



EBOOK:

Compliance for Healthcare & Life Sciences Organizations with AWS





Contents

Healthcare and Life Sciences Compliance and AWS.....	2
Advantages of AWS for Healthcare and Life Sciences Compliance.....	3
AWS for HIPAA, HITRUST, and GxP.....	5
Why AWS for Healthcare and Life Sciences Compliance.....	6
Featured APN Healthcare Partners.....	8
Featured APN Life Sciences Partners.....	11
Getting Started.....	14

Healthcare and Life Sciences Compliance and AWS

Cloud computing offers compelling benefits for organizations in the fields of Healthcare and Life Sciences, but organizations that are new to the cloud often have questions about compliance and regulatory requirements. “How can I use the cloud and comply with requirements for handling electronic Protected Health Information (PHI)?” “How can I validate regulated systems running in the cloud?” “How do I audit a cloud-based system?” If these questions remain unanswered, they can keep Healthcare and Life Sciences organizations from utilizing the flexibility, elasticity, and cost efficiency of cloud computing solutions.

Amazon Web Services helps organizations address their compliance requirements by providing a secure, robust, and scalable cloud infrastructure. Our customers develop, validate, and operate cloud applications based on their industry-specific security and compliance requirements, as supported by the [AWS Shared Responsibility Model](#).

This eBook highlights advantages of using AWS to create and maintain cloud-based solutions for Healthcare and Life Sciences organizations with specific compliance requirements, and features use cases from diverse organizations that have utilized AWS when moving to a cloud-based IT model in these fields.

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The flexibility we have today is dramatically improved. It allows us to instantly put environments in place to support my engineering teams. They can develop and test new applications and get them to market faster so we can respond to business change.

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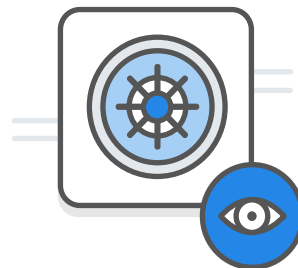
James Lawson
Chief Solutions Officer
Verge Health

Advantages of AWS for Healthcare and Life Sciences Compliance

Deploying on AWS allows organizations to adapt and innovate more quickly. AWS provides a global infrastructure platform for building and maintaining cloud-based solutions for HIPAA and other regulated workloads. AWS allows organizations to focus on their core competencies while relying on a suite of back-end services that may be configured and used by customers to meet global compliance requirements.

AWS offers security and compliance services that enable organizations to build cloud-based solutions that have the ability to:

- Align to major cloud security frameworks
- Validate infrastructure with fine-grained controls
- Store, move, and track sensitive data securely



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Use the cloud to protect the cloud. Our most successful customers who are security conscious are leveraging all of the features and functions that are available to them through AWS and our partner ecosystem.

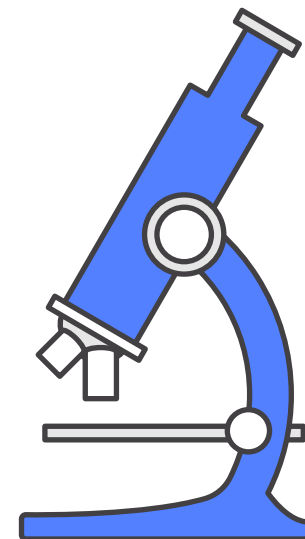
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Hart Rossman
Director, Global Security Practice
AWS

Advantages of AWS for Healthcare and Life Sciences Compliance (cont'd)

Additionally, Healthcare and Life Sciences competency partners in the AWS Partner Network bring deep expertise and technical proficiency to help accelerate customer innovation. These companies extend the benefits of AWS by offering consulting and technology solutions that help customers meet Healthcare and/or Life Sciences regulatory requirements.

The AWS Marketplace is an online store that helps customers find, buy, and immediately start using the software and services they need to build products and run their businesses. AWS Marketplace complements programs like the AWS Partner Network and is another example of the commitment AWS has made to grow a strong ecosystem of software and solution partners.



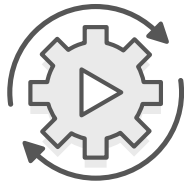
AWS for HIPAA, HITRUST, and GxP

AWS offers HIPAA Eligible Services including Amazon EC2, Amazon S3, and Amazon RDS, among many others that can help organizations meet the requirements laid out by the U.S. Health Insurance Portability and Accountability Act (HIPAA). HIPAA Eligible Services can be used by covered entities and business associates to build, maintain, and run cloud-based solutions that create, receive, maintain, or transmit PHI in compliance with HIPAA. (A full list of AWS's HIPAA Eligible Services can be found [here](#).) In addition, Healthcare customers and partners can leverage AWS's HIPAA, ISO, SOC and other compliance programs to meet the certification requirements for Health Information Trust Alliance (HITRUST) and Electronic Healthcare Network Accreditation Commission (EHNAC).

For Life Sciences organizations that produce pharmaceuticals, biotherapeutics, medical devices, and medical applications, AWS services enable IT teams to set up the fine-grained access control, auditability, and automated guardrails necessary for the creation and maintenance of regulated workloads following Good Laboratory, Clinical, and Manufacturing Practices (GxP).



Why AWS for Healthcare and Life Sciences Compliance



Aligns with all major global security frameworks:

- AWS has a wide range of certifications and attestations aligning to compliance programs from around the globe
- AWS certifications and attestations can be leveraged by customers to meet their industry-specific compliance requirements such as the HITRUST Common Security Framework or the Electronic Healthcare Network Accreditation Commission (EHNAC)



Enables infrastructure qualification with fine-grained controls:

- AWS offers access to the same fine-grained controls for qualifying infrastructure as are typically used for qualifying software
- The AWS infrastructure-as-code model allows development of a secure environment in the cloud with AWS resources provisioned according to the compliance standards defined by security administrators

Why AWS for Healthcare and Life Sciences Compliance (cont'd)



Offers tools for storing and moving regulated data securely:

- AWS gives customers the ability to encrypt their data at-rest and in-transit, fine-grained access controls, and access to instant audit trails for forensic analysis
- AWS services enable organizations to build large-scale, global applications that can store, process, and transmit clinical and patient data, while still ensuring they can meet local and regional regulatory requirements



Featured APN Healthcare Partners



ClearDATA provides an easy-to-use Compliance Dashboard with comprehensive security, privacy, and compliance solutions for healthcare customers looking to move to the cloud. With customized AWS-specific DevOps Automation combined with extensive healthcare expertise, ClearDATA enables healthcare organizations to securely deploy multiple workloads in a HIPAA and HITRUST compliant application environment, ultimately providing for a better healthcare experience.



Cloudticity focuses exclusively on helping healthcare organizations design, build, migrate, and manage HIPAA solutions on AWS. Cloudticity managed services, built around the Cloudticity Oxygen™ platform, ensure providers, payers, and healthcare services companies maintain required security and compliance postures for HIPAA and HITRUST compliance, as well as the speed and technical agility needed in the cloud to optimize patient experiences and advance medical care.

ClearDATA Case Study: CareCloud

CareCloud is the leading provider of cloud-based revenue cycle management (RCM), practice management (PM), electronic health record (EHR), and patient engagement solutions for high-performance medical groups. The company currently serves more than 17,500 medical professionals working at 5,000 medical offices and manages more than \$4 billion in annualized accounts receivable on its integrated clinical and financial platform.

CareCloud found that they could better manage large spikes in usage, manage regulatory compliance, and speed innovation by using Amazon Web Services (AWS). CareCloud chose to partner with ClearDATA, an AWS Partner Network (APN) Advanced Consulting Partner and Healthcare Competency Partner. CareCloud runs its primary application platform on the ClearDATA Healthcare Managed Cloud on AWS.

ClearDATA provides highly secure, direct access to the AWS API, giving customers full control of their environments, while mitigating risk through ClearDATA's Compliance Dashboard. ClearDATA's security standards, built into the dashboard, are aligned with the controls in the HITRUST Cybersecurity Framework and are designed to exceed minimum HIPAA requirements.

By running its applications on the ClearDATA Healthcare Managed Cloud on AWS, CareCloud can innovate more rapidly. Now, instead of focusing on managing IT operations, the organization is focused on developing innovative software. "Working with ClearDATA and AWS, we can deliver a pipeline that helps us build out new services quickly, and then we can work with the ClearDATA DevOps team to determine the best way to get into production efficiently," says Josh Siegel, Chief Technology Officer of CareCloud.

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Running our SaaS platform on ClearDATA on the AWS Cloud takes a lot of guesswork out of compliance and high availability. That gives us fewer things to manage, so we can spend our time creating new features that help us grow right alongside our high-performing practice clients.

”

Josh Siegel
Chief Technology Officer
CareCloud

Cloudticity Case Study: Verge Health

Verge Health offers software-as-a-service applications for practitioner management, organizational compliance, and patient and employee safety through its Converge Platform. As a partner to healthcare organizations, Verge Health is subject to the Health Insurance Portability and Accountability Act (HIPAA).

HIPAA compliance in a SaaS context encompasses technical issues ranging from firewall configuration, to log monitoring, to data retention. When Verge Health decided to migrate its software and services to AWS, they chose AWS Advanced Consulting Partner Cloudticity to assist with the migration because of its expertise in designing, building, migrating, and managing some of the largest HIPAA solutions on AWS. The resources created by Cloudticity during the migration used security and privacy best practices under HIPAA.

“We already had AWS Service Catalog expertise because we use it to deploy Cloudticity Oxygen™, our proprietary, HIPAA-specific managed services platform,” says Gerry Miller, founder and chief technology officer of Cloudticity. “We used that knowledge to create a catalog of components matched to the patterns of requests we were seeing from Verge Health during their migration to AWS.”

By moving to standard configurations that could be self-provisioned by Verge, the team was able to solve compliance, resourcing, and consistency challenges. “Using reliable, HIPAA resources deployed from AWS Service Catalog, we can accelerate our time to market while continuing to lead conversations around security,” says James Lawson, Chief Solutions Officer for Verge Health. “The move to AWS and our partnership with Cloudticity will help us remain best-in-class.”

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James Lawson
Chief Solutions Officer
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Featured APN Life Sciences Partners



Turbot runs inside an organization's AWS account, seamlessly orchestrating and automating operations, security and governance for an entire cloud ecosystem. Turbot provides over 600 pre-configured guardrails and policies enabling organizations to implement detective, preventative and corrective controls that enforce best practices for highly-regulated workloads, including GxP and HIPAA. Turbot's solution automatically enables AWS best practices including least privilege, fine-grained access, and time-limited elevated privileges.



SAP collaborates with Life Sciences organizations and AWS in a digital world to improve patient outcomes. SAP's compliant cloud platform improves, simplifies and accelerates enterprise-wide processes, enabling Life Sciences organizations to leverage cutting-edge technology to improve focus on the patient and caregiver, while enhancing global health in new and innovative ways.



Deloitte's end-to-end IT Quality and Compliance consulting services enable Life Sciences organizations by helping IT departments navigate the regulatory landscape in the most effective and efficient way possible. Our services allow organizations to be fully prepared to implement and support emerging technologies to drive value while meeting regulatory requirements.



Turbot Use Case: Regulated Cloud Workloads

Turbot helps organizations that are subject to specific regulatory controls achieve operational, compliance, and security best practices in their cloud ecosystem. Turbot's solution helps IT teams implement these regulatory controls across all areas of their cloud. This includes networking, data protection, elevated access, periodic access, patch management, and reporting and audit requirements, among many other regulatory needs.

Turbot's Software Defined Operations (SDOps) platform provides enterprise minded guardrails for cloud infrastructure, allowing healthcare and life sciences organizations to achieve agility, ensure control, and accelerate best practices through continuous compliance and adherence of centrally defined policies across a multi-account AWS model.

For example, multi-account automation would allow a research organization developing many different types of pharmaceuticals to dedicate an AWS account to each project; enabling the organization to keep records for each project in separate locations. Each of these accounts are created with automated policy protections ("guardrails") that regulate how authorized users can use AWS. This type of isolation limits audit scope, enables advanced GxP controls and enables multi-party collaboration.



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Turbot can be used to create, regulate, and automate the tasks associated with meeting regulatory requirements.

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SAP Case Study: Moderna

Moderna Therapeutics is undergoing a digital transformation with full integration in a GxP environment. According to Marcello Damiani, Chief Digital Officer at Moderna, “We worked with SAP and AWS because we wanted to take advantage of the flexibility that AWS provides and, at the same time, ensure compliance with all the applicable regulations of the biopharma industry. In the GxP space, it was very helpful that AWS had the industry experience to help guide us and work with our quality team to understand what this all meant in the cloud, while SAP can help us digitize our end to end processes.”

Moderna was founded with the mission of using messenger RNA to disrupt traditional pharmaceutical research, development, and production practices. By using AWS, Moderna has produced 12 drug-development candidates. Moderna uses AWS to conduct massively parallel computational processes, connect cloud-unaware lab instruments to the cloud, and run a GxP-compliant SAP enterprise-resource-planning (ERP) solution.

“Seven years ago, Moderna didn’t exist, and by using AWS we’ve grown to a 500-employee biotech with a dozen drugs in the pipeline and a one-person IT department,” says Damiani. “And soon, we will have the unprecedented ability to produce drugs customized for the genetic signature of specific patients. That really shows you the power of the AWS Cloud.”



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We worked with SAP and AWS because we wanted to take advantage of the flexibility that AWS provides and...ensure compliance.

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Marcello Damiani
Chief Digital Officer
Moderna



Deloitte Case Study: Bringing Oracle Argus to AWS

Deloitte & Touche LLP provides IT Quality and Compliance Services for Life Sciences companies looking for effective and efficient IT quality programs across various technologies. One Life Sciences organization engaged Deloitte when moving a regulated workload to AWS for the first time. Deloitte was tasked with assisting a broad effort to upgrade the client's instance of Oracle Argus on AWS, as well as implementing Deloitte's evidence-based platform for safety intelligence, ConvergeHEALTH Safety™ (CHS). Both the Oracle Argus and CHS solutions needed to be validated on the AWS platform.

The challenges to the implementation were many. The implementation of the solutions required collaboration between multiple vendors and applications on the cloud. This was also the client's first use of AWS and GxP systems on the cloud. The entire implementation needed to be validated for compliance in order to ensure that the client would be able to meet requirements for cloud-based regulated workloads.

The result of the engagement with Deloitte is that both the platform (AWS) and the solutions (Argus and CHS) have been qualified for use with regulated applications. The resulting implementation meets GxP and security compliance standards for platform qualification and data security, allowing the client to move regulated workloads to AWS.



Deloitte helps Life Sciences organizations qualify both platforms and solutions for use with regulated applications.



Getting Started

For more information on Compliance for Healthcare and Life Sciences organizations with AWS, visit:

- [Healthcare Compliance on the Cloud](#)
- [Life Sciences Compliance on the Cloud](#)

About AWS

For 11 years, Amazon Web Services has been the world's most comprehensive and broadly adopted Cloud platform. AWS offers over 100 fully featured services for compute, storage, databases, analytics, mobile, Internet of Things (IoT) and enterprise applications from 44 Availability Zones (AZs) across 16 geographic regions in the U.S., Australia, Brazil, China, Germany, Ireland, Japan, Korea, Singapore and India. AWS services are trusted by more than a million active customers around the world – including the fastest growing startups, largest enterprises, and leading government agencies – to power their infrastructure, make them more agile, and lower costs.

To learn more about AWS, visit aws.amazon.com/health/.





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