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 **Sparta
Systems**

The Enterprise Value of a Cloud Quality Management System (QMS)

How to gain faster access to critical business insights
with lower costs and fewer risks

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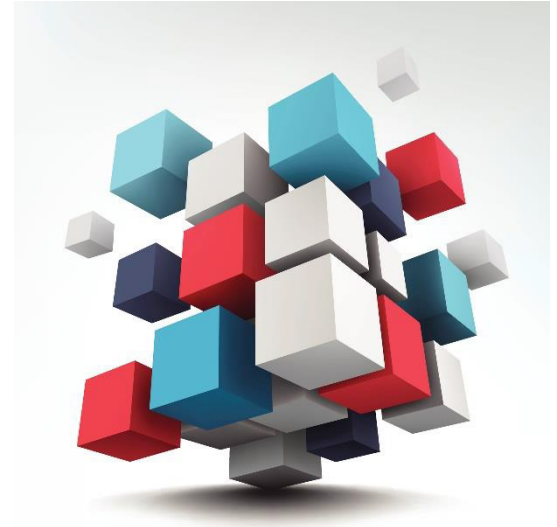
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Introduction

While many global life sciences manufacturers are still using on-premise quality management systems (QMS), change is coming in the form of the digital revolution. To remain competitive in today's business environment, companies need access to information, faster and easier and at a lower cost to support continued innovation and growth. They also need enhanced security to protect data cross-functionally within the enterprise, and out to third party suppliers and other business partners. This simply cannot be achieved using existing legacy systems. It's time for quality in life sciences to move to the cloud.

Leading life sciences manufacturers that have switched to cloud-based QMS have not only overcome the challenges of traditional quality management (e.g. costs, complexity, risk), but have also positioned themselves to take advantage of Industry 4.0 technologies (e.g. artificial intelligence (AI), machine learning, and continuous manufacturing), which provide the backbone for the Quality 4.0 evolution.





Across industries, nine out of 10 companies have already moved some of their applications or computing infrastructure to the cloud, and the rest plan to do so by 2021. Software as a Service (SaaS) is the most common cloud service model, with 89 percent of companies surveyed using it in their information technology (IT) environment. Other cloud delivery models are growing in use as well. Among those surveyed, 73 percent are using Infrastructure as a Service (IaaS) and 61 percent are using Platform as a Service (PaaS) models.¹

When it comes to the life sciences industry, interest in cloud QMS technology is growing as manufacturers recognize the quality function's critical role in driving improved financial and operational performance. A 2018 survey of pharmaceutical professionals found 43 percent plan to evaluate or experiment with Quality 4.0 technology in the next 12-16 months,² while a 2018 survey of mid-sized to large MedTech companies revealed that 64 percent are looking to develop more digitally enabled solutions and software.³

In this eBook, we explore the enterprise value of a cloud-based QMS and present the benefits derived from transitioning quality management from on-premise into the cloud.

1. 2018 Cloud Computing Survey, IDG Communications

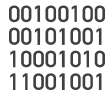
2. 2019 Pharmaceutical Technology Survey, Sparta Systems

3. The Next Wave of Innovation Technology and Value-Based Care Are Transforming MedTech R&D, Deloitte

The Case for the Cloud



Data Security Risks: Legacy systems increase the risk for data security breaches. Thousands of organizations run the majority of their computers on outdated operating systems, nearly tripling chances of a data breach.¹



Limited Information Access: Quality teams struggle to get the data they need from their current on-premise QMS platforms. Nearly half of pharmaceutical industry professionals named data access and analysis as the biggest challenge with existing QMS. More than three-quarters say quality data is very or extremely important to their teams and leadership.²



Supplier Quality Management: Life sciences manufacturers are increasingly using third party suppliers, with more than 70% of data coming from external sources,³ but their current on-premise QMS platforms do not provide the necessary visibility and control to manage supplier relationships and risks.

Organizations are no longer questioning whether they should move to the cloud. They're now focusing squarely on how best to leverage the new generation of cloud services by adopting new delivery models and enabling multi-cloud architectures.²

1. A Growing Risk Ignored: Critical Updates, BitSight, 2017
2. 2019 Pharmaceutical Technology Survey, Sparta Systems
3. Data-driven Pulse of Life Sciences, Reltuo, 2015

The Case for the Cloud



Inadequate Analytics and Reporting: The role of quality is rapidly expanding beyond compliance and into driving enterprise-wide performance, but less than one-fourth of senior executives and quality professionals say their enterprises have extensive metrics for quality efforts in place.¹



Heavy IT/IS Resource Burden: Significant IT/IS resources are required to manage and maintain outdated quality systems. Companies across multiple industries report that the primary reason for their cloud investments is to enable IT to meet business demands for speed, agility, and responsiveness.²



Entry Into Quality 4.0: 70% of senior executives and quality professionals report that digital processes and the movement to digital enterprises have been transforming their continuous improvement initiatives.¹ Manufacturers can't embrace the digital evolution and transition into Quality 4.0 when they are still using manual, paper-based processes for quality management.

1. The Rising Economic Power of Quality, Forbes Insights, 2017

2. 2018 Cloud Computing Survey, IDG Communications, Inc.



Data Security

A primary concern for life sciences manufacturers is the security of their quality data. Traditionally companies felt data needed to be within their own four walls in order for it to be secure.

With the digital revolution upon us, manufacturers are beginning to understand that their data is far more secure in the cloud versus on-site.

Data breaches are more likely to occur when security is managed by a smaller team of people. Life sciences manufacturers with on-premise quality management systems and data behind their own firewalls are limited in how often they can perform system penetration testing, with most only conducting it on a weekly or monthly basis.

On the other hand, with a cloud provider there is an army of people responsible for data security who are performing daily penetration testing of systems. This enables them to rapidly identify and address security threats in order to protect client data.



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Information Access



Quality impacts every aspect of a life sciences manufacturer's operations, but with a traditional on-premise QMS the quality team typically operates in a silo. With a legacy QMS it can be challenging to integrate additional systems in which quality data resides (e.g. regulatory, manufacturing). As a result, the quality team has limited visibility to valuable insights throughout the enterprise. They also struggle with storing and managing data in locally saved files where version control is a constant challenge.

Cloud-based systems, on the other hand, are much more flexible and easily facilitate the integration of external systems and applications. This in turn enables the integration of data, in real-time, from various sources into a centralized repository in the cloud. Quality teams can easily and quickly access this data from their QMS for use in analysis and reporting.



Supplier Quality Management

As life sciences manufacturers increasingly rely on external suppliers in the development, manufacturing and distribution of devices and drugs, supplier quality management (SQM) has become critical to product efficacy and safety.

With an on-premise QMS, quality teams struggle to add system users outside of their firewalls. In order to provide a supplier access, the company's IT team must set up a VPN connection and perform all of the necessary steps to securely connect them.

Because of this burden, many companies do not provide suppliers direct access to their systems but instead have quality teams copy information from supplier emails into the QMS, which is not only time and labor intensive, but also increases the risk for missing information and other

consequences of manual intervention. The quality system becomes nothing more than a recording device for suppliers.

With a cloud-based QMS, suppliers can simply log into the solution and input information live. While in the system, suppliers are led through a predefined set of processes, including deadlines, to ensure the quality team has the information they need, when they need it. The process is thereby streamlined with greater accuracy and reduced risk.

This level of collaboration applies to internal teams as well. With a traditional QMS, quality might meet with regulatory or manufacturing to discuss an issue, and then have to log the outcome of the meeting into the system for documentation. But with a cloud-based QMS, where all parties have access to the tool, collaboration can occur within the system itself.



Advanced Analytics and Reporting

In a cloud-based QMS, with real-time data inputs from various sources and sites, analytics and reporting are taken to an entirely new level of detail and robustness.

Quality teams have quick access to accurate and timely information for data-driven decision making. The more modern capabilities of cloud-based systems offer functionality never before available, such as information widgets that alert users to trends.

The quality team can generate not only summary reports for executive leaders, but also granular reports at the record level. The QMS reporting paradigm shifts from strictly management-centric to user-centric so that insights can be leveraged at all levels of the enterprise.





Lower IT/IS Burden



Managing a validated, on-premise quality management system is very complex and requires a lot of heavy lifting on the part of the company's information technology (IT)/information systems (IS) department. This includes managing the system servers and software and keeping them up to date.

When a manufacturer transitions to a cloud-based QMS, all of that work becomes the responsibility of the system provider.

The database and operating system are always optimized. The provider's servers are always ready to maintain and manage the system. The quality team always benefits from the latest functionality upgrades and security updates, rather than having to wait for IT/IS to find the time to install them.

The IT/IS team, relieved of this burden, can focus on supporting the system users, establishing new data connections, optimizing processes, configuring new levels of reporting and performing other value-added activities.



Entry Into Quality 4.0

Manufacturers from other industries are already leveraging Industry 4.0 capabilities, including artificial intelligence (AI), Internet of Things (IoT), and continuous manufacturing. In order for life sciences manufacturers to transition to Quality 4.0, and take advantage of the game changing innovations that Industry 4.0 has to offer, they need access to enormous amounts of real-time information. On-premise QMS platforms simply can't provide this level of data compilation, storage and access.

Cloud-based systems, on the other hand, with their ability to seamlessly integrate internal and external people, processes and technologies, provide the backbone for the Quality 4.0 evolution.

They provide a way for manufacturers to look at their data in a way they never dreamed possible. For example, a system equipped with machine learning looks at every element of every record a manufacturer has in its quality system, whether it was migrated from a legacy application or inputted into the current one. The system is "learning" as it analyzes this data and presents to the user insights that would otherwise be overlooked by the human eye.



Summary: Benefits of Cloud QMS

The capabilities enabled by a cloud-based quality management system offer significant benefits to life sciences manufacturers in terms of both operational and financial performance. These include:



Lower Costs: Transitioning to the cloud eliminates the IT/IS burden associated with maintaining and managing an on-premise QMS platform. It automates and streamlines processes for the quality management team, minimizing manual labor and rework that occurs with traditional on-premise platforms. Less time and labor spend on non-value added work equates to savings for the manufacturer.



Enhanced Visibility and Control: With seamless system integration, and real-time access to a comprehensive and accurate repository of data, quality teams have visibility throughout the enterprise. This visibility extends out to the supplier community for greater control of quality beyond the manufacturer's four walls.



Increased Efficiency: The transition to the cloud enables quality teams to work smarter not harder. They can quickly access the information they make data-driven decisions to reduce risk and improve quality for the company – and ultimately patients.

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Scalability: Compared with legacy QMS, cloud-based systems are much easier to configure to meet changing needs. A company can scale up to add new users, systems and suppliers as it grows. With mergers and acquisitions (M&A) in the life sciences industry on the rise, companies can integrate acquired systems and data with minimal effort.



Improved User Experience and Functionality: People today expect systems at work to have the same level of usability as the technologies they use at home, with intuitive interfaces and the ability to access data anywhere. A cloud-based QMS is designed for use right "out of the box" with minimal set up or training required, and users can access the system via any device with a browser.

Resources



To learn more about transitioning quality management into the cloud, please visit www.spartasystems.com or check out the following resources:

[eBook: 3 Steps to Quality in the Cloud](#)

[Whitepaper: Empowering the Life Sciences Organization](#)

[eBook: Deliver More with a Cloud Quality Management Solution](#)



Sparta Systems, a Honeywell Company, is the world's premier provider of cloud and on-premises quality management software. For nearly three decades, companies in the life sciences have relied on Sparta for the innovative tools, analytics and expertise that speed up quality and compliance.

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