

Successfully Transforming Regulatory Affairs Through Technology and Innovation

Nick Littlebury, EVP, Regulatory Affairs at Coronado Research, discusses the latest trends in regulatory affairs and how companies can unlock the full potential of new technologies to reduce regulatory burden and help them focus on what matters most – the patient.

The pharmaceutical industry is undergoing a period of transformation as it embraces new technologies and artificial intelligence (AI). Until now, there has been a lack of focus on specific areas like Regulatory Affairs, but that is about to change. AI and automation are reshaping the way we work, allowing us to complete tasks not just more quickly and cost effectively but more comprehensively.¹

We are already seeing practical examples of how AI is being used to create pieces of evidence for the regulatory process. The use of generative AI (GenAI) to write Clinical Study Reports (CSRs) at Novo Nordisk is reportedly reducing creation time from 12 weeks to 10 minutes, with high quality outputs and lower staff resource.²

New technologies are also reducing staff burden and unlocking new possibilities in personalised medicines.³ However, to fully seize the opportunities on offer, companies and regulatory teams need to combine science and technology, while also keeping humans in the loop. Cross collaboration and innovation will be fundamental if we are to continue to ensure we are doing everything we can to get medicines to patients as quickly as possible.

Doing More with Less

Post COVID-19 has been a testing time for the pharmaceutical industry, with less funding overall. While there are signs of improvement, year-on-year companies must complete more regulatory activities with either the same or less resource.^{4,5} Regulatory professionals are resilient and have stepped up to the plate, but we cannot keep asking them to do that. We must find new ways of working. The answer often lies in innovation.

This is where new technologies offer a huge opportunity for the industry. AI and large language models (LLMs) free skilled professionals up to do more of what they should be doing rather than just keeping their heads above water. They allow people in Regulatory Affairs to do what they do best – the science – rather than focusing on scientific administration.

Instead of high operational burdens caused by repetitive tasks, AI allows us to apply greater strategic oversight. This allows regulatory professionals and teams to make even more of a positive impact which will ultimately benefit patients.

Embracing technology will allow organisations to work more effectively than they have in the past. Efficiencies enabled by new technologies like those outlined above may have a particularly significant impact on biotechs which are operating with limited budgets to get their medicines to patients.

Accelerating Personalised Medicines

The move to new technologies offers opportunities to accelerate the development of personalised medicines even further. While the blockbuster model still has its place, it is vital we support smaller biotechs to make sure they can get the medicines they are developing to patients in the best way possible.

We expect to see an increase in regulatory engagement and flexibility to ensure medicines are available to patients who need them. This support is already happening to some degree with the MHRA's Early Access to Medicines Scheme and the relaunch of the Innovative Licensing and Access Pathway (ILAP).^{6,7} The European Medicines Agency (EMA) also provides support for promising new medicines through the PRIME initiative and has begun joint ways of working between regulators and health technology assessments for promising therapies through the new joint clinical assessment (JCA) regulations coming into force since January, initially for oncology and advanced therapy products.^{8,9}

Working with Regulators

When working with pharmaceutical and

biotech companies, regulatory teams and professionals should always consider how they can add value. That can be through strategic oversight and the use of technology tools, but it is also vital to stay up to date with the latest guidance and engage regulators early on to ensure provisional buy in for regulatory developments.

The EMA recently updated its AI workplan guiding the use of AI in medicines regulation.¹⁰ The FDA has also issued draft guidance for the use of AI to support regulatory decision making.¹¹

We are expecting to see more oversight in the coming years as regulation catches up with activity. As companies try new ways of working, health agencies and health authorities will look at what is being done and what guidance might be needed to ensure patient safety is protected and pharma companies are operating with optimal practices.

Keeping Humans in the Loop

There is still some reticence about the use of AI throughout the pharmaceutical industry. People have concerns about job displacement, privacy and accuracy. However, when deployed effectively, AI can reduce repetitive tasks and allow staff to focus on activities where humans can add more value.

Any innovation must be balanced against the need to maintain, or even improve, patient safety. A fundamental component of this is that humans remain in the loop to provide oversight of new technologies. There is a need for supervision.

The final review will always be with the human expert – even if AI has supported them to get to that point in a faster, more comprehensive way.

Training and Cross-collaboration

There are some simple steps companies can take to overcome initial reticence about the use of AI tools and other new technologies.

Firstly, having basic digital fluency training and positive early interactions with regulatory teams is important. This means



going in and explaining what the available tools are and how they work. Second is having a clear AI policy at an organisational level.

Lastly companies should be asking how we can use these tools to improve how we work across our industry. Regulatory teams and regulatory professionals will increasingly need access to technology experts and AI data scientists as part of their day-to-day working – cross collaboration is key.

There will also be a mindset shift. Regulatory professionals will begin asking themselves a straightforward question for each activity they work on- is this still the best way? As questions like this get asked more often the wheel starts to churn.

Once we reach a place where people are working in more effective ways and sharing best practice, AI ceases to be this big unknown and instead becomes a tool to be embraced.

Conclusion

Regulatory Affairs is constantly evolving. We have already seen some of the changes outlined above to some degree in big

pharma with large-scale transformation teams. However, we are now expecting more widespread adoption across companies of all sizes in 2025 and beyond.

2025 is going to be a year of transition from purely manual to more automated ways of working. To do this successfully, we need to ensure staff engagement, the correct organisational structures are in place, and there is adequate support for implementation. Regulatory professionals can work hand-in-hand with technology experts such as data scientists to achieve these goals.

When new technologies are deployed effectively alongside science and human experts, they have the power to optimise the drug development pathway, increase efficiency, and, ultimately, deliver better outcomes for patients.

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