Jonathan Burd

INNOVATION IN QUALITY MANAGEMENT SYSTEMS

HOW IS CLOUD INFLUENCING CHANGE?

The pharmaceutical industry is in an age of change. Rapid innovation is driving new ways of working, while digitalisation continues its journey across an ever-more complex landscape. The quality function, though historically conservative by necessity, is not immune. In an issue of Quasar dedicated to the theme of innovation, this article considers the impact of industry change on quality teams and the potential of cloud technologies to drive forward a patient-safety agenda.

Fundamentally, the role of the quality department has changed very little. In the product world, the qualified person continues to have responsibility over the release of a manufactured product. However, sweeping change is creating new challenges and greater responsibilities, driving the quality function to evolve how it operates. Within a community that has tended to be sceptical about widespread digitalisation, the potential to leverage the benefits of modern, cloud-based systems can no longer be ignored.

First, let's consider some of the major changes affecting the industry and impacting quality functions today:

- **Organisational structure** – recent years have seen an increasing trend in fragmentation of organisations and growth in contracting out many operational areas. This has resulted in considerably longer supply chains, particularly in the areas of production and distribution, which many organisations have little to none in-house.
- **Nature of products** – the growth of biologically-based and manufactured products and the increasing presence of 'personalised medicine' significantly increases the complexity and challenges for quality assurance processes, compared to 'traditional' batch-produced, small molecule-based products.
- **Manufacturing approach** – there has been a general move towards the exploration and in some cases adoption, of continuous as opposed to batch-based manufacturing. In parallel and to some extent as a consequence, increased work around process analytical technology (PAT) to support parametric batch release has been ongoing. This has seen a number of products benefiting from the advantages it can give, particularly in the area of steam sterilisation, where culturing for microbial growth as part of the terminal sterility testing adds a significant quarantine period prior to release.
- **Patient interaction** – there has been a fundamental shift in the way that patients interact with their healthcare, including the information they expect to have access to and how that impacts their expectations of treatment and providers. Over a short period of time, the balance has significantly shifted to require pharmaceutical companies to participate more in social and digital media in order to manage their profile and position in the new digital world.
- **Digitalisation of pharmaceutical** – in addition to these changes, the technology environment in which pharma operates is entering its 4th generation (Pharma 4.0), albeit at a somewhat slower pace than some other sectors. The advent of the 'industrial internet of things' (IIoT) is beginning to see innovative developments within the manufacturing space. The use of predictive techniques based on the analysis of big data generated by machines along the line will provide challenges for a quality and validation culture which historically has been conservative.

THE CHALLENGE TO CHANGE

Set against this back-drop, let us consider the impact on the quality function within the organisation and how it is being challenged to change.

Now more than ever, quality teams are asked to take responsibility for process areas that are not within their own organisation. They are required to pull together data from a range of different sources in order to have sufficient information to make a qualified decision.

In addition, the traditional quality control testing of a sample from the batch is no longer the only – and sometimes not the appropriate – way of assuring quality and safety. This has resulted in greater – and in some cases total – emphasis placed on validation of the process to arrive at the required outcome on a repeated basis, followed by confirmation of adherence to the validation, in order to enable release. This is particularly highlighted when creating novel personalised medicines delivered as a batch of one, for a specific individual.

The greater involvement of partners in longer supply chains is increasing the need for the provision of more-timely and 'linked' information. Over the last couple of years, the topic of data integrity has been high on the agenda of both regulators and the industry itself. Although much of the guidance leans towards consolidation of activities fundamental to managing information in a regulated environment, it was encouraging to see that the recently published MHRA guidance on the topic includes a section on the impact of adopting more modern cloud and Software-as-a-Service (SaaS) offerings.

So, does cloud technology hold the key to tackling the challenges faced by quality today – and is it the gateway to transformational change?

WARMING TO CLOUD

From Veeva's perspective, acceptance of cloud services delivered from a 'regulated cloud' has been significantly increasing over the last three to five years. Historically there was a general scepticism towards these systems, with much of the distrust coming from a perceived loss of control and potential risks relating to security and access.

Today, the professionalism and focus of cloud data centre providers, combined with increasing external threats faced by on-premises systems, has resulted in greater incorporation of modern solutions into the standard IT portfolio. However, narrow views of how cloud complies with regulation still remain, so there is still work to be done on educating the industry.

For quality teams who have adopted modern quality systems in the regulated cloud, users are experiencing a range of innovative benefits. These include:

- **Unified systems and a platform approach** – the delivery of a single unified system to manage controlled content and data collected during QMS processes – such as deviations, corrective and preventive actions (CAPAs), complaints, audits and change control – enables streamlining and optimisation of quality management. Non-compliance risk is reduced with seamless processes that involve both data and content. Change control is a good example, where bringing together content and data is critical. Often changes impact documents and with a unified platform, resulting change actions can link directly to the controlled content. In fact, when these platforms extend across more areas of the organisation, such as into clinical or regulatory processes, the change control process can be even more streamlined. Teams can easily gain visibility into the regulatory impact of a change and have continuous transparency into the status of these variations with regulatory authorities.
- **Simplified external access and involvement** – the cloud is easily and securely accessible. Everyone who has access rights can use the cloud on any device, at any time, from anywhere. There is no need to navigate VPNs or a host organisation's firewalls. Of course, this does not mean that everyone who logs in can see or do the same things – security profiles and underlying access schemas provides granular control for every individual in the system. The key advantage is – for the first time – it is as easy to set-up, provide access and involve an external partner in the quality process or to sign-off on documents, as it is for one's own staff. There is no need to download content, attach it to emails requesting participation or transcribe

responses back into the system. For complaints, CAPAs, audit findings, document updates and other quality processes, companies can streamline tasks while reducing data integrity risks.

- **Improved system acceptance and usage** – for as long as systems have been implemented, the challenge is often not execution but change management – getting the system incorporated into the staff's working patterns. The deployment of modern, web-based systems help break down these barriers by providing a user experience that more closely mirrors the digital experience outside the workplace. The use of flexible, intelligent searching and property-based filters to access content, rather than navigation on multi-level folder structures, raises the usability factor by a significant degree.

THE ROAD TO PHARMA 4.0

There has been much debate in forums, such as the ISPE and RQA conferences, around the progress of digitalisation and innovation in the industry and the role the quality function plays in either progressing or impeding it. In general, the conservative culture, in tandem with the pivotal role that the quality function plays in assuring product safety, has led to slow acceptance of innovation in some areas.

Now, with increasing adoption of newer, more innovative, modern quality management solution offerings from industry cloud providers like Veeva, confidence is growing. There is increasing trust that the information being contributed – both from within an organisation and from participating partners – can provide greater levels of assurance and visibility to enable more rapid progress.

As the industry makes further strides towards Pharma 4.0, supporting systems will continue to play their part in that journey – providing better and more timely information that is drawn from a multitude of sources and consolidated to provide intelligent decision-support. Ultimately, this will help deliver on patient-driven safety.

PROFILE

As a Strategy Director for Veeva Vault Quality in Europe, Jonathan is responsible for market-facing operations for Veeva Quality products, focusing on the small and medium business sector in the region. A pharmacist by training, he has more than 35 years of experience in healthcare and life sciences. He entered consultancy in 1995 from the UK Health Service and for the last 18 years, Jonathan has worked with life sciences clients to understand and solve enterprise content management and compliance problems, deploying solutions built on a range of platforms.