Driving a Vision for a Data-driven Regulatory Ecosystem

A data-driven Regulatory ecosystem has huge potential, beyond the opportunity for operational improvement. However, Regulatory and product teams will need updated data skills to deliver this vision, reports Amplexor's Renato Rjavec.

Even in today's eCTD+ world, most life sciences Regulatory teams currently still think and work in terms of documents, paragraphs and sentences when putting together collateral for marketing authorisation and variations submissions. Yet it is data, rather than pre-prepared dossiers, that is moving into central focus now.

That's as stakeholders across the life sciences and healthcare ecosystem realise that a data-first approach to collecting, managing and communicating product information will be the most efficient and reliable way to maintain consistent, definitive, current and high-quality record of a product entering or on the market. One that can be interpreted and use in a wide range of use cases, by the broadest possible range of people (from regulators to clinicians, pharmacists and ultimately patients).

Professionals in a range of roles are now used to converting their particular information e.g. about the medicinal product's clinical properties, chemical composition or information for patients in the narrative form. But are they ready to adopt new, more structured ways of dealing with such information at the source? Or is there an expectation that the Regulatory role will effectively assume the burden of data extraction and data entry assistance for them?

Adapting to a Data-centric Approach

Given that this data-centric approach will be the new reality before long, the question for existing product information managers/ regulatory teams is whether their skill sets now need to be refreshed to reflect the target new ways of working (first, data and document sets needing to be carefully aligned, then a direct flow of good data to the regulators).

So where are companies with all of this today? With the exception of very large pharma organisations with the budget and people resources to have already started exploring the wider possibilities, most companies still lack awareness both of the wider potential and of the work ahead of them in building the right capabilities.

At one level, this is about how they manage product information so that (a) it fulfils the demands of new IDMP structured data requirements, and (b) becomes sufficiently reliable to form a foundation for not only product registrations and their maintenance, but all sorts of other processes too.

On another level, the opportunity extends to leveraging reporting and analytics to smart effect – first to help users fill gaps and increase the quality of the data; then with a more strategic emphasis, even using AI-assisted tools to investigate scope for process improvement (based on insights into how data is currently being managed and where recurring patterns are emerging).

Extra Layer of Quality Checks

It can be tempting to imagine that IT is going solve all of this, and that by default users will be swept along on the journey. Yet failure to adapt internal Regulatory capabilities, and to cultivate new data skills, is likely to severely compromise Regulatory Affairs' data-based progress.

Of course, having efficient and user-friendly solutions that have been built not just with additional data fields to satisfy IDMP – but also with an appreciation for what new

data-centric process management models will mean for Life Sciences Regulatory and other teams (and for the pharma industry in general) – will be important.

But equally, the teams involved will need help in adapting to the demands of IDMP. They will need guidance, support and help with validation to ensure that the right data is being entered in the right way, and that any gaps or issues are spotted and flagged. And, given the huge weight of new responsibility that will be placed on this critical 'source of product truth', it also follows that an additional layer of quality checks will be needed to cement confidence in the new bank of structured data.

As teams look to use this 'live' data to build reports, they will need help understanding how to make the most of analytics and of pre-built dashboards, too. And as basic data interrogation becomes more commonplace and comfortable, teams will need to be able to transition towards more advanced analytics.

Into the Realm of Data Science

For every user with a role to play in shaping the data, this work needs to be as simple and as user-friendly to achieve as possible, enabled by intuitive tools. If users are not brought along on the journey from this earliest point, anything that comes afterwards will be in vain (as the reliability of the data will be compromised from day one). Once teams are comfortable with working with data, and are confident in its quality – because they are adept at the process of capturing, enriching and managing it – Regulatory operations can start to be more ambitious in their next-level plans.

This takes them deeper into the realm of data science, as they start to harness AI-enabled tools to interrogate the data for signs of how this could be improved, and where entire data-based processes could benefit from a new, streamlined approach.

Yet it is here that existing teams are most likely to find that they lack the appropriate skills and will need to bring on board new talent in the form of qualified data discovery professionals. In pharma Regulatory Operations, data scientists are not widespread.

Targeting Pain Points

The challenge in building the right balance of skills might feel both vague and insurmountable at this point, but the reality of that challenge is undeniable. Regulatory teams will ultimately need access to a holy trinity of domain, tool and data discovery knowledge, but this optimal combination is likely to prove elusive. This is likely to mean building their software and Regulatory domain knowledge as their starting point, and growing the data science capabilities more organically through a combination of collaborative team-building and targeted training and skills transfer.

The best advice is to approach new skills adoption step by step, across a pilot initiative that targets Regulatory's biggest pain points, or the most complete source of existing data. That way, Regulatory Operations leaders can start the process towards achieving the wider potential of a data-driven Regulatory ecosystem that goes way beyond operational enhancement.

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