are using regulatory insight to improve decision-making, reduce development risk, and accelerate market access.

There are five priorities for regulatory leaders driving this evolution:

Build a trusted data foundation.

AI, automation, and advanced RIM capabilities are only as effective as the data that supports them. Data quality, governance, and visibility should be established before scaling more sophisticated digital initiatives.

Measure business impact, not just regulatory output.

Submission volumes and approval timelines remain important, but they are lagging indicators. Regulatory leaders should also measure contribution to development decisions, risk reduction, launch readiness, and market access outcomes.

Develop strategic capability within regulatory teams.

Future-ready RA professionals will need more than regulatory expertise. They will require stronger data literacy, greater business understanding, and the ability to influence decisions across functions.

Redesign operating models, not just technology platforms.

Digital transformation delivers limited value if legacy processes, handoffs, and organizational bottlenecks remain unchanged. The greatest benefits come when technology, processes, and operating models evolve together.

Position Regulatory Affairs as a market access enabler.

At its best, RA helps organizations make better decisions earlier. When regulatory strategy is embedded in innovation, development, manufacturing, and commercialization activities, companies can improve launch predictability while bringing healthcare solutions to patients more efficiently.

The most successful organizations will not be those with the largest regulatory teams or the newest systems. They will be those that combine regulatory expertise, trusted data, modern technology, and strong governance to make better decisions across the product lifecycle. In that environment, Regulatory Affairs becomes a strategic business capability rather than a function measured solely by submission throughput.

Final thought

Organizations need to rethink the role RA plays in innovation, market access, and business performance with the overarching goal of positioning RA to influence critical business decisions earlier and with greater influence on market access activities.

The organizations that realize the greatest value from digital transformation will be those that build trusted data foundations, modernize operating models, develop strategic capability within RA teams, and create the conditions for responsible adoption of AI.

The future of RA belongs to organizations that move beyond a document-centric mindset and empower regulatory professionals with connected data, intelligent automation, and greater visibility across the product lifecycle. In these organizations, RA is engaged early, helps shape development and commercialization decisions, and plays a critical role in accelerating market access.

When organizations position RA as a true strategic leader with early influence on market access projects, the benefits on improved commercial performance and greater global accessibility to healthcare solutions are a significant market differentiator.

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07.2026.ATS. 26-CRS-2339-07JUL