Five reasons why quality management needs a GxP-regulated cloud

The global shift from traditional IT offerings to cloud services continues

In fact, Gartner predicts that, by 2020, more than $1 trillion in IT spending will be directly or indirectly affected by the shift to the cloud.[1] With cloud-based technology promising agility, scalability and innovation — alongside sizeable cost benefits compared with maintaining and upgrading internal IT systems — it's no surprise that organisations are pursuing cloud adoption strategies and making the transition to software-as-a-service.

In life sciences, an industry that has lacked software innovation for decades, it is no different. Faced with ever-growing pressure to reduce costs, increase efficiency and accelerate time to market, life sciences companies are exploring new business models and technology that can drive innovation and improve collaboration.

A key area that can benefit from modernisation with cloud-based technology is quality management. In line with IHC Q10 guidance for more holistic and effective quality systems, organisations are looking to simplify and improve access for better visibility and control of GxP-critical processes. As a result, they are replacing outdated technology with modern cloud solutions to improve productivity and reduce quality risks.

Not all clouds are created equal

When it comes to modernising quality management, key aspects such as a single source of truth, data integrity across multiple sites and external collaboration are highly valued in the life sciences industry. However, many solutions on the market masquerading as "cloud" aren't truly cloud or purpose-built for GxP areas. In reality, these solutions are often existing applications simply offered in online hosted models. In other words, these applications are online versions of

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legacy software and therefore do not deliver all of the benefits of an industry cloud.

The defining attribute of a true cloud solution is multitenancy. Multitenancy enables the secure deployment of only one version of cloud software to all customers. It supports quick, ongoing innovation that minimises the IT and validation burden. In contrast, legacy software hosted online requires the application supplier to maintain multiple versions of the software, which can result in infrequent upgrades that are time consuming for customers to implement.

A true multitenant cloud, purpose-built for the life sciences industry, has clear benefits that can't be matched by online legacy applications. With that in mind, here are five characteristics of an industry cloud solution that address today's needs for quality in manufacturing:

1 Complete: everything in a single system

A unified, cloud-based suite brings together multiple solutions, such as quality management systems (QMSs) and document management for improved control, visibility and partner collaboration. Global harmonisation on a single system means processes and document templates can be standardised, reducing the risk of errors or duplication.

2 Inclusive: collaborate securely with external stakeholders

Organisations can bring external stakeholders into internal business processes easily and securely to reduce manual efforts and improve collaboration. A multitenant cloud solution gives any authorised user access from any device, at any time, from anywhere, which enables the harmonisation of different business processes. For example, bringing all stakeholders into quality processes with a unified, cloud-based QMS and document-control solution means that when changes are made, all parties are involved and can collaboratively solve the problem.
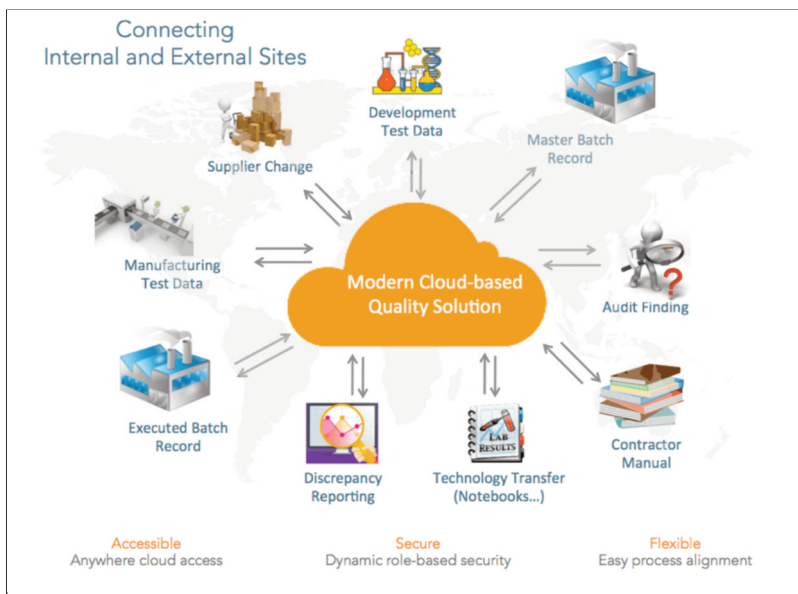
3 Innovative: keep pace as the business scales

With a multitenant cloud solution, the provider makes continual investments to deliver ongoing application updates and keep up with the latest industry best practices. This increases the agility of business and IT and shifts the focus to fine-tuning the applications to align with the business needs. In addition, industry cloud solutions for GxP areas means that all applicable regulations, such as 21 CFR Part 11 and EU-GMP Annex 11, are fulfilled, including a full validation programme.

4 Intuitive: ease of use drives adoption and efficiency

Multitenant cloud applications are intuitive and easy to use. For example, managing document lifecycle and taking documents from draft through review, revision, approval, issuance and training are simplified with an industry cloud solution, which, in turn, encourages user adoption.

Connecting Internal and External Sites

Supplier Change — Development Test Data — Master Batch Record — Manufacturing Test Data — Modern Cloud-based Quality Solution — Audit Finding — Executed Batch Record — Discrepancy Reporting — Technology Transfer (Notebooks...) — Contractor Manual

Accessible — Anywhere cloud access
Secure — Dynamic role-based security
Flexible — Easy process alignment

A good user experience will subsequently result in users consistently working within the system, helping to drive quality and improving return on investment in the technology.

5 Accurate: make decisions with real-time data

Users can easily view the real-time status of activities and conduct ongoing analyses to identify areas for improvement with a unified, cloud-based quality management system. This makes it easier to generate recurring regulatory reports or satisfy the upcoming need for submitting quality metrics. For example, companies can run reports on a wide range of QMS metrics across their enterprises so they can anticipate potential bottlenecks or compliance risks well in advance. This shifts an organisation from being reactive to proactive … and can positively impact business areas beyond compliance.

Realise true change with an industry cloud solution

The transition to the GxP-regulated cloud will continue to gain momentum. However, with multiple cloud options available, at first glance it may seem difficult to decide on the best solution. It's worth remembering that online versions of legacy applications cannot offer the same benefits as a true multitenant industry cloud solution that's purpose-built for life sciences.

With the latter, because all users work on the same platform, in a system that allows for secure collaboration and increased visibility, the productivity and efficiency gains can be considerable. And because it is the responsibility of the cloud solution provider to manage software updates and ensure the applications stay current with regulations, your organisation has the freedom to realise true change — without needing to upgrade your software first.

REFERENCE
1. www.gartner.com/newsroom/id/3384720.

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