# Cloud platforms: Bringing consistency, control and compliance to manufacturer and supplier collaboration management

by Fierce Custom Publishing

SPONSORED BY

amazon web services™

Published by
FierceMarkets

The need for platforms that support efficient, compliant collaboration with remote sites is greater than ever. Next year, for the first time, drug developers will spend more on contract R&D services than in-house operations, according to the Tufts Center for the Study of Drug Development[1]. Increased R&D outsourcing is part of a broader move from vertically-integrated operations to networks of collaborators.

Outsourcing cuts fixed costs while ensuring access to expertise, technology and geographic breadth. These benefits persuaded biopharma companies to embrace the approach despite its problems. Email, fax and third-party technology systems facilitate these collaborations, but create security, compliance and efficiency challenges. Now, the emergence of cloud collaboration platforms is promising to fix these failings.

"Up until now, life sciences companies have collaborated primarily through email and fax. They would discover a non-conformance with a CMO, and proceed to exchange emails with them," said Bruce Kratz, vice president of product development and quality management specialist at Sparta Systems. "When they needed a signature on a supplier's corrective action, that was accomplished through fax. It was inefficient, and made compliance reporting challenging."

Biopharma companies can manage their global networks of suppliers and partners by deploying common cloud platforms. Once deployed, the platform acts as a central hub for the network. Internal and external research, development and manufacturing facilities automatically upload data to the common platform, either via streaming or batch transfer. The headquarters of the drug company has access to all the data. These systems enable biopharma companies to improve consistency, quality and compliance while realizing the benefits of collaboration.

## Achieving compliance and control

The cloud eliminates many of the failings of legacy approaches to collaboration. Historically, the lack of shared platforms forced biopharma companies to rely on systems run by their collaborators for data

1 "Insights Into Capturing Collaborative Value". Applied Clinical Trials, 2016. Web. 14 Nov. 2016.

capture and storage. Ceding control to third parties hinders companies' ability to ensure data security and regulatory compliance. The cloud allows biopharma companies to regain control.

"Instead of having information stored at remote facilities, which may or may not be part of your own organization, you can create a shared cloud environment where essentially all documents and all information is stored centrally, which has a tremendous benefit for these companies in terms of protecting their intellectual property," said Mark Johnston, director of global business development, healthcare and life sciences at Amazon Web Services (AWS).

Biopharma companies set the policies and controls covering the data and documents uploaded to their shared cloud environments. This is true of models that use third-party systems, too. The difference is the cloud makes it impossible for contractors to deviate from policies. When imposing controls on a third-party system, a company entrusts its collaborator to adhere to its policies. Cloud platforms essentially turn policies into code, guaranteeing the controls are continuously enforced.


This guarantee frees companies from manual monitoring of collaborator compliance. The use of automated, error-free data transfers also provides reassurance that if information is requested by an auditor, it will be available, accurate and stored in a regulatory-compliant manner.

Audit readiness is a strength of cloud systems. Time-stamped audit trails are generated. Log files are monitored. Metrics are collected and tracked. Alarms go off if metrics cross thresholds. These and other auditability and traceability services mean cloud logging systems stand up to rigorous scrutiny and are more proactive than on-premise alternatives.

"When you put a validated workload in the cloud you can achieve continuous compliance rather than a point-in-time type of approach, which is historically what's been done with on-premise infrastructure," Johnston said. The consistency of controls and reduction in manual errors achieved by cloud collaboration platforms make the model well-suited to meeting the demands of regulators.

The industry was initially reluctant to move good laboratory, clinical and manufacturing practices (GxP) workloads to the cloud, though attitudes are changing. Amazon Web Services, working with an internationally recognized compliance consulting firm, has published guidance on running GxP systems in the cloud[2]. A number of biopharma companies have begun deploying these systems on AWS.

"Companies are much more comfortable with how the industry is addressing security. There are now good safeguards, methodologies and frameworks, like the EU-U.S. Privacy Shield, in place," Sparta's Kratz said.

## Showing cloud collaboration works

The emerging willingness to run regulated workloads in the cloud is undergirded by the experiences of early adopters of the approach. Solution providers such as Medidata, Sparta and TraceLink have shown the cloud works in fields covered by GxP.

2 "Considerations for Using AWS Products in GxP Systems". 2016. Web. 14 Nov. 2016. (https://d0.awsstatic.com/whitepapers/compliance/Using_AWS_in_GxP_Systems.pdf)

TraceLink built a collaboration platform on AWS to help clients protect product integrity and comply with global track-and-trace regulations. The system supports the exchange of lot-level and serialized data between biopharma companies, CMOs and other organizations in the drug supply chain. These data must be secure. TraceLink and its clients, which include four of the top 10 global drugmakers, trust AWS to provide infrastructure that meets their security standards.

Running the platform in the cloud has a range of benefits. Serialization requirements have increased the amount of data generated by the supply chain. The cloud makes it fast and affordable to scale up the collaboration platform to meet the resulting growth in compute and storage demand.

"Companies only have to pay for what they use, and they can turn on new business modules and enable new connections in minutes, eliminating the traditional large up-front capital outlay for enterprise software and supporting hardware infrastructure," said Peter Spellman, the former senior vice president of product and cloud engineering at TraceLink.

Sparta has realized similar benefits by running its Quality Business Network collaboration platform on AWS. The company helps its biopharma customers manage their quality processes and demonstrate compliance to the FDA and other agencies. For most of its 22-year history, Sparta provided Quality Management Systems to large enterprises. With the advent of cloud technologies, they can help customers extend those systems to smaller partners or move all or parts of their quality management to the cloud.

The benefits of moving to distributed systems connected through a secure cloud platform extend beyond scalability, flexibility and cost.

"When we talk about document sharing and collaboration, I think most of the industry takes what they've been doing on paper and converts that to a digital document," Kratz said. "But there's a better way to exchange that information. If we get it out of documents, we can exchange it securely. We can perform analytics on it. We can gain insights and spot trends that can help the business proactively."

These benefits mean cloud platforms do more than just fix the failings of fax, email and other legacy collaboration systems. The cloud supports real-time analysis of quality data, as well as predictive modeling to mitigate risk and identify opportunities. Complex networks of collaborators are made manageable. Operational execution is improved.

## Reaching the tipping point

Working on solution providers' fully-validated, regulatory-compliant collaboration platforms has familiarized biopharma companies with running GxP workloads in the cloud. In parallel, AWS has worked with the industry, liaised with FDA and subjected itself to a mock regulatory inspection to tailor its cloud offering to the needs of biopharma companies. The result is a growing acceptance of the use of cloud platforms to handle regulated workloads.

Biopharma companies may need to acquire new skills or adapt policies so cloud platforms can be used to collaborate with CROs, CMOs and other remote sites, but a blueprint for the process is in place. Those that make the transition will be rewarded with platforms tailored to today's collaborative models, not the in-house-focused approaches of the past.

The modern biopharma industry is striving to be fast and agile while continuing to adhere to the highest compliance standards. Companies need collaborative platforms that share and facilitate this ambition. This is what the cloud delivers.