

Why AWS for GxP regulated workloads?

An executive summary

Move, or build, GxP workloads in the cloud with help from the AWS Life Sciences Practice

The AWS life sciences practice and dedicated GxP experts help biopharma and medical device companies build new, or move, regulated workloads to the cloud. Organizations can achieve higher productivity, increased operational resilience, greater agility, improved transparency and traceability, and a [lower TCO](#)¹ and [carbon footprint on AWS](#)² compared to on-premises systems. AWS offers a secure cloud platform for automating compliance processes and providing enhanced management related to running your GxP workloads.

Some of the biggest enterprises and innovative startups in life sciences have moved, or built new GxP systems on the AWS Cloud. Decades of expertise in the life sciences space enable us to help you move away from on-premises regulatory paradigms as your trusted advisor to becoming regulated cloud native.

Evidence of success: AWS customers

moderna

[Moderna](#) power their R&D and manufacturing environments on AWS to accelerate the development of mRNA therapeutics and vaccines.

Idorsia

[Idorsia](#) house 90% of IT operations on AWS, including GxP compliant virtual data centers, giving them 75% cost savings compared to physical data centers

Bristol Myers Squibb™

[Bristol Myers Squibb](#) use AWS to create consistent, scalable, and repeatable process to streamline compliance with GxP and other regulatory requirements.

Evidence of success: AWS partners

aizon

[Aizon](#) use AWS to enable real-time visibility and predictive insights that address GxP compliance.

**CORE
INFORMATICS**

[Core Informatics](#) developed a platform on AWS that enables GxP-validated applications in the cloud for its customers.

tracelink

[Tracelink](#) choose AWS to support its life science cloud solution to meet customer compliance needs.

¹ IDC, [Fostering Business and Organizational Transformation to Generate Business Value with Amazon Web Services](#), 2018

² 451 Research, [The Carbon Reduction Opportunity of Moving to Amazon Web Services](#), 2019



Take advantage of AWS cloud security and security management best practices

With AWS, you benefit from the significant resources applied to ensuring security of the cloud. **The AWS cloud is designed and managed in alignment with IT security standards such as SOC 1, 2, 3; ISO 9001/ISO 27001/ISO 27017/ISO 27018; HITRUST; FedRAMP; and CSA Security, Trust and Assurance Registry (STAR).** Plus, the underlying cloud infrastructure for your GxP workloads are monitored and protected 24 x 7 by redundant and layered controls and continuous verification and testing, and automation.

In addition, security best practices from AWS help you define and build a set of security policies and processes for your organization that protects your data and assets. You get an overview of how to protect your assets on AWS and manage access to AWS resources, along with suggestions for how you can secure your data, operating systems, applications, and overall infrastructure in the cloud.



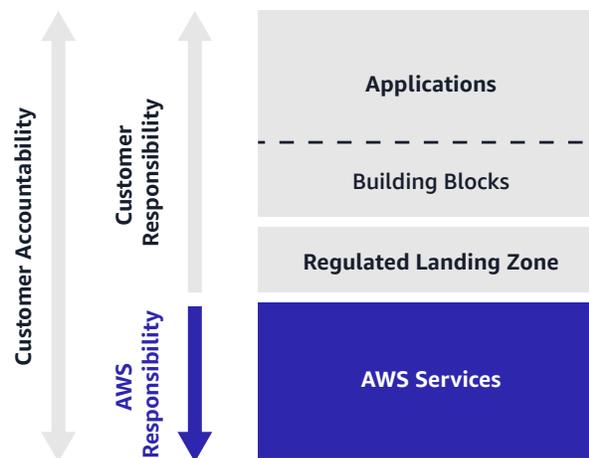
Leverage the AWS Quality Management System for your GxP-regulated products

Using an ISO 9001:2015 certified provider like AWS can make your own certification process [easier](#). Formal, documented policies and procedures from AWS life science experts guide you through AWS operations and information security and address purpose, scope, roles, responsibilities, and management.



Build on a cloud backed by the AWS shared responsibility model

In the shared responsibilities model for compliance, AWS is responsible for the compliance **of the cloud**, and customers are responsible for compliance **in the cloud**.



AWS' responsibility for compliance "of" the cloud includes physical hardware, global infrastructure, and how regions, availability zones, and edge locations function and operate. It also encompasses the virtual infrastructure for compute, storage, database, and network services. There is also a set of AWS services available for setup and governance, security and user management, operations, DevOps, and DevSecOps. The Regulated Landing Zone is your GxP compliant production environment.

Leverage the most comprehensive set of cloud services

Setup and governance services



[AWS Control Tower](#)

Set up and govern a new, secure, multi-account AWS environment based on best practices.



[AWS Config](#)

Assess, audit, and evaluate the configurations of your AWS resources.



[Private Amazon Machine Images \(AMIs\)](#)

Create Amazon Machine Images that only you can use to call an instance.



[AWS Audit Manager](#)

Automatically collect and organize evidence as defined by each control requirement.

Security and user management services



[AWS CloudTrail](#)

Leverage governance, compliance, operational auditing, and risk auditing of your AWS account.



[Amazon CloudWatch](#)

Log, continuously monitor, and retain account activity related to actions across your AWS infrastructure.



[Amazon Inspector](#)

Automatically assess applications for exposure, vulnerabilities, and deviations from best practices.



[Amazon Cognito](#)

Enable the delivery of scoped temporary credentials to mobile devices and other untrusted environments.



[AWS Identity and Access Management \(IAM\)](#)

Manage access to AWS services and resources securely.



End-to-end encryption

Get the configuration needed for data security.

Operational services



[AWS Lambda](#)

Run code without provisioning or managing servers with a serverless compute service that creates workload-aware cluster scaling logic.



[AWS Security Hub](#)

Get a comprehensive view of your security alerts and security posture across your AWS accounts.

DevOps and DevSecOps services



[AWS CloudFormation](#)

Leverage a service that treats infrastructure as code.



[AWS Service Catalog](#)

Create and manage catalogs of IT services that are approved for use on AWS.



[AWS Code Pipeline](#)

Get help with automating your release pipelines for fast and reliable application and infrastructure updates.



Simplify change management with AWS Config and other services

Change management doesn't have to be complex. When your GxP regulated workloads move to AWS, these processes are automated and simplified. Continuous deployment methodology ensures changes are automatically built, tested, and deployed, with the goal of eliminating as many manual steps as possible. For example, AWS Config controls how changes to configuration items are made, including an assessment of the potential impact on the GxP applications that it supports.



Use AWS services that make configuration easy

AWS services help simplify your cloud configuration process by applying tags, labeling, collecting, and organizing resources and components within services. AWS services continuously monitor and record your AWS resource configurations and lets you automate the evaluation of recorded configurations against configuration goals.



Track and measure your resources and infrastructure with AWS monitoring

You can monitor resources and the applications on AWS, collect and track metrics, monitor log files, set alarms, and automatically react to changes in AWS resources. You can also track and log the behavior of the customer application landscape, triggering events based on that behavior.



Ensure business continuity

You can't predict a disaster, but you can be prepared for it. For disaster recovery, AWS Regions provide multiple physically separated and isolated Availability Zones connected with low-latency, high-throughput, and highly redundant networking. [Availability Zones](#) are more highly available, fault tolerant, and scalable than traditional single or multiple data center infrastructures and are well-suited for keeping your GxP workloads online. A multi-Availability Zone architecture can withstand a complete failure of one or more zones.

The ability to back up and restore is required for all validated applications. It is therefore a common capability that can be centralized as part of the regulated landing zone. [AWS Backup](#) is a fully managed backup service that makes it easy to centralize and automate the backup of data across AWS services.

AWS is right for GxP

AWS helps your life sciences organization innovate while providing the infrastructure, services, and industry experts that best support your GxP workloads. Access the new [GxP on AWS whitepaper](#) to dive deeper on best practices for architecting for regulated workloads in the cloud.