

AWS and SAP:

How and Why Companies Run Regulated Workloads in the Cloud



Change is the only constant in today's biopharma industry. To succeed, companies must collaborate and outmaneuver the competition against a backdrop of fast-evolving regulations and technologies. Being nimble is essential. To help companies achieve this state, Amazon Web Services has partnered with SAP. Multi-year upgrade projects are out. Rapid iteration is in.

For years, biopharma companies have relied on AWS and SAP to support different parts of their operations. The AWS cloud has enabled preclinical researchers, marketing teams and other groups to store, share and analyze data, innovate and collaborate while freeing themselves from the costs and constraints of on-premise infrastructure.

In parallel, SAP has reimagined its enterprise resource planning (ERP) system for the digital era. Today, data generated and collected through the networking of businesses, processes, data and equipment makes it

possible for companies to gather real-time insights that improve their operations. These insights are a key differentiator in the fast-moving digital economy but accessing them using legacy systems is challenging.

SAP responded to these challenges with HANA, a platform that adds real-time computing to the features that made its traditional ERP system perhaps the most mission critical suite of applications run by businesses.



In 2017, AWS and SAP partnered to accelerate the convergence of their offerings. The result is a faster and simpler way to move from on-premise hardware and get started with SAP HANA in the AWS cloud. Companies can bring their own licenses and software to the AWS cloud. The perceived barriers to running regulated workloads in the cloud have fallen away.

Established companies that make the migration and startups that skip the on-premise era and go straight to





the cloud are realizing a range of significant benefits, from more cost-effective uptime of mission critical applications and the ease with which they adapt to changing regulations, to more rigorous security and greater business agility.

WHY AGILITY IS DRIVING CLOUD MIGRATION

Some of the benefits of moving SAP to the AWS cloud are variants on the gains companies realize when they adopt cloud systems in other parts of their businesses. On-premise SAP installations need large internal teams, may take significant effort to upgrade and are sized to support peak volumes, resulting in day-to-day underuse of infrastructure support and investment. Cloud systems cost less, iterate faster and scale automatically.

These differences factored into Amgen's decision to start migrating its SAP applications away from on-premise infrastructure.

"SAP was running on a physical hardware, which was very complex, very hard to manage, very expensive," Harish Mundre, Principal Cloud Solution Architect at Amgen, said at AWS re:Invent 2017. "We're not moving to the cloud to save the cost. If you save any cost, that's a bonus for us. Mainly we are looking for expedient agility. On-demand self service ... is the biggest benefit for our global ERP team."

As Amgen's focus on agility suggests, the value of the cloud is magnified by the pace at which the biopharma industry and the rules that govern it are changing. New, major regulations are coming down the pipe at a daunting rate, forcing companies to adapt to legislation such as the U.S. Drug Quality and Security Act and Europe's Falsified Medicines Directive simultaneously.

SAP helps its customers adapt to these rules and other requirements by releasing new modules. Yet, as these modules require updated ERP software to run, uptake is limited by the speed at which companies move to the latest ERP Central Component (ECC). This can require new infrastructure for on-premise installations.

The cloud eliminates this constraint on the uptake of new modules by enabling the rapid, ongoing iteration of the ECC version. This makes it trivial for companies to keep their ECC up to date and, by extension, to quickly adopt modules SAP releases to facilitate compliance with new regulations.

HOW THE CLOUD IMPROVES COMPLIANCE, RELIABILITY, AND SECURITY

Agility is one of the main motivations for moving to the cloud. Compliance is another.

By treating infrastructure as code, companies can control infrastructure like software. Testing and validating each change to the environment becomes a simple task. Once companies are up and running in the cloud, automated traceability and audit processes enable continuous compliance.

Reliability and resilience are also big factors, particularly when working with mission-critical applications such as those provided by SAP.

The uptime of these applications is vital to the smooth

functioning of businesses. Migrating to the cloud hands responsibility for ensuring the applications are available at all times to a specialist with global infrastructure. The result is super up time that is architected into the solution.

This performance is underpinned by AWS' multiple regions and multiple Availability Zones within each region. Regions are isolated from each other to ensure compliance with regulatory requirements. The zones are also isolated from each other to prevent contagion in the event of a failure in one part of the network. Yet, the zones are also connected in a way that allows one zone to automatically step in if another has a problem, ensuring uninterrupted uptime.

Access to global infrastructure comes into play in disaster recovery, too. AWS designed its disaster recovery system to enable companies to quickly recover critical IT systems and data without having to maintain a physical backup location. In the case of regulated workloads, AWS is combining this



Availability Zone-enabled model with SAP HANA System Replication.

The approach has found favor with drug developers.

“We just use AWS regions settings to do disaster recovery,” Marcello Damiani, Chief Digital Officer at Moderna Therapeutics, said. “it’s been flexible enough to allow us to build in a very fast fashion.”

Moderna has also had a positive experience with the security features provided by AWS and SAP.

“There is always discussion about security but for us it’s a no-brainer,” Damiani said. “When you look at the number of security people AWS has compared to what we could afford to have it’s an easy decision.”

HOW AWS AND SAP ARE SIMPLIFYING MOVING TO THE CLOUD

Amgen and Moderna exemplify how different types of drug developers can run SAP in the cloud.

Moderna was founded in 2010 with a cloud-first strategy. Back then, the biotech only needed to run unregulated workloads. Now, Moderna has a clinical-phase pipeline and manufacturing facility. These are regulated operations traditionally seen as requiring on-premise infrastructure. Yet, Moderna management stuck with its cloud-first strategy after concluding the obstacles to running regulated workloads on AWS are more imagined than real.

That conclusion has been validated by Moderna’s experience in establishing a Good Manufacturing Practice (GMP) environment in AWS. Moderna is now up and running with GMP workloads using SAP on the AWS cloud. Despite its position at the cutting edge of the transition to GMP workloads in the cloud, Moderna found the setup process quick and easy.

“It took us five months to implement and it was a non-event for the company,” Damiani said. “It proved that the holdup on running SAP in the AWS cloud was more due to outdated perceptions than anything else.”

Moderna’s positive experience was underpinned by the work AWS and SAP have done to simplify the process of getting started with regulated workloads in cloud environments. Amgen has also benefited from those efforts but, as a more established business with existing on-premise infrastructure, it has taken a different journey.

Amgen is part way through a phased-migration of SAP to the AWS cloud. In this intermediate state, Amgen runs SAP applications on both its on-premise infrastructure and the AWS cloud. Certain technologies must be used to make this hybrid model work but, supported by AWS and SAP, Amgen has found the migration to be manageable and worthwhile.

“There are not really major challenges,” Amgen’s Mundre said. “Since I worked in on-premise infrastructure for quite a while, the cloud is different ... but there is always a workaround.”

THE FUTURE OF SAP IN THE CLOUD

Amgen and Moderna’s use of SAP in the AWS cloud is breaking new ground and delivering benefits to both businesses. Yet, they, AWS, SAP and the industry

as a whole are still uncovering the full extent of the improvements made possible by running regulated workloads in the cloud.

At Moderna, the next step is to translate leading-edge uses of the cloud to GxP environments. One pilot project is using IoT buttons — like Amazon’s consumer-focused Dash buttons — instead of Kanban cards to manage materials at a production plant. Instead of using cards to indicate when more materials are needed, production-line workers press the button to automatically place an order in SAP.

“This pilot ... represents the fusion of AWS innovation and traditional, validated-SAP interfaces,” Roland Smith, Senior Director of Digital GxP Systems at Moderna, said.

The same can be said of Moderna’s other initiatives. Having seen the benefit of applying traditional analytics and machine learning to data generated in its preclinical operation, Moderna now wants to turn the same techniques on new repositories accrued by its clinical and production teams to drive improvements in both environments.

In doing so, Moderna will write another chapter about the benefits of running SAP in the AWS cloud, adding to the lessons about agility, compliance, reliability and security already learnt by it and other early adopters. ●

For over 10 years, Amazon Web Services has been the world’s most comprehensive and broadly adopted cloud platform. AWS offers over 90 fully featured services for compute, storage, networking, database, analytics, application services, deployment, management, developer, mobile, Internet of Things (IoT), Artificial Intelligence (AI), security, hybrid, and enterprise applications, from 42 Availability Zones (AZs) across 16 geographic regions in the U.S., Australia, Brazil, Canada, China, Germany, India, Ireland, Japan, Korea, Singapore, and the UK. AWS services are trusted by millions of active customers around the world – including the fastest growing startups, largest enterprises, and leading biotechnology, pharmaceutical and medical device companies – to power their infrastructure, make them more agile, and lower costs. To learn more about AWS in biotech and pharma, visit <https://aws.amazon.com/health/biotech-pharma>.
