Accenture Life Sciences

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STRATEGIES FOR LIFE SCIENCES COMPANIES USING MICROSOFT AZURE WITH GXP SYSTEMS

When life sciences companies decide to migrate GxP applications to the cloud, the infrastructure supporting it must comply with GxP requirements. Life sciences companies can create automated reports that show the underlying infrastructure of Azure is qualified, and its security design system exceeds the standards of most life sciences companies. Accenture's assessment of Microsoft Azure demonstrated that life sciences companies can build new GxP applications in the cloud, while ensuring GxP compliance. In addition, they can migrate and upgrade operating Systems and databases for legacy GxP applications and data to Microsoft Azure, while retaining compliance and often increasing security.

Today, many life sciences companies are beginning their public and hybrid cloud journeys. Our analysis of the infrastructure underlying Microsoft Azure shows that it can be maintained in a controlled state provided proper change management and automated testing controls and management tools are in place. In this document we show how the key Food and Drug Administration (FDA) regulations (CFR 21 Part 820 and CFR 21 Part 11) apply in a cloud context, but also provide broader guidance that applies to other global compliance requirements, and should also apply to future regulations as they come into force.

ACCENTURE'S ASSESSMENT OF MICROSOFT AZURE FOR GXP SERVICES

After a careful technical review of Microsoft Azure and its Quality Management System (QMS), our Compliance Team found that all essential procedural controls were in place at Microsoft. The following table outlines the key areas that need to be considered for cloud service providers that equip an infrastructure for GxP compliant applications, and demonstrates how Microsoft meets these requirements.

KEY AREA	REQUIREMENTS FOR SERVICE PROVIDER	HOW MICROSOFT MEETS REQUIREMENT IN MICROSOFT AZURE
Security	• Manage access through physical security for datacenter and logical access controls for underlying systems. • Provide network isolation and encryption in case of multi-tenancy. • Prove capability of the physical systems to support the hosted applications by way of qualified infrastructure. • Ensure that systems used to manage and control the physical infrastructure and related underlying components work according to defined processes. • Demonstrate controls are in place to support data integrity. • Retain and record data ownership. • Support requirements for data retention. • Allow data to be retrieved whenever required.	• Supported through Microsoft Azure's standard security measures and Service Level Agreements (SLAs). • Data integrity is ensured by proper client security at the file, database, and application design level. • Microsoft Cloud Infrastructure and Operations is responsible for physical security of the Microsoft Azure datacenters, data protection, physical hardware asset management, and network services. • These datacenters are managed, monitored, and operated by Microsoft operations staff delivering online services with ceaseless continuity. In addition to datacenter, network and personnel security practices, Microsoft Azure incorporates security practices at the application and platform layers to enhance security for developers and service administrators. Microsoft Azure contracts allow data to be retrieved whenever required. **Note:** • Requirements for physical systems do not apply, as public cloud does not provide direct access to physical systems for the customer. • Depending on the criticality of data and the systems to be hosted on public cloud, life sciences companies should use their due diligence in incorporating additional controls/mitigations to ensure business continuity and audit readiness.
Incident Management	• Have robust disaster recovery in place for both datacenter and service. • Establish contracts for Recovery Time Objective (RTO) and Recovery Point Objective (RPO).	Microsoft Azure's datacenter and data replication models provide underlying resiliency. It maintains three copies of data in the datacenter, and can be configured to store additional copies. Microsoft Azure Backup Service and Microsoft Azure Site Recovery meet RTO and RPO requirements.

KEY AREA	REQUIREMENTS FOR SERVICE PROVIDER	HOW MICROSOFT MEETS REQUIREMENT IN MICROSOFT AZURE
People Management	Have adequate processes in place for people training and management.	Microsoft hiring managers define job requirements prior to recruiting, interviewing, and hiring. Job requirements include the primary responsibilities and tasks, background skills, and personal qualifications desired. Once the requirements are determined, managers create a job description, and use it to identify potential candidates. When viable candidates are identified, the interview process begins to evaluate candidates and make an appropriate hiring decision. Ongoing training curriculum/training records ensures that employees have the skills needed to support the cloud environment.
Solution Development	Provide a robust solution development process.	Solutions are developed according to the security development lifecycle, consisting of training, requirements gathering, design, implementation, verification, release and response phases. **Note:** While the current documentation practices in place are comprehensive in general, some life sciences specific expectations (qualification plans and summaries), reviews and approvals, etc. may need to be incorporated.
Quality Management	• Create a Quality Management System. • Demonstrate control on underlying physical and software systems including change management, incident management, problem management, patch management, service requests, capacity management, etc.	Quality Management System is in place, and defined processes are followed for change management, incident management, problem management, patch management, service requests, and capacity management. **Note:** While the current documentation practices in place are comprehensive in general, some life sciences specific expectations (documentation of changes, evaluation and approvals of changes prior to implementation in production systems, maintaining documents for baseline and changes) may need to be incorporated.
Datacenter of Public Cloud	Design a datacenter following an approved standard/certifiable process.	Standardized design for datacenters across all geographies, meeting global requirements for datacenter design, build and operations.

It is important to note that the traditional support processes may need to be updated within the life sciences company itself when they contract with cloud service providers for any service. Cloud service providers assist based on specific contract details that may be difficult to change. A typical agreement with a service provider covers the following support and maintenance functions:

1. Service management
2. Change management
3. User access control and logging
4. Incident management and CAPA
5. Problem management
6. Configuration management
7. Data retention, backup and archiving
8. Disaster recovery
9. Service termination and service transfer
10. Employee training for those handling the above processes
11. Periodic review of the above to process adherence
12. Support to life sciences companies during external audits

CONCLUSION

Our comprehensive review of the suitability of Microsoft Azure for GxP applications reveals that the security design, procedural controls, and tools of Microsoft Azure meet the standards of the life sciences industry. We believe companies can realize significant business benefits moving GxP applications to Microsoft Azure and most certainly in developing new GxP applications using Microsoft Azure as the base infrastructure.

Life sciences companies looking to take advantage of the capabilities offered by Microsoft Azure should examine the portfolio for the best candidates. Partners such as Accenture can be very helpful in identifying the right applications, in helping organizations with validation challenges, and with recommendations associated with application migration.

Over time, the process of qualifying the public cloud infrastructure should continue to simplify as more tools and capabilities emerge. However, it is perfectly possible to run GxP applications in a compliant state in Microsoft Azure today, and organizations looking to do so now have an opportunity to gain strategic advantage over their competitors, and improve patient outcomes with new categories of products and services.

ABOUT THE AUTHOR

Adrian Perry is an Executive and Global Supply Chain Compliance expert for Life Sciences working out of the Accenture New York Office. He has over 20 years of experience working across strategy and operations, and with his teams has validated over 3500 GxP systems across Manufacturing, R&D, and Enterprise Systems such as SAP. He has also worked on programs across over 25 manufacturing sites for Biopharmaceuticals / Medical Device in Europe, Asia, and North America.

We would like to also thank David Evans for contributing to this paper.

David Evans is a senior technology and clinical research executive with over 35 years of experience in the clinical research, regulatory and healthcare industries. Mr. Evans has extraordinary experience in corporate development, clinical information management, clinical trial management, complex clinical data warehousing, regulatory data analysis, automated data capture, regulatory information standards, regulatory quality management and compliance, and clinical business process engineering. He is recognized industry-wide as a leading technology visionary for developing and implementing complex process and system solutions. He serves as the Head of Quality Governance and Regulatory Compliance for Accenture R&D Services.

ABOUT ACCENTURE LIFE SCIENCES

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We have decades of experience working hand-in-hand with our clients to improve their performance across the entire life sciences value chain. Accenture's Life Sciences group connects more than 15,000 skilled professionals in over 50 countries who are personally committed to helping our clients achieve their business objectives and deliver better health outcomes for people around the world.

ABOUT ACCENTURE

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