Building Solid Foundations for Regulatory Data Automation

Automating regulatory processes delivers undeniable benefits, ranging from accelerating time to market to reducing error. But life sciences companies are widely grappling with the basic issue of getting up-to-date and consistent data to talk to each other across functions and systems. Iperion's Duncan van Rijsbergen offers five practical starting points to build a solid data quality foundation.

Life science companies are increasingly focused on the need for digital transformation in the pharmaceutical industry. But data quality issues are impeding systems integration and automation. Regulatory systems contain data on products and their licences. There is also procedural data, recording interactions with the authorities about a licence, from the initial application through to post-authorisation changes to the licence.

Elsewhere, expert functions from manufacturing to clinical teams generate the basic data that feed the regulatory dossier that supports the licence. Typically, there is no direct communication between regulatory systems and expert functions systems. Manufacturing or clinical teams collate their data into a summary document and send it to the regulatory function. The regulatory team then takes that data and pulls it together in a submission dossier, ready to send to competent authorities for approval.

In manufacturing and the supply chain, the enterprise resource planning (ERP) system typically holds data about products and materials. Meanwhile, in the regulatory function there will be a regulatory information management (RIM) system which also contains data about the same products, but from the perspective of regulatory approval. Those systems are most often in completely separate worlds, with little or no interoperability. Yet, a change made in the manufacturing world must be reflected in the licence. Similar issues apply between the systems for management of clinical trials and the regulatory tracking of clinical trials applications. Currently, sharing that information is done through lots of forms and maybe even an intermediate system, which stores those forms. If these processes were automated, changes made post-authorisation would not delay product delivery or clinical trial start-up, enabling products to be brought to market and made available for patient treatment rapidly.

It is particularly important to get back to basics when it comes to structured, regulatory chemical, manufacturing and control (CMC) data. In just one instance, the process of inputting specification testing data into the laboratory information management system (LIMS), extracting it, entering it into regulatory documents, sending to regulatory bodies and then reversing the process for implementation can easily take a year or more.

Start with Data

A data-first starting point is key. If companies store clean and consistent data, rather than documents, they will be in a much better position to automate processes and share this data efficiently with regulatory bodies. Yet, companies continue to struggle with basic data quality issues.

First, there is the compliance issue, where licences must accurately reflect activity relating to clinical trials or manufacturing. In a regulated environment, compliance failure could lead to product recall, licence suspension or fines. Datasets in operational settings may not align with datasets shared with the authorities. While the data is essentially the same, the way the data is presented may not be aligned exactly across the two systems. The granularity of the data, how it is worded or linked, might be slightly different.

Secondly, there are issues tracking changes in data over time. Drugs that are produced over many years will experience changes in, for example, composition or manufacture. These must be reflected both in regulatory systems and in the company's operational systems. There is a need to change the data but also to keep it in sync. That synchronisation becomes much more difficult if there is a long-winded process, with multiple steps in it, where the data changes form multiple times, going from structured to document, and back to structured again, with manual copying along the way.

Ideally the syncing process should be integrated with the regulatory process. That way, when the company introduces improvements to the product, testing data can be shared with the regulator much more quickly, accelerating the time it takes to get product enhancements to market. Reducing manual processes also eliminates the potential for human error and reduces costs.

Practical Action Points

Commonly, compliance has become a goal in itself. Ideally, though, compliance should be effortless, a by-product of a company's activities, not the focus of them. When data is aligned and kept in sync automatically, through a proper aligned process, then compliance is secondary – it will just happen by itself.

Here are five practical action points to help get companies started on their data quality journey:

1. **Communicate with all the stakeholders** involved in the process. Together, identify the use cases for data flow continuity and agree on how best to measure the benefits of automating data integration. Getting everyone's buy-in and developing solutions collaboratively drives transparency and improves trust among functions. This approach enables people within a fairly long process chain to know how their data affects their predecessors and successors. It provides confidence that predecessors have done things correctly and successors get data they can work with.

2. **Develop a shared vocabulary** to talk about data held in common across functions. Presenting product data across the organisation in a way that everybody understands, with commonality of language, also builds

trust as well as driving operational excellence and innovation.

3. **Standardise data descriptions.** Once use cases have been identified and a common vocabulary agreed, consider how best to standardise data relating to complex products. The IDMP model is a valiant effort to find a common way to describe product data. The quality and consistency of individual data is also key to data standardisation initiatives, such as the US FDA's drive to standardise Pharmaceutical Quality CMC (PQ-CMC) data elements for electronic submission. The more widely accepted a product model is, the easier it is to share with external parties. This includes regulators, and also partners such as labs, manufacturers and research organisations.

4. **Ensure processes are properly aligned.** There needs to be a robust process for capturing and sharing changes over time – and making sure that systems keep in sync and that there is as little time lag as possible. Focus on bottlenecks. There may be one process in an operational setting and another in the regulatory function. Where do they meet? Where does the data gets exchanged and how could that be improved?

5. **Identify suitable technological solutions.** The initial focus should not be on finding the right software, but on the system architecture and how and where to connect systems. One approach could be to build a bridge between two systems, a point to point connection. The issue is maintaining the link and upgrading functionality in two discrete systems that talk to each other. A better option would be to develop a looser coupling, and this is where the common language model comes in. It is important not to take a static approach – how do I solve the problem now – but to also consider maintaining the solution and innovating over time. This is not about individual systems but about a system of systems.

Ensuring data quality and integration won't in itself generate innovation but it will provide a platform on which to innovate. The core business of a pharma company is to get the best medicines to its patients. Data processing should be a hygiene factor.

Technology, systems and software are not, on their own, the answer to data quality issues. They are secondary to a good understanding of the data and data flows within the business. The first steps are to map then standardise data. This will provide a solid foundation for life science companies to put in place technology to integrate and automate data processes, joining the regulatory dots and speeding time to market.

Duncan van Rijsbergen

Duncan van Rijsbergen is Associate Director Regulatory Affairs at Iperion, a globally-operating life sciences consultancy firm which is paving the way to digital healthcare, by supporting standardisation and ensuring the right technology, systems and processes are in place to enable insightful business decision-making and innovation.

Email: duncan.vanrijsbergen@iperion.com