AXENDIA™

MODERNIZING QUALITY IN MANUFACTURING WITH INDUSTRY CLOUD

AN EXECUTIVE REPORT FOR CDMO AND GENERICS MANUFACTURERS

An Axendia Executive Report Presented by Veeva Systems

Veeva

Introduction

In the life sciences industry, globalization and outsourcing has elevated the strategic priority for contract development and manufacturing organizations (CDMO) and generics manufacturers to sharpen their focus on improving manufacturing efficiency and product quality.

The time to rethink legacy quality system approaches is now. Axendia's primary research and interviews with executives from innovative companies like Arranta Bio, Bluepharma, Sagent Pharmaceuticals, Tolmar, Ultragenyx, and Upsher-Smith Laboratories reveal the need to modernize quality systems to increase agility, visibility, and collaboration.

This report is based on firsthand experiences of executives from CDMOs and generics manufacturers that have successfully implemented cloud quality systems. We found that forward-thinking organizations are shifting to modern, native cloud-based quality solutions to improve productivity and are adopting a true "risk-based approach" to validation.

Executives indicated that implementing a native cloud quality solution streamlined quality processes and accelerated product release. They also shared that cloud enabled their companies to connect disparate processes, consolidate data and content, and eliminate redundancies. Furthermore, this report reveals how the use of cloud quality systems cost-effectively improves efficiency, quality, compliance, and communication across the entire life sciences value network.

Lastly, we discuss end-to-end capabilities needed to manage quality and compliance requirements, compare different cloud deployment options, and offer suggestions on solutions best suited for CDMOs and generics manufacturers. **Companies are adopting a cloud culture to lower the cost of implementation and enable collaboration with partners outside of their own four walls.**

Research Approach

This research was intended to identify the challenges and opportunities facing CDMOs and generics manufacturers and the role of cloud technology in getting them future-ready.

To support this research, Axendia conducted a series of interviews with executives representing CDMOs and generics manufacturers who have transformed quality management with a modern cloud solution. We have analyzed these firsthand accounts on challenges, best practices, and the achieved business benefits from adopting cloud quality solutions.

We also sought input from leading cloud quality system providers to gain deeper insights into capabilities currently offered. We then validated, distilled, and refined our analysis through discussions with industry leaders.

Why Cloud? Why Now?

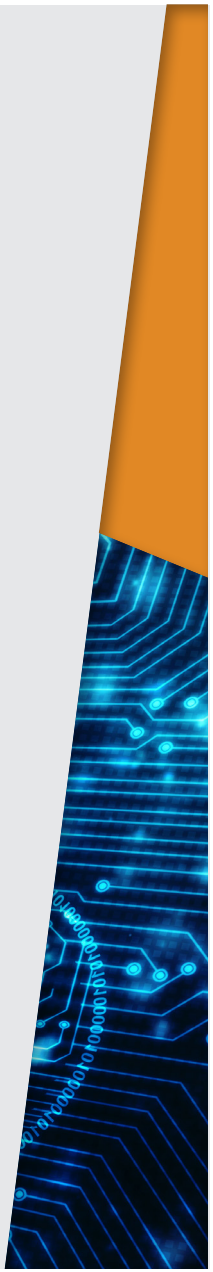
"Our vision is to be the best-in-class CDMO. Our goal is to add value to our customers and help them bring their therapies to patients. Our philosophy is "their success is our success." Obviously, quality and compliance are critical to what we do, but the implementation of systems that increase efficiency and transparency really allows us to add value as a CDMO."

Melanie Cerullo
Senior Vice President Quality and Regulatory
Arranta Bio

For decades, on-premises quality systems have been the gold standard to support audits and other quality processes. However, these applications fall short to meet the new business demands risen by the increase in global outsourcing and the shift from compliance-centric to patient-centric quality. For example, bringing external partners into quality processes is a significant challenge. Data flow issues due to a disconnected system landscape leads to manual tasks, duplicate content, and data integrity problems. These on-premises applications may also have challenges scaling well when it comes to large volume quality events. Traditional solution providers continue to update their software with additional features and functions but fall short of providing the type of visibility, traceability, and access that is needed in today's fast-changing regulatory, business, and technology landscape.

From Axendia's conversations with FDA officials[1], the agency is encouraging the use of automation, information technology applications, and data solutions throughout the product lifecycle. It is recognized that automated systems can provide significant benefits – driving enhanced product quality and safety, thereby reducing patient risk.

Today, leading companies around the world are adopting a cloud culture to lower the cost of implementation and ownership, enable collaboration with external partners, and simplify business processes. A quality system that runs on a modern cloud platform and provides secure, scalable, and flexible functionality to authorized users, anytime, anywhere, from any device is quickly replacing on-premises quality systems.



[1] Source: FDA Shares Insights on Digital Transformation & Manufacturing Modernization

Why Cloud? Why Now? (Continued)

Cloud quality systems enable faster time-to-value and streamline validation while supporting regulatory compliance.

Modern cloud platforms have been designed from the ground up to meet very stringent government regulatory and global standards and availability requirements including ISO 27001, 27107, 27018, FedRAMP, HIPAA, GDPR, SOC and HITRUST. Executives we interviewed agreed that modern cloud platforms have a secure infrastructure with very high availability and uptime. They highlighted increased business process efficiency, improved system accessibility, and better user experience as a result of unifying business functions on a cloud platform.

"We've had several customer and regulatory audits from different agencies from around the world. We haven't had one finding, observation or recommendation related to the Veeva platform in any of these inspections. And we've always been able to provide any kind of data that is being requested within minutes. It's like night and day compared to what we experienced before," said Wayne Oleski, IT Program Manager at Tolmar.

CDMOs and generics manufacturers are directing their resources to focus on the business of high-quality manufacturing and distribution rather than building and maintaining complex IT infrastructures or grappling with the daunting task of upgrading outdated, on-premises solutions. These companies are adopting a cloud culture that supports streamlining of business processes, while taking advantage of the availability and security associated with cloud platforms.

> "We are all on a single instance. We have definitely embraced the cloud and vendor hosting and it works well for us"
>
> **Ed Schipp**
> Vice President of IT
> Sagent Pharmaceuticals

STRINGENT GOVERNMENT REGULATORY AND INTERNATIONAL STANDARDS

AICPA SOC

ISO 27001 International Organization for Standardization

ISO 27017 International Organization for Standardization

ISO 27018 International Organization for Standardization

HIPAA

FedRAMP

HITRUST

Why Cloud? Why Now? (Continued)

Axendia's research[2] shows the majority of the industry is cloud comfortable. Companies of all sizes are driving towards a "cloud-first" approach, utilizing this proven application platform for supporting quality and regulatory functions with a modern quality system. Executives we interviewed stated they already had experience implementing a variety of business systems in the cloud including: Email, CRM, ERP, document management, serialization, and HR systems.

Executives also agreed that modern cloud platforms and native cloud applications are not only available and proven to work but can drive significant value. This value goes well beyond mobility, accessibility, availability and less IT infrastructure. Forward-thinking CDMO and generics manufacturing executives are looking to the cloud as a means to aggregate data to gain actionable insights. The ability to manage quality metrics and key performance indicators from Internet of Things (IoT) enabled, connected devices in the cloud and correlate it with quality events can drive manufacturing efficiencies and reduce quality issues.

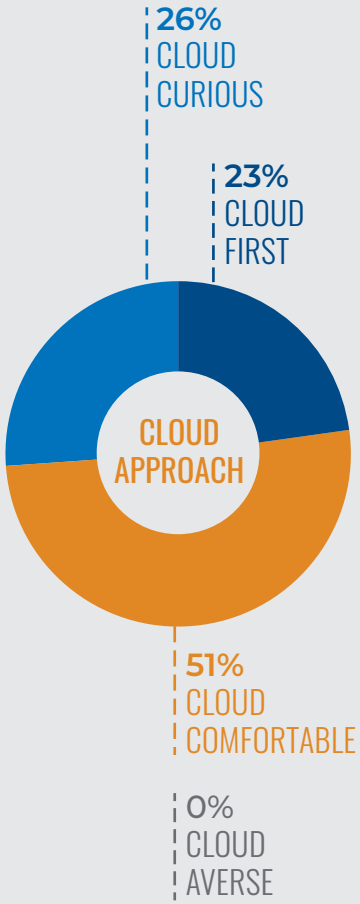
"We see a big advantage of exploring the IoT to extract and process quality data, for actionable insights that can be of high value for our business and customers. We need to store this information somewhere; the cloud is clearly the most proper place to put it, as opposed to maintaining physical servers in our facility," said Sérgio Paulo Simões, Founder and Board Member at Bluepharma.

"Transparency is trust. The goal is to offer electronic solutions where clients can have visibility to what is happening with their product as well as our performance," said Cerullo.

At Sagent Pharmaceuticals, the organization is driving improvements in product quality and regulatory compliance in the cloud. "When we're reviewing quality documents or batch records with Veeva, it's easy to search a specification and compare it to a certificate of analysis or certificate of compliance to ensure the data is matching the appropriate specifications," said James Horger, Vice President of Quality.

Upsher-Smith Laboratories is improving product and manufacturing quality by leveraging real time data reporting. "We now have the ability to see and extract data in real-time...especially if a deviation occurs on the manufacturing floor. We're able to leverage our system and perform a search to determine if it's a repeat deviation or something brand new. That data isn't available if relying on a paper process. By moving to a cloud-based solution, we have definitely made data visibility improvements," said Roxanne Hill, Manager, Quality Systems.

Bluepharma is reducing its exposure to risk. "It is very difficult to reach perfection in the pharmaceutical industry, but we have to keep trying, and eliminating the chances of error, or attacking the root cause of problems and have things under control – that's our mindset. And I think Veeva will bring some of these ingredients to us," said Simões.



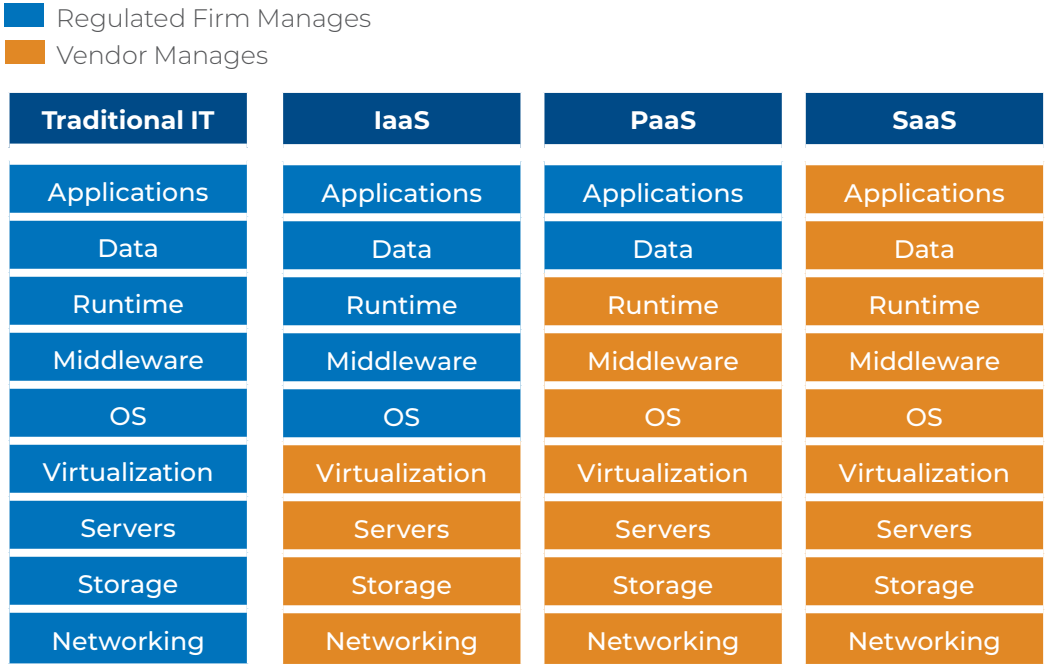
[2]Source: Axendia Straight from the Source Webinar - Using Connected Manufacturing to Overcome a Disruption in Life-Sciences

Not All Clouds Are Created Equal

According to the National Institute of Standards and Technology (NIST [3]), "Cloud computing is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction."

Cloud computing is the collection of hardware and software that supports three service models as seen below compared to the traditional on-premises IT model

(From ISPE; Pharmaceutical Engineering January/February 2014 Vol. 34 No. 1).



[3] Source: The NIST Definition of Cloud Computing

SaaS can be delivered through hosted or multitenant cloud:

Private cloud (Single-Tenant or Hosted Model)

Many on-premises software vendors offer Software-as-a-Service (SaaS) licensing models for hosted versions of legacy solutions. However, these solutions are typically online versions of legacy software hosted off premises. Simply offering a subscription license model that converts a perpetual license into an expensive rental licensing model, does not meet the definition of modern cloud computing.

Public cloud (Multitenant or Native Cloud Model)

Multitenant or native cloud platforms are built from ground up to scale with a shared pool of computing resources – hardware, network, etc. All customers have the same software version and use shared resources, while retaining logical separation of customer or user data. Multitenant cloud applications can easily scale to organizations of any size and are configurable for each customer without coding – shortening the implementation time. Users can also try out the solution during evaluation instead of waiting until after the solution is implemented. In a multitenant cloud, incremental innovation is delivered frequently and transparently which reduces the cost and effort of massive upgrade projects. Customers are always on the same, latest version. Vendors do not have to maintain multiple older application versions, allowing more resources for innovation.

Not All Clouds Are Created Equal (Continued)

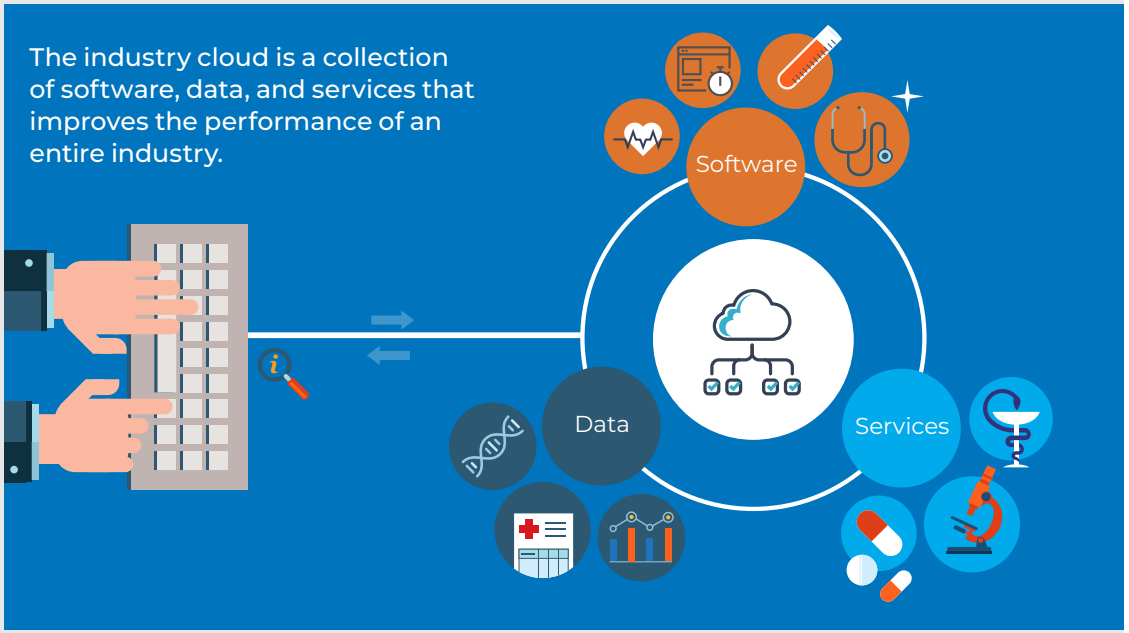
Industry Cloud

The industry cloud provides all the benefits of a true multitenant cloud plus the standardized best practices out-of-the-box. It includes software, data, and services to meet an industry's specific needs like life sciences.

- **Software** – Designed with built-in best practices and open application programming interface (APIs) to integrate with other applications, enabling software and business process integration.
- **Data** – Seamlessly works with both purchased data and data created through the use of the software.
- **Services** – Delivered services focused on a particular industry by the cloud vendor or other service providers in the ecosystem.

While the out-of-the-box functionality accelerates deployment, the configuration flexibility allows companies to easily tailor the application to their requirements. The user experience, application workflows, and backend administration are built and optimized for business processes. Industry cloud applications for life sciences continue to evolve and improve with new learnings and business needs.

The cloud model allows quick deployment of new features under a change control process leveraging the provider's validation program. With cloud solutions, companies are always on the latest version of the software and have modern capabilities to meet constantly changing business and regulatory requirements.



To learn more, see The 5 Essential Characteristics of Cloud.

Executive Accounts of Cloud QMS Success

Executives we interviewed unanimously agreed that leveraging a modern cloud infrastructure is helping drive efficiencies across the organization.

"Our expectation is that we will be able to take simple actions and have integrity of information. With the right level of security, everyone will be able to make decisions based on data and make things happen fast. And, perhaps in the future, we can reallocate some of our resources performing manual tasks to other strategic projects that are of higher value to the organization and our customers."

Sérgio Paulo Simões
Founder and Board Member
Bluepharma

"Most people in the pharmaceutical industry are already familiar with Veeva. If you're adding staff, it's easy to onboard new employees because they already have experience with the system even if some sites have slightly different configurations."

James Horger
Vice President Quality
Sagent Pharmaceuticals

"One of the biggest benefits of moving to the cloud is we no longer have to worry about upgrades and we're always on the latest version. And, since everyone started working remotely, another benefit is not having everyone on the VPN in order to do their jobs. Users log into Veeva Vault and do their work without ever connecting to the VPN, which is really nice because that's one less point of failure."

Wayne Oleski
IT Program Manager
Tolmar

"Paper puts an additional barrier to making changes. The right electronic system removes the barrier and increases efficiency in support of improved quality and lends itself to continuous improvements in manufacturing and distribution."

Melanie Cerullo
Senior Vice President Quality and Regulatory
Arranta Bio

"I don't have to be on-site to dig through a filing cabinet to see a batch record revision history - it's all in Veeva. And I'm able to extract what I need or provide a snippet and give direction to somebody on the floor to keep the business going."

Roxanne Hill
Manager Quality Systems
Upsher-Smith Laboratories

The Cloud Drives Efficiencies Across the Value Network

Technology innovation continues to accelerate. Keeping up with the future requires a modern cloud platform capable of supporting advancements such as AI, machine learning, big data, and analytics to effortlessly and seamlessly capitalize on new opportunities.

Driving efficiencies across an organization to not only reduce costs but to support improved business outcomes is the new reality for many life sciences companies and their CDMO/CMOs. **"The ability to track and trend our quality issues has allowed us to mitigate risks proactively. As a result, we have seen an increase in operational throughput,"** said Oleski.

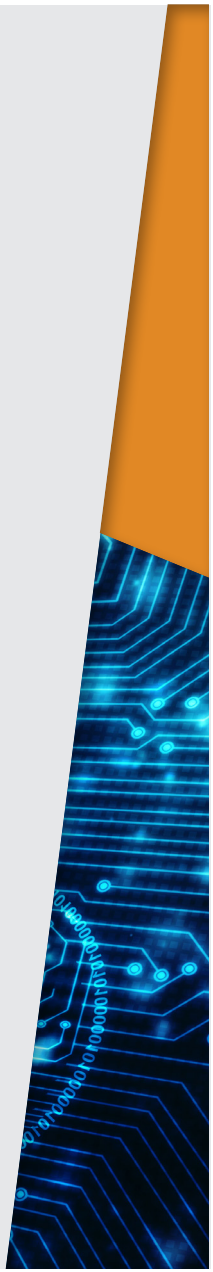
"On-premises solutions require significant internal IT and QA technical expertise to be able to build that properly with the proper controls, so cloud solutions really allow smaller companies to implement in a more efficient manner"

Melanie Cerullo
Senior Vice President Quality and Regulatory
Arranta Bio

The interoperability of systems is a driving force to the adoption of modern cloud platforms and solutions. An industry once obsessed with 'Great Mounds of Paper (GMPs)' is changing its course. Cloud quality systems are uniquely poised to support the needs and wants of life sciences companies:

- Mobility, accessibility, availability
- Less IT infrastructure to manage
- Secure access to data; less paper
- Increased time-to-value; lower risk and cost
- Less burdensome validation by leveraging vendor documentation processes
- Seamless connections across applications

Mobility, accessibility and the availability of cloud QMS reduces friction across the organization. According to Joe Vigil, Director of Quality Systems at Ultragenyx, "A system that is browser agnostic and available anywhere that has an internet connection was a primary driver for selecting a modern cloud-based quality system. We have remote employees who need to be able to easily access the system on a tablet, smartphone, etc."



The Cloud Drives Efficiencies Across the Value Network (Continued)

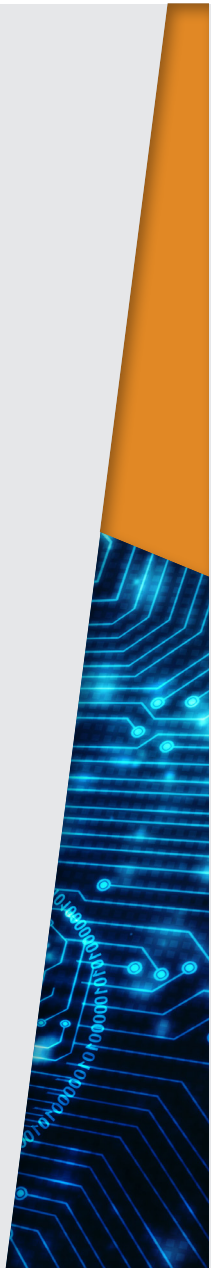
Executives pointed to the need for global scalability and digital continuity to support intelligent decision making. "If I am going to roll out a system to multiple sites, I am not worried about scaling the technology. We look for applications that are multilingual and Veeva is one of them," commented Schipp.

Life sciences companies are seeking an integrated business community or ecosystem that leverages the same platform for their unique business needs. Cloud quality system vendors can provide relevant features to their clients quickly and efficiently. In a multitenant cloud environment, upgrades do not disrupt client configurations or workflows, minimizing validation efforts.

Leveraging modern cloud platforms, CDMOs and generics manufacturers have the opportunity to take advantage of promising new technologies such as the Industrial Internet of Things (IIoT), smart machines, AI, and big data analytics. Legacy on-premises quality system providers are unable to easily offer secure access to these advanced functionalities. It is also critical that technology continues to perform at scale – especially as the number of companies on the platform and their data rapidly grow.

As organizations continue to globalize and outsource, a modern cloud quality system supports community portals for collaboration and visibility. "At first, Veeva appeared to be a sophisticated tool that is used for larger organizations, much larger than us. However, we realized that although we're a medium-sized company in the generics field, we could benefit from a sophisticated tool to improve our services. We are able to provide the right level of transparency on documents and processes to our customers. We offer versatility as well, in that they have secure access to our systems and together we are able to monitor where we stand in terms of responding to different issues that are related to quality management," said Simões.

"It's more efficient to review, route, and approve documents in an electronic quality system. The bottlenecks that often occur in paper-based systems are quickly eliminated and efficiencies are quickly realized," commented Cerullo.



End-to-End Quality System Capabilities

Most companies are leveraging the cloud to support end-to-end quality functions instead of integrating point solutions. However, not all vendors offer the same level of functionality. From an industry standpoint, what is needed are end-to-end capabilities to consistently and flexibly manage both quality and compliance.

> "Strategically, Veeva is the right fit because we knew we needed a solution for document management, quality management, and eventually we were going to need it for training. Since Veeva has all of that in one solution, it's a huge upside."
>
> **Wayne Oleski**
> IT Program Manager
> Tolmar

In the cloud, to successfully manage quality, life sciences organizations need to consider end-to-end capabilities in a single platform, including:

Lessons Learned

To successfully implement a cloud quality system, executives we interviewed recommended the following best practices:

Address the Fear of Losing Control

Moving to the cloud does not mean a company loses control. Stakeholders must still decide what information is stored in the system and more importantly who can access various applications and what a user can do once access is granted. Axendia recommends companies take the time to understand the appropriate level of security required for users in cloud applications.

"Make sure users have a validated system security access level that aligns with the associated business process." By having the appropriate checks and balances over system security, we were able to make sure we were in a compliant state that aligned with business needs," added Vigil.

Don't Bring On-premises Baggage to the Cloud

Axendia recommends organizations avoid developing requirements based on legacy, on-premises quality system baggage. Start with a clean slate and develop requirements that leverage native cloud quality system capabilities as much as possible. Consider whether it securely allows external parties to access the application. Take advantage of the out-of-the-box functionality and built-in best practices. **"In hindsight, we should have taken a closer look at Veeva's delivered application configuration for QMS, especially with Veeva releasing new features all the time which are directed toward that delivered application configuration,"** suggested Oleski.

Understand Your Processes and Requirements

Cross-functional meetings with subject matter experts (SMEs) across the organization are vital to ensuring requirements are documented, rationalized, and agreed upon.

"Spend the necessary time upfront to understand what the system needs to be able to do on the back end. Be sure to identify the reports you need to run, the data you want to collect, and how you want to slice it upfront because that has implications to what gets turned on or not in the configuration. Lastly, think about how resources will use and access the information so that can be built into the configuration," suggested Cerullo.

"Don't just force your paper process into an electronic system; instead, use it as an opportunity to refine your process. Ensure you have the right people in the room when making decisions on what a record is going to look like, how a workflow is going to actually work or how a document will be used downstream," said Hill.

Conclusions and Recommendations

It is clear that CDMOs and generics manufacturers are taking a fresh approach to managing their quality systems and are adopting a cloud culture. These organizations are looking for ways to improve manufacturing efficiency, product quality, and transparency across the value network.

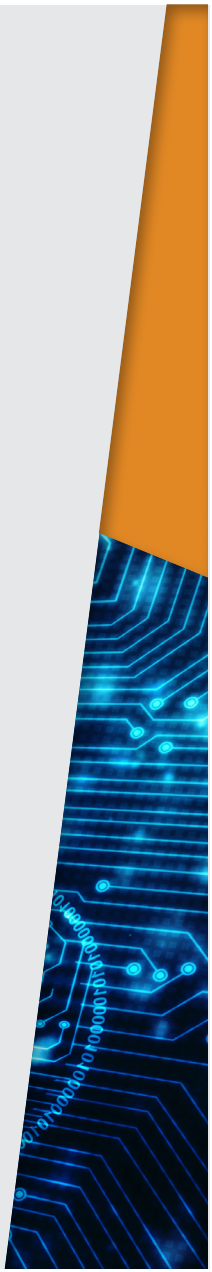
Through firsthand interactions with CDMO and generics manufacturing executives, we determined that innovative companies are now driving towards a "cloud-first" mandate that enables secure, scalable, and flexible QMS functionality to authorized users – anytime, anywhere, from any device.

Forward-thinking companies are taking not only a paperless but a data-driven approach to managing quality across the enterprise. Driving efficiencies across an organization not only reduces costs but supports improved business and patient outcomes.

There are different cloud solutions and there are strict definitions for each type according to NIST. Selecting the cloud model that best suits your organization today, and in the future, will greatly improve the successful rollout and utilization of your quality system.

Axendia recommends organizations avoid restricting themselves by developing requirements based on legacy, on-premises quality systems. Start with a clean slate that capitalizes on the advantages of a modern cloud quality system and leverages native capabilities as much as possible.

Beware of hosted versions of legacy solutions offered as cloud solutions. The hosted, off-premises versions of legacy software do not meet the definition of cloud computing. When evaluating a cloud quality system, verify that the availability of end-to-end functionality is available within a single quality platform. Not all cloud quality system vendors offer the same level of functionality and business requirements vary from company to company. Selecting a platform that meets your needs today and can support scalability and interoperability will eliminate the need to integrate point solutions in the future.



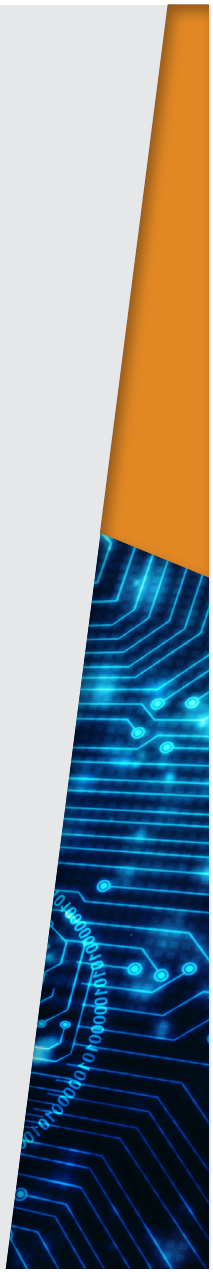
Conclusions and Recommendations (Continued)

To this end, life sciences organizations must evaluate whether a proposed solution consistently and flexibly supports improving quality while meeting ever changing regulatory requirements.

Additionally, a cloud quality system enables faster time-to-value and streamlines validation while supporting regulatory compliance. The corporate leaders we interviewed also highlighted the cost savings achieved by unifying processes, data, and content in one system. They saw business process efficiencies with tangible payback and an improved user experience with ease of use. Executives also pointed out that a cloud quality system is a ready-to-use, scalable application with built-in best practices and automated workflows to support efficient operations and improved product quality.

Culture change is imperative to the success of any organization transitioning to the cloud. This applies to both system selection and implementation as well as how your company approaches computer system validation. Simply stated, you cannot validate a cloud solution the same way as an on-premises quality system.

Finally, keep in mind that the value of any system must be measured by its ability to drive improvements in product quality and accelerate manufacturing efficiency in a timely and cost-effective manner while supporting regulatory compliance.



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Veeva is the global leader in cloud software for the life sciences industry. Committed to innovation, product excellence, and customer success, Veeva serves more than 975 customers, ranging from the world's largest pharmaceutical companies to emerging biotechs. As a Public Benefit Corporation, Veeva is committed to balancing the interests of all stakeholders, including customers, employees, shareholders, and the industries it serves. For more information, visit veeva.com

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