IQVIA TECHNOLOGIES

White Paper

Speed Can Mislead: Why Velocity Matters Most in Global Regulatory Affairs

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Executive summary

Artificial intelligence is changing how MedTech and Pharma organizations manage regulatory data, submissions, and compliance. The expectation is straightforward: faster preparation, faster responses, and faster approvals.

But in practice, speed alone doesn't deliver better outcomes.

Many organizations are moving faster, but not necessarily in the right direction. Submissions are increasing across global markets, yet a growing number are delayed or rejected. Even when they are technically complete, issues such as inconsistent data, unclear lineage, and gaps in clinical or regulatory context often surface during review.

The problem isn't AI itself. It's how it's being used.

When AI is focused primarily on speed and output, it can introduce risk instead of reducing it. Errors get replicated more quickly. Inconsistencies become harder to trace. And instead of accelerating approvals, teams end up dealing with more questions, more rework, and more scrutiny from regulators.

What actually matters is velocity. Not just speed, but speed combined with direction.

That direction comes from context. It comes from understanding how data connects, how evidence supports claims, and how a submission will be evaluated in real-world regulatory settings. AI only adds value when it operates within that context and supports teams in building clear, consistent, and defensible submissions.

Organizations that get this right don't just move faster. They move more effectively. Submissions are stronger from the start, approvals are more predictable, and patients gain faster access to the products they need.

Speed does not equal faster approval.

When AI is optimized for throughput instead of contextual understanding, organizations move faster toward denials, rework, and regulatory risk rather than patient access.

The problem: Faster submissions, more denials

Regulatory teams are under increasing pressure to move faster while managing more complexity than ever.

Product lifecycles continue to shrink, and the nature of regulatory data is evolving. Innovations like software as a medical device, real-world evidence, combination products, and AI-enabled solutions are adding new layers of complexity. At the same time, many organizations are working with limited resources and a shortage of experienced regulatory professionals.

To keep up, teams have turned to automation and AI.

On the surface, that should help. In reality, the results have been mixed. Submissions are being completed faster, but approvals are not necessarily following. In many cases, they are slowing down.

The issue is not speed itself. It is the lack of direction behind it.

When submissions do not fully reflect clinical and regulatory context, gaps start to show during review. Regulators are also using more advanced tools, which means inconsistencies and issues are being identified earlier and more systematically.

Problems that could have been addressed upfront instead appear all at once, leading to additional questions, rework, and delays.

The pattern is becoming familiar: faster submissions, but slower approvals and higher risk.

Why speed-first AI falls short

Speed-first AI tends to fall short for a simple reason. It focuses on completeness, not correctness.

Many systems are good at checking whether required sections are present. What they struggle with is determining whether the content actually makes sense. Is it consistent? Is it accurate? Does it reflect what regulators expect to see? That is where things start to break down.

As a result, submissions can look complete on the surface while still containing contradictions or gaps that are easy for regulators to spot.

For example, inconsistencies between clinical evidence and labeling claims may pass automated checks but quickly surface during review, especially where regulators now have access to their own AI tools for consistency checks. When that happens, teams are pulled back into clarification cycles that could have been avoided.

Cross-functional alignment is another weak spot. Clinical, technical, quality, and regulatory inputs might all be correct individually, but still fail to come together as a cohesive story. Experienced reviewers will see those gaps immediately. Most speed-driven systems will not.

There is also a more fundamental issue. Regulations are not just checklists. They are frameworks used to evaluate patient risk, clinical benefit, and real-world use. When AI is built for throughput, it tends to treat them like a series of boxes to check rather than something to interpret and apply.

At scale, the impact compounds. AI does not just accelerate productivity. It accelerates mistakes as well, including hallucinations. And when flawed submissions are reused across regions, those issues multiply quickly.

Instead of gaining efficiency, organizations end up managing more scrutiny, more questions, and more rework.

WHY SPEED FIRST AI BREAKS DOWN

- Validates completeness, not correctness
- Misses cross-functional inconsistencies
- Treats regulations as checklists, not intent
- Scales errors as efficiently as it scales outputs

Shifting the focus: From speed to velocity and patient-centric reasoning

At its core, regulatory decision-making is about one thing: patient safety.

Speed only matters if it moves businesses towards that outcome. Intentional direction is what separates speed from velocity.

Velocity is not just about moving quickly. It is about moving in the right direction. In a regulatory context, that means building submissions that are grounded in clinical evidence, aligned with regulatory expectations, and clearly connected to real-world use.

Getting there requires a different approach to AI.

Instead of simply accelerating tasks, AI needs to support the critical thinking of global regulatory affairs professionals. That includes understanding clinical context, evaluating risk, and recognizing how different pieces of evidence come together to support a coherent submission.

When that happens, something shifts. Teams are not just moving faster. They are moving with more confidence and intentional direction.

Speed becomes a natural result of clarity and alignment, not something that is forced.

> *Every global submission must answer one fundamental question: Can the product be used safely and effectively?*

What patient-centric AI reasoning really means

Patient-centric AI reasoning for regulatory affairs goes beyond automation. It is about applying information and reasoning to the clinical context of the regulatory submission.

At a practical level, this means looking at a submission as a whole and asking whether it tells a clear and credible story about patient outcomes.

Are risks identified and addressed consistently?
Does the clinical evidence support the claims being made?
Do the technical, quality, and labeling elements align with each other?

These are the kinds of questions regulators ask. AI needs to help answer them.

That requires connecting data across sources, not treating documents as isolated inputs. It also requires focusing attention on what actually matters, particularly issues that could affect safety, performance, or regulatory confidence.

AI plays an important role here, but it does not replace regulatory expertise. It supports it.

By surfacing inconsistencies and highlighting risk, patient-centric AI helps teams build stronger, more defensible submissions from the start.

Ultimately, regulatory work comes down to a simple question:
Can patients and healthcare professionals trust this product to be safe, effective, and used appropriately?

Embedding artificial intelligence into regulatory activities

AI has the most impact when it is built into the way regulatory work actually happens, not layered on top as a way to move faster.

In practice, that means embedding AI directly into regulatory processes. Strong AI-enabled RIM solutions do more than process documents. They work within the full regulatory context, checking for consistency across submissions, variations, and renewals, aligning claims with supporting evidence, and keeping regulatory content in sync with quality and labeling.

When this is done well, teams start to see issues earlier. Potential objections can be identified before submission. Deviations from prior approvals become easier to spot. Risks that could affect patients can be addressed upstream instead of showing up late in the review process.

Over time, these systems get better. As they learn from regulatory outcomes, they become more effective at identifying patterns of risk and helping teams avoid repeat issues.

That said, AI does not replace regulatory expertise. The accountability for the accuracy and completeness of a regulatory submission still sits with regulatory professionals. They are the ones who ensure that a submission tells a clear, accurate, and defensible story, grounded in both the product and its intended use.

A good example of where this matters is monitoring global regulatory changes and understanding their impact. This is only possible when the underlying data is clean, controlled, and relevant. With the right data foundations in place, AI-enabled RIM solutions can track evolving regulations, assess what has changed, and help teams determine what actions are needed.

That might include updating an in-flight submission, adjusting an approved product, or planning remediation activities before issues arise. Without strong data models, this kind of visibility just does not scale.

Organizations that invest in these capabilities operate very differently. Instead of reacting to issues as they appear, they anticipate them. Instead of moving quickly and fixing things later, they move with more precision from the start.

Why patient-centric AI delivers better business outcomes

Organizations that take a patient-centric approach to AI tend to see clear, measurable improvements.

Submissions are accepted more often on the first pass. Review cycles become shorter, without sacrificing quality. The amount of rework and remediation drops, which reduces both cost and pressure on internal teams.

Just as important, consistency starts to build trust.

When submissions are clear, aligned, and supported by strong data, regulators have more confidence in what they are reviewing. That translates into smoother interactions, fewer surprises, and better overall outcomes.

Over time, this consistency pays off. Approvals become more predictable, and regulatory processes run with less friction.

The impact goes beyond operations. It directly affects patients, who gain faster and more reliable access to safe and effective products.

The executive reality...

Faster submissions do not reduce regulatory risk.

Higher quality submissions do.

The future of AI in regulatory affairs

AI will continue to play a bigger role in global regulatory operations, but how it is used will make all the difference.

The most effective systems will not focus on speed alone. They will be designed to understand regulatory expectations, prioritize patient safety, and work within structured, compliant processes. This pivot to velocity, in other words moving with speed in an intentional direction that improves the quality of global regulatory submissions, is where the real value sits.

The goal is not simply to move submissions faster. It is to achieve approvals more consistently and with greater confidence.

When AI is aligned with patient-centric reasoning, regulatory teams gain more than efficiency. They gain a level of assurance that the work they are putting forward is sound, aligned, and ready to stand up to scrutiny. That confidence is what allows organizations to move forward with greater clarity and control.

That is what accelerates approvals that support the provision of safe and effective products in global healthcare markets.

About SmartSolve®: SmartSolve is an AI-enabled, Microsoft Azure-based platform that helps Life Sciences organizations streamline and automate global quality management and regulatory compliance. SmartSolve® eQMS centralizes enterprise-wide quality processes, from design and manufacturing to post-market surveillance, while SmartSolve® RIM manages regulatory submissions, product registrations, and health authority interactions. Built on industry best practices, SmartSolve connects teams, data, and workflows in a single platform to drive an optimized focus on patient safety, product quality and commercial performance.

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05.2026.ATS. 26-CRS-1656-05MAY