

Compliance Complexity in the Data Management Landscape

Just as Rome was not built in a day, regulatory compliance demands will not be resolved overnight. However, until life sciences companies change their approach to projects, underlying issues will never be overcome

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With regulatory complexity soaring, the momentum behind product data management transformation should be peaking. However, the evidence suggests that this is not the case and that life sciences companies may be investing uneconomically each time they digitise a process or update an existing IT system, because they are continuing to approach each project in isolation, instead of as part of a bigger vision. While, encouragingly, organisations now appear to recognise the need for a more holistic approach, in 2019, life sciences companies will need to focus attention on developing a vision for delivering this and mapping it to a hard strategy. If not, companies risk throwing good money after bad by enhancing existing information silos and will fail to make a dent in expanding regulatory compliance workload.

There is no question that regulatory compliance demands are growing more onerous. In addition to a growing emphasis on expanded product detail and high data quality, integrity, and consistency, the different regulatory bodies around the world retain their own particular focus on what needs to be delivered, and how. Between the transition to the ISO IDMP medicinal products database in EU markets, similar ambitions in the US, and more diverse information digitisation initiatives in regions such as Asia, life sciences firms have their work cut out to ensure they have, and can easily find, all of the data they need, and combine and deliver this in an efficient and reliable way to the regulatory authorities.

Something Has to Give

For now, compliance and complexity go hand in hand. Between the diverse IT systems and particular processes employed by different functions across organisations, to the number of products and countries these are sold into and their respective regulatory expectations, there are thousands of elements, and millions of data points, that must be aligned to achieve marketing authorisations and keep products in the market. Furthermore, each change to a requirement or to a process can increase the complexity one hundred-fold.

Therefore, it was not surprising when Gens & Associates' global life sciences industry survey 2018, the latest in the respected annual series of stake in the ground research,

revealed increased interest in a more joined up, end-to-end approach to regulatory information management (RIM) (1). The 2018 findings suggested that, having put in the groundwork in stabilising their RIM environments, companies are increasingly looking for ways to build on this investment, not least by automating particularly repetitive facets of information preparation using options including structured authoring.

However, the gap between where most companies are now, and where they would ideally like to be in future, remains significant. As things stand, for the vast majority of pharmaceutical and medical device companies (including many tier one global players), the new processes needed to govern a fuller set of data do not yet exist. More often than not, regulatory affairs teams do not know where to look for the data that is needed – assuming that sufficient detail is being captured in the first place.

Gartner picks up on this vision/reality gap in its sector by sector review of global IT spending (2). It notes that, in life sciences, 75% of IT budgets are still accounted for by maintaining legacy systems, with only 25% allocated to new investment. It has been observed that, at best, 30% of life sciences firms, even including top tier players, are actively investing in something other than an immediate like-for-like replacement of older systems for which vendor support is being withdrawn. The vast majority of firms continue to make targeted best-of-breed system replacements, even though there will still be integration issues where the updated platforms need to share data with other applications across departments.

The trouble with this approach is that it leaves companies no better off – the new system is merely the latest in a long line of substantial, painful compliance costs. It does not add new value for the business or for regulators. In the meantime, markets are moving on. The ISO IDMP database for medicinal products is expected to be fully in play by 2020, along with the new EU medical device regulations, all of which demand much more detailed insight into products, which in turn require new system and process capabilities. Replacing legacy systems with equivalent 'point' solutions takes firms no closer to that goal.

In parallel, the pressure to remove costs from life sciences operations is immense, and growing. Efficiency, productivity, and accelerated time to market are paramount if firms are to remain competitive and viable.

With all of this going on, over the coming year, the industry needs to set out its plan for change and begin to take some initial purposeful action to progress that plan. This need not involve throwing out everything that has gone before. A big bang change programme is likely to be too disruptive and daunting, not to mention impractical and unaffordable. However, what companies can do is take a modular, step-by-step approach to next-generation RIM by looking at the bigger picture and making the optimum swap each time an upgrade or replacement is needed; something that achieves the current purpose and takes operations towards where they need to be.

The Ideal State

Ultimately, the situation companies should be moving towards is akin to commercial operations' use of enterprise resource planning systems, such as SAP, which serves multiple business functions and processes from a single, consolidated master database. This is what life sciences organisations should visualise as their end state: a master data resource and centralised capability that helps them manage their product data, processes, data, documents, submissions, and registration processes more intelligently, effortlessly, and efficiently.

Part of the reason companies have not made more progress towards more holistic, joined up product data management before now is that they have not been able to clearly see what it is they should be working towards, or what might be needed to get there. Making manual processes digital and undoing the way things have worked for the last 10-20 years is a big deal. However, unless the industry accepts the scale of change needed, firms cannot hope to be ready for a next-generation drugs market.

What firms should be aiming for now is close integration and extended visibility across operational systems beyond the regulatory function. By reaching for this, companies will start to enjoy improved data flow, measurement, automation, and continuous improvement, thus leading to higher efficiency and productivity.

The bigger part of the challenge is behavioural-, rather than technology-related. It requires a change of mindset, away from working in silos and following old routines of data capture, recording, verification, and preparation – processes which involve considerable repetition, a lack of central coordination, the risk of human error, protracted delivery, and high cost. In 2019, companies must start to chip away at their legacy mindset. The technology exists to break down borders, create, track, and prompt data flow, and automate routine

tasks such as form preparation using preapproved master datasets. Now it is just a case of taking advantage of what is possible by being open to new ways of working.

A next-generation approach to RIM offers scope not just to collaborate more efficiently internally across the organisation, or with affiliates in other countries, but, also, to work more closely with regulatory authorities, through access and sharing of data electronically – so that both parties benefit from more successful first time marketing authorisation submissions, for instance.

Driving Operational Improvements

Rather than viewing digital transformation or enhanced compliance preparation as a threat or a necessary evil to be endured, companies should treat the challenge as an opportunity to advance – a chance to invest in the future. Working towards transformation steadily over the next 2-5 years, module by module and one improvement at a time, makes it possible for companies to pragmatically and economically turn compliance into a contributor to other business priorities.

Companies do appear to be registering the importance and value of acting now. The Gens & Associates 2018 RIM survey included a series of five-year total cost of ownership studies with larger life sciences firms. These showed a positive economic benefit to moving to a consolidated, end-to-end RIM capability versus outgoing best of breed/point solution approaches.

Commenting on the findings, Steve Gens noted that life sciences organisations are increasingly “looking for a RIM capability that will allow them to be smarter and more efficient, as well as more accurate, as they collate, manage and use regulatory information.” With the right strategy, they can tackle regulatory complexity head on.

References

1. Visit: gens-associates.com/wordpress/wp-content/uploads/2018/10/GensAssociates_ExecutiveWorldClass_RIM_Whitepaper_Fall2018_Edition_101218.pdf
2. Visit: gartner.com/doc/3533917/predicts--life-science-rd

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