



## Case Study

# Transforming Pharmaceutical Infrastructure Streamlining AWS Cloud Provisioning for Operational Excellence & Compliance

**Client:** Industry-Leading Pharmaceutical Company

## Key highlights



**50%** reduction in infrastructure provisioning time with self-service capabilities.



**70%** decrease in manual effort through infrastructure automation.



**100%** compliance achieved with launch constraint roles and policies.



**80%** increase in scalability and reusability of infrastructure configurations with code management practices.



## Background

### The Pharma Compliance Landscape

In the face of rigorous compliance demands confronting pharmaceutical companies, especially regarding adhering to GXP standards and associated controls, the need for robust cloud infrastructure services becomes paramount. These standards encapsulate various dimensions such as standardization, security, compliance, and governance, all of which are critical for safeguarding the integrity and reliability of infrastructure provisioning within the pharmaceutical sector.

Pharmaceutical companies are mandated to rigorously comply with regulatory requirements, particularly concerning GXP standards (Good Manufacturing Practice, Good Laboratory Practice, and Good Clinical Practice), to uphold the quality, safety, and efficacy of their products.

To effectively leverage cloud infrastructure while maintaining the integrity, security, and regulatory compliance of their operations, pharmaceutical companies must ensure adherence to the following requirements and controls.



## Unlocking Pharmaceutical Cloud Compliance

- ▶ GXP standards are pivotal in pharmaceuticals, ensuring quality throughout the product lifecycle. GMP focuses on manufacturing processes, GLP on laboratory studies, and GCP on clinical trials.
- ▶ Companies must ensure that their cloud infrastructure complies with GXP standards. This includes validating cloud services, ensuring data security and privacy, and aligning with regulations such as HIPAA, GDPR, and FDA requirements.
- ▶ Robust data security controls, aligned with industry best practices, such as encryption, access controls, and data anonymization, must be implemented to protect sensitive information stored and transmitted through cloud infrastructure.
- ▶ Ongoing adherence to regulatory requirements is crucial. Cloud service providers should offer assurances of compliance through certifications and audit reports.
- ▶ Pharmaceutical companies must validate cloud infrastructure to meet GXP requirements. This involves risk assessments, validation of data backup and recovery processes, and thorough documentation of configuration and management.

- ▶ Companies should implement change control processes, document changes, and conduct validation activities to ensure compliance and prevent disruptions, clarifying the types of changes covered and their implications.
- ▶ It's essential to assess and monitor cloud service providers' compliance with GXP standards, including evaluating security controls, conducting audits, and ensuring contractual agreements include compliance provisions.
- ▶ Robust backup and disaster recovery plans are necessary to protect against data loss and ensure business continuity, meeting regulatory requirements.
- ▶ Implementing comprehensive audit trails and logging mechanisms helps track access to sensitive data and detect unauthorized activities, ensuring traceability and accountability.
- ▶ Employee training on cloud infrastructure use and compliance with GXP standards is crucial, covering security best practices, data handling procedures, and regulatory requirements.
- ▶ Maintaining detailed records of cloud infrastructure configurations, validation activities, security controls, and audit findings is essential to demonstrate compliance with GXP standards.
- ▶ Regular assessment of cloud infrastructure, updates to security controls, and addressing identified deficiencies are necessary for maintaining compliance with GXP standards.



# Key Considerations for Qualifying Pharmaceutical Service Providers

Pharmaceutical companies can effectively qualify services by considering these holistic factors. This ensures that their specific needs, requirements, and regulatory obligations are met while maintaining the integrity, security, and effectiveness of their operations.

- ▶ **Standardization:** Ensuring adherence to industry standards and best practices to maintain consistency, interoperability, and compatibility with existing systems.
- ▶ **Security:** Implementing robust security measures such as encryption, access controls, authentication mechanisms, and data privacy safeguards to safeguard sensitive data.
- ▶ **Compliance:** Demonstrating compliance with regulatory standards like GXP, HIPAA, GDPR, and FDA requirements through certifications, audit reports, and adherence to industry best practices.
- ▶ **Governance:** Establishing an effective governance framework, policies, and procedures for decision-making, risk management, and accountability, including risk management processes, escalation procedures, incident response plans, and compliance monitoring mechanisms.
- ▶ **Data Privacy:** Implementing policies and practices to protect the privacy of data particularly sensitive information such as patient health records or proprietary research data.
- ▶ **Reliability and Availability:** Providing guarantees of reliability and availability, including SLAs, uptime commitments, and disaster recovery capabilities.
- ▶ **Scalability and Performance:** Ensuring the service's scalability and performance capabilities to accommodate growing business needs and resource-intensive tasks without compromising performance.
- ▶ **Interoperability:** Ensuring compatibility and interoperability with existing systems, applications, and workflows within the pharmaceutical company's ecosystem.
- ▶ **User Experience:** Focusing on usability, intuitiveness, and overall user experience of the service for end-users within the pharmaceutical company.
- ▶ **Cost-Effectiveness:** Assessing the total cost of ownership (TCO) of the service, including upfront expenses, ongoing fees, and potential hidden costs, relative to its benefits and capabilities.
- ▶ **Vendor Reputation and Support:** Evaluating the reputation, track record, and customer satisfaction levels of the service provider, including vendor stability, financial viability, industry expertise, and quality of customer support.
- ▶ **Innovation and Future Readiness:** Demonstrating a commitment to innovation, research, and development to address emerging industry trends and technological advancements.

# Phases of Infrastructure Qualification

The Infrastructure Qualification process verifies that the cloud environment is suitable for hosting critical applications and managing sensitive data in compliance with industry regulations and requirements. This process comprises the following stages.

## Plan

- Develop a detailed plan outlining objectives, scope, and timeline of the qualification process.
- Gather requirements from stakeholders - regulatory standards, industry best practices, and organizational needs.
- Gain insight into the cloud environment - architecture, services, and configurations.
- Define the scope of services qualified, considering critical applications, and compliance needs.

## Design

- Create an architectural diagram depicting the structure and components of the qualified infrastructure service.
- Create a Design Specification document outlining technical specifications, configurations, and dependencies.
- Generate Installation Qualification (IQ) and Operational Qualification (OQ) documents specifying test procedures and acceptance criteria.

## Build

- Translate the Design Specification into a CloudFormation template or equivalent infrastructure-as-code (IaC) script.
- Use automation tools and scripts to deploy qualified infrastructure service consistently across environments.
- Publish the infrastructure service as a catalog item in the Service Catalog or equivalent platform for easy provisioning and management.

## Test

- Execute Installation Qualification test cases to verify that the infrastructure is installed correctly according to specifications.
- Perform Operational Qualification tests to ensure that the infrastructure operates as intended under normal operating conditions.
- Validate functionality, performance, security controls, and regulatory compliance.
- Document test results, deviations, and corrective actions for future reference and audit purposes.

## Maintenance

- Develop and implement comprehensive maintenance procedures specific to each qualified infrastructure service.
- Establish a schedule for regular maintenance activities, including monitoring, patching, backups, and upgrades.
- Monitor service health, performance metrics, and security alerts to proactively identify and address issues.
- Update documentation, including IQ and OQ documents, to reflect changes and enhancements to the infrastructure service.



## Empowering Operational Agility: Streamlining AWS Cloud Infrastructure Provisioning

As an industry-leading pharmaceutical company prepared to spin off one of its subsidiaries into a standalone entity, the need to swiftly provision AWS cloud infrastructure became a top priority.

Manual processes resulted in delays, errors, and concerns about over-provisioning, exacerbating operational inefficiencies. In collaboration with Altimetrik, the company sought to overhaul its infrastructure provisioning using Infrastructure as Code (IaC) principles.

This case study provides a detailed overview of the project's objectives, challenges faced, solutions implemented, business outcomes achieved, and potential future engagement opportunities.

### Pain Points

Manual provisioning methods led to delays and errors, exacerbated by inadequate controls that raised worries regarding potential over-provisioning. Moreover, the company encountered notable operational hurdles due to the delay in provisioning of AWS services.

Addressing these critical issues required prompt action to streamline processes, strengthen control measures, and enhance the organization's responsiveness to evolving demands.



## Key Objectives

- Accelerate cloud infrastructure provisioning.
- Implement Infrastructure as Code (IaC) using CloudFormation templates.
- Ensure compliance with GxP standards.
- Enable self-service capabilities for infrastructure provisioning.

To enhance operational efficiency, the company aimed to expedite cloud infrastructure provisioning by adopting Infrastructure as Code (IaC) principles. Utilizing CloudFormation templates facilitated automated and standardized deployment. Additionally, stringent measures were implemented to ensure AWS infrastructure compliance with regulatory GxP standards, crucial in the pharmaceutical sector. Furthermore, the introduction of self-service capabilities empowered users to independently provision infrastructure resources, reducing reliance on manual intervention and enhancing overall agility.

## Solution

Altimetrik devised a tailored approach, addressing compliance and automation complexities inherent in pharmaceutical infrastructure provisioning. This involved developing detailed design specifications, automating deployment processes, and conducting rigorous qualification procedures.

### The process included:

- **Design Spec Development:** Creating comprehensive architectural diagrams and specifications for each AWS service to ensure standardized and secure infrastructure configurations.
- **Automation:** Addressing automation challenges specific to the pharmaceutical industry, ensuring seamless provisioning of services to engineering and product development teams.
- **Installation and Operation Qualification:** Testing the infrastructure through Installation Qualification (IQ) and Operational Qualification (OQ) processes to validate functionality and compliance with regulatory standards.

# Automation Challenges

Unique challenges in the pharmaceutical sector, such as compliance requirements and data security, were addressed through Infrastructure Qualification in AWS, detailed architectural specifications, and self-service capabilities via AWS Service Catalog.

Our solution focused on:

- Implementing Infrastructure Qualification (IQ) in AWS to ensure compliance with regulatory standards.
- Developing detailed architectural diagrams and specifications for each AWS service.
- Converting design specifications into CloudFormation templates.
- Testing infrastructure through Installation Qualification (IQ) and Operational Qualification (OQ) processes.
- Enabling self-service capabilities for provisioning infrastructure via AWS Service Catalog.
- Implementing launch constraint roles and policies to ensure secure infrastructure provisioning.

Through our tailored approach, we effectively addressed the automation challenges specific to the pharmaceutical industry while ensuring compliance and operational efficiency in cloud infrastructure provisioning.

## Conclusion

Through collaborative efforts with Altimetrik, the company achieved notable business outcomes:

- Establishment of self-service capabilities for users, facilitating quicker infrastructure provisioning.
- Increased efficiency in infrastructure provisioning through automation, resulting in reduced manual effort and streamlined processes.
- Creation of launch constraint roles and policies, ensuring secure infrastructure provisioning and mitigating potential risks.
- Implementation of code management practices, guaranteeing scalability and reusability of infrastructure configurations, thereby enhancing long-term adaptability and efficiency.

By revolutionizing AWS Cloud Infrastructure Qualification, we've not only achieved remarkable efficiency gains but also ensured stringent compliance standards. This has set the stage for future growth and innovation in the pharmaceutical sector.

## About Altimetrik

Altimetrik is a pure-play digital business services company. We focus on delivering business outcomes with an agile, product-oriented approach. Our digital business methodology provides a blueprint to manage data and develop, scale, and launch new products to market faster. Our team of 6,000+ practitioners with software, data, cloud engineering skills help create a culture of innovation and agility that optimizes team performance, modernizes technology, and builds new business models. As a strategic partner and catalyst, Altimetrik quickly delivers results without disruption to the business.