Why Agility Holds the Key to Transformation in Life Sciences

PEER REVIEWED

The priority that will unite all life sciences companies in 2016 is the pursuit of greater agility. As long as organisations keep taking a short-term view, investing in standalone information management systems for each new business requirement, the only thing they'll successfully grow is cost, warns Mark Evenepoel, Group CEO at AMPLEXOR Life Sciences. The real focus should be flexibility and responsiveness to whatever the market demands next.

The fact that life sciences organisations continue to feel stretched in all directions should be a clue that something is fundamentally wrong in the way they are organised. Not necessarily in logistical terms, but in the way they manage their information.

Traditionally, systems have been built up to serve specific applications in defined parts of the business. This single-purpose approach is now preventing them from adapting at the speed and to the degree required to meet today's business needs – including regulatory compliance in an environment where the goalposts keep changing.

Running an international life sciences business is challenging enough in an intensely competitive global playing field. But as new pressures mount – to enter new markets, position products differently, develop new business models, and meet a raft of strict new regulatory demands - the best that companies can hope for is that they are agile enough to respond quickly, efficiently and while the opportunity is still ripe.

Tackling each new requirement as a project in its own right this can be counteractive to efforts to move the business forward, because each set of standalone task forces, processes and supporting administration – creates a new bureaucratic dead-end, which goes against any plan to become more adaptable and agile. Breaking this habit of disparate, ad-hoc, single-application projects needs to be a primary goal this year. Unless they do this, companies will continue to build new barriers and fence themselves in.

The healthier alternative is to take a higher view – identifying and exploiting the common, underlying facilitator linking all of these ventures. Simply put, that's data – in all of its rich and varied forms. Whether the immediate priority is to create new transparency and more detailed and consistent reporting for regulators, or to make inspired new decisions about customer/product alignment, it is simplified access to reliable, complete supporting information that holds the key to moving forward.

One Data Source, Multiple Applications

The more that the entire discipline of information management can be consolidated, centralised and automated, the lighter the associated workload and the shorter the time to task completion.

Over the year ahead, the life sciences industry faces increasingly complex regulatory challenges and operational risks: the result of technology advances, clinician and patient expectations, and a globally-connected healthcare market.

One of the biggest preoccupations for data managers over the coming months is emerging EU legislation requiring the implementation of new data standards (Identification of Medicinal Products or IDMP). This will enable the unique identification of medicinal products at an international level, improving patient and consumer safety. To comply, life sciences organisations must develop a method and process for generating global product identifiers, which can then be used for product reconciliation and linking across the entire product supply chain. The specifics of IDMP compliance requirements will continue to evolve over the next two years, a reminder of why an agile approach to data management is so important. Significant investment will be required not only to align key product data across a wide range of functions – from research and development (R&D) and manufacturing to the supply chain – but also to pursue operational excellence in R&D and customer safety: the ultimate goal of the new requirements. From a regulatory and risk perspective, these requirements absolutely must be met. But companies need to do this in a way that is both efficient and adaptable – as new regulatory requirements will continue to appear, and not all of these can be predicted in advance.

Commercial Priorities

There are commercial implications too. If laborious internal processes are needed to collate and file detailed product lifecycle data in the mandated format, this could cost companies dearly in time to market – a serious consideration in today's aggressively global playing field.

Other forms of transformation and realignment are high on the business agenda too. The last year has seen a lot of strategic change in the life sciences industry, as organisations have sought to re-imagine their value propositions in line with specific customer groups, for example hospitals versus over-the-counter pharmacies. Selling customer solutions rather than product features is not only more appealing to customers, it also presents additional cross-selling opportunities. Yet behind the scenes, operations aren't currently conducive to enabling this readily – due to the numerous different information systems and processes, dispersed across multiple geographies. This fragmentation inhibits progress, preventing new types of collaboration, for example. Mergers and acquisitions further add to the complexity. This situation is detrimental to the organisation's strategic goals. The aim now must be to simplify and streamline processes, and lower operating costs and administrative barriers, so that companies can seize opportunities and extract value.

Without Agility, Businesses Can't Evolve

Put all of this together, and it's not hard to see why agility is becoming more important now than ever before. For a whole host of reasons, life sciences businesses now need to be better positioned to adapt and take advantage of emerging situations and opportunities. As part of the transformation that is required, new strategies need to be set out which promote greater collaboration and information-sharing – both among internal functions and with external partners. This is necessary

to create a global supply ecosystem which is more closely integrated, more responsive, and more focused on the patient. All of this must begin with a single, centralised approach to product lifecycle data management. Each time companies approach a new information management project as a distinct entity, to meet a specific new need, they are creating a new data and process silo that adds to, rather than alleviates, their current challenges – and limiting the return on investment in new systems, processes and training. This might sound like a tall order for organisations with the scale and structural complexity of a large international pharma brand. But it is achievable – if companies commit themselves to a new approach to content management which looks beyond a single set of current needs, and which is capable of meeting not only current requirements, but also those that will emerge in the future.

This cannot be achieved overnight, but it should be the overarching aim. By this time next year, pharma organisations should aim to have a clear roadmap for transformation, and be ready to get stuck in.

Formulating a Plan

Even where there are long-established legacy systems to be taken into consideration, it is important to establish some kind of centralised strategy for master data and product lifecycle information management as a first step. This doesn't have to involve a lot of physical upheaval: it could be achieved virtually. Tools such as integration 'middleware' can help in the interconnection of disparate and ostensibly incompatible systems, but companies can leave this kind of detail to external experts. The great positive in all of this is that life sciences organisations typically already have most of the data they will need to become more agile, thanks to the rigorous demands of regulatory compliance which have imposed the need for comprehensive record-taking over the years. The catch is that much of this information exists in an unstructured format. One of the first priorities, then, must be to address this so that information can be more readily consolidated, accessed and shared to serve the broader needs of the organisation. Appropriate actions are proposed in the adjacent boxes.

2016 will be a pivotal year in life sciences, with the multitude of challenges and new opportunities now on the horizon. Provided companies don't ignore the call to be more agile, adaptable and responsive; it could be the start of a bright new future as a consolidated approach to data management allows several things to fall into place at once.

Box copy 1:

As the life sciences industry adapts to modern business challenges, companies need a reliable way to manage a wide range of content – from what is submitted to regulators, to what goes out on and in their product packaging and on their website, and what's distributed across digital and social media – in every region and every country.

Research by Gens and Associates in 2015 found that the majority of life sciences companies aspire to adopt an enterprise-wide approach to content management governance between now and the end of the decade. Aims include improving operational efficiency as well as information exchange with regional and local affiliate offices, for example as they prepare input for regulators.

Where a pan-organisation view of content is lacking, Gens has found evidence that as much as 40% of affiliate time is taken up by coordinating and managing regulatory information – much of it on very basic tasks such as data re-entry. Even so, firms were found to typically lack confidence in the quality of information maintained in their global systems.vWhere life sciences organisations are managing content more holistically across the business, the payback on systems is significantly higher, Gens and Associates has found.

Box copy 2:

The Roadmap to Greater Agility
Practical Steps to More Holistic Information Management

- Formulate an overarching transformation plan for the way information is managed across the organisation and its various operations
  - Aim to turn product and other everyday business data and content assets into a pan-organisation master content resource
  - Think beyond single applications towards building a centralised pool of (business, product, operational, financial) knowledge – even if this is achieved virtually
- Standardise and streamline the way data is captured, stored and managed, to enable easier integration, and deeper analysis and cross-comparison
- Consider how you will plan and handle system design, integration, migration, reformatting
- Drawing on external experts could pay dividends by relieving already-overstretched internal IT teams of complex work that may exceed their expertise and capacity and distract them from day-to-day tasks
- Improve content accuracy, completeness and currency, ensuring regulatory compliance and patient safety
  - Address data duplication
  - Aim to create a 'single version of the truth' – i.e. the fuller picture of a situation as a whole, based on complete and up-to-date detail
- Make information easy to share, and quick to access – aiding transparency and paving the way for new innovation as new potential is identified
- Reduce reliance on static, period-end reports, empowering business users to find the insight they need on demand
- Automate workflow where possible
  - Reduce the administrative workload associated with delivering regulatory information, or providing the business with the latest operational and commercial insight
- Don't delay
  - Competitive and regulatory pressures will continue to mount, and each project that takes place outside of the context of improved agility will increase costs and slow overall business progress

Mark Evenepoel is Group CEO at AMPLEXOR Life Sciences, a digital solutions company offering global compliance, digital experience and content solutions. Mark is charged with group strategy and development and has overall responsibility for global communications & marketing, HR and sourcing and solutions development.

Email: mark.evenepoel@amplexor.com