



Regulatory Affairs

Unlocking value with digital transformation



It is high time for life sciences organizations to use digital technologies to reimagine the regulatory affairs (RA) function. Automation and cognitive technologies hold enormous potential for not only improving the function, but also for driving continuous value creation for the organization.

To be clear, most RA functions have made significant efforts to transform through large-scale system implementations. Companies have invested in new systems aimed at improving efficiency and reducing compliance risk.

Yet – despite all these efforts – our experience suggests that few life sciences RA functions have managed to fully realize their transformation objectives. Many still rely on manual processes and siloed systems to meet key deadlines and achieve their business goals. However, as health authorities increasingly require digital transmission of critical information, relying on manual processes and workarounds will be unsustainable.

Opportunities lost

In part, the problem is symptomatic of the function itself. RA activities rely heavily on specialized systems, each of which focuses on a subset of information, e.g., Registration Data, Submission Documents, Submission Publishing, and Labeling. In the past, this approach helped organizations comply with maturing regulations, eCTD for example, and consolidate regulatory information globally.

At the same time, although many systems have been upgraded and improved, they are often not fully utilized. We see cases where employees perform their work ‘outside of the system’ and then enter data and documents to meet compliance

requirements. So the technology solutions are functioning as auditable repositories, but they are not transforming the way people work on a day-to-day basis.

Even when companies successfully connect their various RA systems and data, most still face significant challenges getting their systems to work with functions outside of RA. Opportunities are, therefore, lost to improve product releases, change controls and pharmacovigilance, for example. And that means the RA function may fall short in its efforts to become a more valuable business partner to the rest of the organization.

See the future

Based on this evidence, it is clear that implementing off-the-shelf IT solutions has limitations as a path to transformation. It's critical for companies to look beyond classic system implementation projects. Companies should also consider ways to achieve seamless connectivity between documents and data across the entire product life cycle. Enabled by the right combination of systems, processes and resources, physical products can live side-by-side with their digital attributes.

Organizations that are able to accept and embrace this shift in the basic paradigm of the RA function will be able to finally unleash the full potential and value of their organization's digital transformation agendas.

Get there faster

Our experience suggests that life sciences RA functions can increase the pace of transformation through the targeted use of new technologies that are unlocked and enabled by digitalization.

The adoption of automation-related technologies has dramatically increased across industries. Many companies are making investments to realize the benefits of advanced automation across the product life cycle. According to a recent KPMG survey, the current Intelligent Automation market is expected to grow 20X over the next seven years, with 75 percent of companies expecting to use RPA and 49 percent expecting to use Cognitive/AI at scale in the next three years.¹

While, to date, the application of these emerging technologies in the RA space has been somewhat limited, we are starting to see more life sciences companies initiating pilot programs. These technologies have already been implemented in many back office functions, and companies now need to shift focus to using technologies like robotic process automation, machine learning and natural language processing in 'middle office' areas like RA. Adopting these technologies will be key to achieving a sustainable workload going forward.

1) 4Q 2017 KPMG Global Insights Pulse Survey Report

Intelligent Automation can help RA functions with:



Publishing:

Current manual processes, such as document linking and document ID management, can be automated to speed up the publishing process and reduce the potential for errors.



Authoring:

Initial draft documents based on existing content components can be created with Intelligent Automation tools. Over time, more and more of the draft can be created using machine learning.



Approval Notifications:

Coordination across the business can be improved by automating internal notifications of submission approvals – a process that is currently managed through manual forms and emails.



Document Conversion:

Captive information can be easily and quickly converted into controlled metadata from Word and PDF documents using automation.

Encourage transformation

Another way to use Intelligent Automation to help accelerate digital transformation is by building connected web-based 'apps' that complement core IT solutions. There are many platforms available that allow RA functions to build highly configurable applications that address key gaps in the system portfolio and eliminate highly manual processes.

Further, these apps can help encourage transformation in the day-to-day culture and work environment of the organization, helping employees more easily adopt new technologies rather than work around them.

Look beyond the daily pressure

In today's highly competitive and increasingly digital marketplace, RA functions are facing massive change, disruption and pressure. On the one hand, they are asked to rapidly digitalize and transform alongside the organization. On the other hand, they are expected to manage the growing number of competing priorities required to get new submissions to health authorities and comply with increasingly complex regulations across the various markets in which they operate. Although balancing the two priorities is necessary, it won't be easy.

Our experience suggests that the most successful organizations will be those that see digital enablement as a continuum of methods to automate certain activities, rather than aiming for wholesale change. For example, some might consider focusing on workflow and rules-based process orchestration first, before jumping into more complex technologies like cognitive and machine learning.

What is certain, however, is that RA functions that can adopt these new digital enablement technologies and integrate them into their core processes will be able to leapfrog the competition and achieve the full value of their transformational efforts and investments. And those that fail to do so will find it increasingly challenging to keep pace with critical day-to-day business activities.

5 potential benefits of adopting Business Process Management tools

1

Easy to integrate with base IT systems

2

Simple to configure to enable faster design and improvement

3

Can be owned and managed (in part) by the business

4

Enables governance of key workflows in a traceable and transparent manner

5

Can serve as a portal or single access point to other systems

How KPMG can help

KPMG is a leading professional services firm with senior healthcare and life sciences practitioners dedicated to regulatory affairs, data & analytics, R&D and commercial strategy, risk consulting, and M&A.

Our one firm approach to client engagements results in an enterprise-wide view from strategy through results. In particular, our life sciences advisory team focuses on providing strategic support to pharmaceutical and medical device companies seeking to transform their Regulatory and Quality functions. These transformational changes help life sciences companies bring products to market more quickly, while reducing compliance risk and enabling a sustainable approach to regulatory maintenance activities.

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