Generating Entire Regulatory Dossiers – The Logical Next Step for GenAI in Life Sciences?

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Generative AI (GenAI)'s ability to digest, assess and summarise key insights and findings from across vast and diverse bodies of existing content, and data - even as this is being continuously refreshed – make the technology ideal for high-volume everyday tasks completed by regulatory affairs teams. As it is, GenAI is already making its mark with some impressive early pilot solutions.

For instance, initial GenAI applications have demonstrated the ability to pre-empt agency queries and build stronger marketing authorisation applications, by applying insights gleaned from historical health authority (HA) interactions, where these have been put into an accessible knowledge base – serving as a significant process accelerator and productivity tool. Across 23 different languages, pilot applications have seen more than a dozen fields of data extracted with 90% accuracy – with up to 80% faster processing and three times fewer handovers than if teams were trawling through agency correspondence themselves.

The technology is also demonstrating powerful potential in monitoring and proactively using the latest global regulatory intelligence, for instance as part of impact assessment/change management. Early pilot projects here too have yielded 50- 80% faster processing, and in this case half the handovers compared to manual lookup and intervention.

But the truly transformational potential is still ahead – on course to be realised within the next two years. This will be the point at which regulatory teams are able to lean on the technology to generate and cross-check entire regulatory submissions automatically, with a quality review from RA professionals requiring just a fraction of the effort expended today. This capability will be particularly powerful in transforming regulatory submission lifecycle management, which today consumes significant time and budget.

Despite the increasing trend of data-oriented submissions, the reality of content-based submissions is here to stay for the foreseeable future. At a conservative estimate, large pharma organisations typically generate around 600–800 submissions per month. Even a very modest time saving, of just 1–2 hours per submission, would make a substantial difference to associated resource allocation, and that is the minimum saving expected once GenAI is harnessed in earnest to automate the collation and assembly of content, extrapolating from initial regulatory use cases of the technology.

The Best is Yet to Come

Among the enablers of this automation leap within regulatory affairs, to the creation of complete submissions, are GenAI's accelerating pace of advancement, its steady maturation, and the technology's rapid acceptance and perceived reliability.

Already, the technology is being used widely and with confidence to analyse and infer meaning from data and content in a wide range and formats, and distil what is needed into whatever the desired new format for the target context. This is true in most enterprise settings today – even, as we've seen, within the strictly-regulated life sciences industry, where GenAI is already trusted to transform not only the cost-efficiency and impact of marketing authorisation and licence maintenance, but also the affordability, speed and precision of real-world product safety monitoring.

The next wave of developments will build on all of this important progress, to enable end-to-end process transformation. Next use cases will include the provision of inline regulatory guidance to help users in submission compilation; generation of new draft submission content based on existing content; and cross-validation of final content against regulatory guidance and data (each of these may be delivered at the different times with different scope).

These targeted GenAI applications will be able to identify and draw from the latest correct sources, to collate and repurpose the relevant information and fill the respective submission outline. This will automatically involve cross-checking with the company's regulatory information management (RIM) system, assess what has previously been submitted, ensuring that the new submission is accurate and consistent.

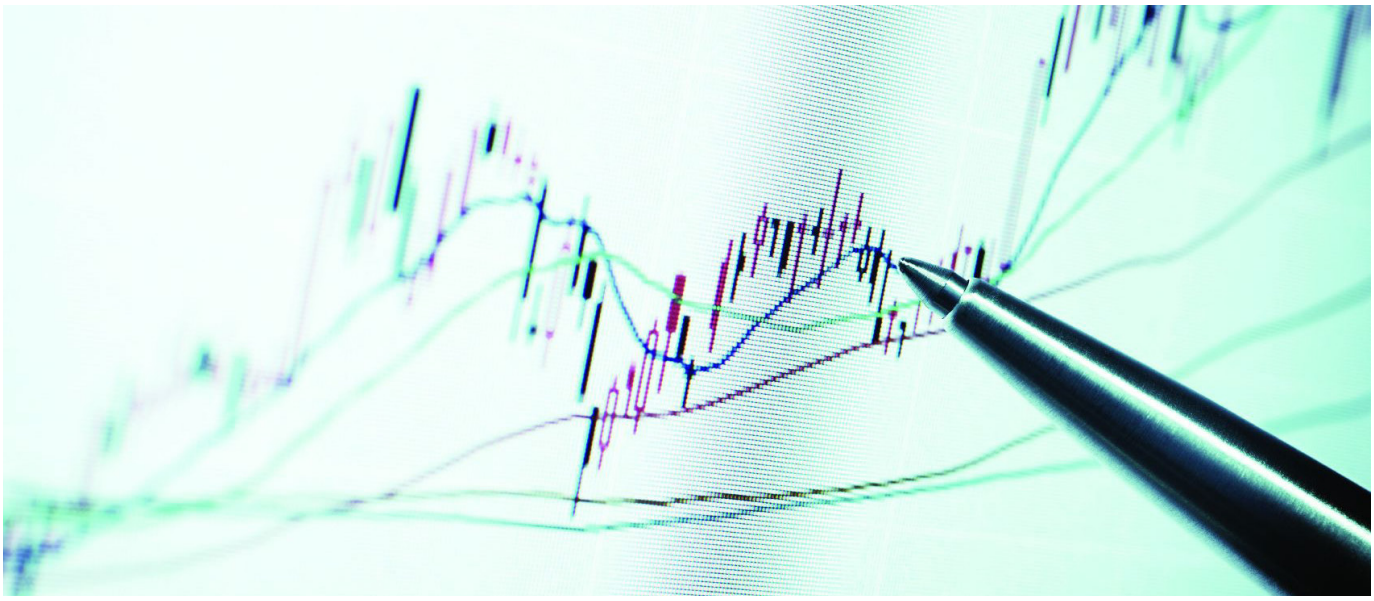
Better, Faster Submissions – in Any Market

Through all of this lightning-fast cross referencing (which will ensure that the correct excipient/ingredient information has been used, for instance), GenAI will expedite submissions compilation. It will also improve the quality, accuracy, and success rate of submission updates, reducing the 'return' rate, and boosting the company's track record and associated standing with regulatory agencies.

In other words, on top of substantial time and cost savings, as GenAI does all the heavy-lifting and content cross-checking, significant additional benefits will include a significant uptick in quality as accuracy, consistency and submission success rates go up.

In the meantime, skilled teams will be free to focus more of their attention on scientific work – activities that add more value for the organisation.

In addition to fulfilling the demands of agencies in mature regulatory markets such as the EU and North America, advanced automation in regulatory submissions generation could transform the efficiency of dealing with less developed markets.



Emerging markets together account for a sizeable proportion of the global life sciences opportunity . Growth in pharma sales in emerging markets is set to accelerate over the next decade, with medicine use in Latin America and Asia expected to rise faster than other regions over the next five years.

As more mature markets lean toward well-defined electronic submissions, it is a stark reality that the rest of the world continues to rely heavily on non-electronic files; for submission to authorities whose requirements are less standardised. The ability to streamline associated submissions with advanced end-to-end automation promises to be very powerful in this context, to help companies navigate the differing requirements, deduce "what good looks like", and swiftly collate and format what's needed.

Building Knowledge Bases, Enriching Data and Experimenting with what is Possible

Additional opportunities for GenAI in a regulatory affairs context include automated cross-checks to identify discrepancies and anomalies in data and its formatting, as part of companies' efforts to get their IDMP data standardisation in order, by honing and formalising associated data governance. Further possibilities include more efficient and effective maintenance of labelling compliance internationally across the product lifecycle, again boosted by automated, GenAI-enabled cross-referencing.

With all of this potential on the horizon, it is important that organisations across life sciences start to get to grips with GenAI technology now. Testing out the possibilities will give companies a feel for how far GenAI can go, how quickly results can be reliably honed, and how much time and budget this could buy back for hard-pressed regulatory teams.

Simply adding a GenAI capability alone is no magic bullet, of course. The more robust the assets GenAI can draw from, the more reliable and transformational associated process automation initiatives will be. The more diverse the available checkpoints, meanwhile, the more confidence there will be in the newly-generated output.

In parallel, then, companies will need to do some work to proactively bolster their regulatory intelligence knowledge bases (comprising non-public information and soft intelligence that has accumulated within companies based on their experience and direct HA relations). They should also continue or recommit to existing initiatives to clean up, standardise, and unify their product data. All of this is crucial groundwork that is needed anyway, and will optimise the success and impact of GenAI-based process automation.

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