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STRATEGIES FOR LIFE SCIENCES COMPANIES USING MICROSOFT AZURE WITH GXP SYSTEMS

INTRODUCTION

The pressure on profit margins that life sciences companies face today is well documented. Government control on drug expenditure and the availability of generic options after the recent spate of patent expirations are putting pressure on top and bottom line growth. In the short term, many life sciences companies are focused on adjusting operating models and trimming costs, including IT costs.

Organizations can only cut costs so far while retaining a thriving business. So increasingly life sciences companies are looking to embrace digital transformation as a core part of the strategy to sustainably restore profit margins and have a positive impact on revenue generation. This new focus on digital transformation should see IT move from a cost center to a key enabler of business growth and revenue generation.

For any organization, public cloud computing services are likely to form a core technology component of digital transformation. The promise of near-unlimited computing; storage and networking resources at low cost; easy access to new value-added services; rapid technology innovation; and financial flexibility all combine to create a compelling value proposition for any organization looking to maximize the business value of their IT investments.

However, fully embracing digital transformation, and particularly the shift to public cloud services, is not as easy for life sciences companies as in some other industries. These companies must balance the need for change against the requirements of their highly regulated industry. They must continue to clearly identify and mitigate the risks that arise; be able to respond effectively to audit requests and to changes in regulations when they occur.

Today, many life sciences companies are beginning their public and hybrid cloud journeys. Although they are making some investments in the public cloud, it is typically in parts of the business that are subject to less regulation. Currently their public cloud spend represents a small fraction of their overall investment in IT. This is based on current portfolio management at top 10 pharma companies.

Accenture's 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.

ABOUT THIS WHITEPAPER

This paper will help life sciences companies to:

- Analyze the controls required to leverage Microsoft Azure.
- Define how Microsoft Azure can meet those controls.
- Define the levels of ownership and participation from Life Sciences companies when validating and maintaining GxP systems hosted on Microsoft Azure.

We have divided this paper into eight sections:

1. **Why Public Cloud for GxP Applications** discusses the business benefits life sciences companies can realize if they invest in the public cloud for GxP applications.
2. **Key regulatory requirements for IT environments in life sciences companies** summarizes the key regulatory requirements that global life sciences companies must adhere to when adopting public cloud services.
3. **Security capabilities of Microsoft Azure** examines the steps that Microsoft has taken to ensure the security of its cloud platform and how it meets the needs of life sciences companies.
4. **Accenture's assessment of Microsoft Azure for GxP Services** provides some detail on Accenture's assessment of Microsoft's cloud platform for GxP applications.
5. **Qualifying the infrastructure underlying Microsoft Azure** demonstrates at a high level how an organization would go through the qualification process, and outlines the challenges a life sciences company may face.
6. **A strategic approach for adopting Microsoft Azure cloud services** provides guidance on how to examine the full portfolio of GxP applications for cloud suitability.

7. **Operational Models for GxP validation in Microsoft Azure** examines how organizations can execute effectively on maintaining validated GxP applications.

8. **Using Accenture to support GxP validation** shows how Accenture can assist life sciences companies looking to validate and maintain GxP applications in the cloud.

This paper is aimed at business decision makers and compliance professionals who are looking to establish the strategy for their GxP applications. However, readers who are most interested in the results of the Accenture's assessment of Microsoft Azure can skip straight to Section 4 (pg. 5).

1 ENSURING ACCESS TO HIGH-VALUE THERAPIES IN AN ERA OF HIGH-PRICED DRUGS

Ever since the dawn of cloud computing, enterprises have been wrestling with how to extract the most value from it. Over time, many have observed "born in the public cloud" companies demonstrating accelerated business growth, and wondered how to gain some of these benefits for themselves without jeopardizing existing operations.

Initially, much of the value proposition for cloud computing was centered on potential cost savings, and in particular around financial flexibility, with spend in IT growing or shrinking based on business conditions. But as the capabilities of the hyper-scale cloud providers have increased, attention has shifted to the unique ways public cloud offerings can drive business growth and increase profit margins. Businesses are seriously examining what the instant availability of nearly limitless computing resources and rapid innovation in IT can do to transform their products, services, and business operations.

In the life sciences field, there is a real opportunity to use public cloud services to accelerate business growth. For example:

- Core infrastructure services can be combined with higher-level capabilities in advanced analytics and machine learning to effectively predict and improve outcomes. These services can transform products and services for the core business and for the health consumer, by possibly lowering hospitalization rates for chronic diseases.
- The highly flexible application of high-performance computing capabilities allows them to be used in a much wider set of circumstances, lowering the cost of failure in research and development, and facilitating the developments of new categories of products and services.

Most life sciences companies have just scratched the surface in terms of realizing the benefits of adopting public cloud services. This is in part because most of the technology investments that yield maximum business value for life sciences companies are subject to regulatory compliance considerations, and it has been unclear to date how to validate these types of applications on a public cloud platform.

Another important consideration for life sciences companies is the underlying security and privacy concerns that lead to high regulation in the industry. Today, cyber-attacks are increasingly frequent and more damaging, with hacktivists, organized criminals and even nation states using networks of compromised systems combined with sophisticated malware to compromise organizations and individuals hosting valuable data. Protecting data integrity is increasingly a board-level issue for life sciences companies. In a world where threats morph every day, and time is of the essence, it is very difficult for most internal IT security departments to keep up. Public cloud companies invest significantly in protecting their customers from constantly evolving security threats, and lead the industry in rapid response.

The FDA Safety and Innovation Act was signed into law on July 9, 2012, but the challenges associated with validating applications as technology evolves have been around for decades. As an example, the introduction of the first programmable logic controllers led to a rule that the custom code for those controllers should be treated as predicate rule records for master production and control records. In many respects, the current concern around public cloud computing is just a continuation of this pattern. Each time a new technology paradigm emerges, there is an initial desire to document its inner workings rather than qualify it as an underlying capability that can be leveraged by the application.

Ironically, over time, cloud computing may come to be seen as key to speeding up the validation process. Organizations adopting public cloud computing are responsible for fewer of the operational activities associated with managing an application, when compared to on premises deployments. The specific responsibilities of the life sciences company will vary according to the type of cloud services used, with differences between IaaS, PaaS and SaaS level services (for more information

on this see the section "Security Capabilities of Microsoft Azure") However, due to the standardized nature of the cloud environment, it should be possible to streamline qualification over time.

The business benefits associated with public cloud capabilities, combined with the medium term validation benefit of using a highly standardized underlying platform for regulated applications means that it is only a matter of time before life sciences companies more fully adopt the public cloud for these applications.

2 KEY REGULATORY REQUIREMENTS FOR IT ENVIRONMENTS IN LIFE SCIENCES COMPANIES

The FDA's Title 21 CFR Part 820 is a set of regulations designed to ensure that quality systems involved in the manufacture of pharmaceutical products and medical devices are adequate. These regulations are mandatory for all life science companies that offer products and services in the United States. 21 CFR Part 820 includes purchasing controls, and so the vendor relationship with Microsoft should be considered for any product or service produced that involves Microsoft cloud services.

The FDA's Title 21 CFR Part 11, which is relevant to companies that produce therapeutic products for use in the United States, captures the requirements for computer systems (including hardware and software), controls, and attendant documentation maintained under this part shall be readily available for, and subject to, FDA inspection [*Ref: 21 CFR Part 11, section 11.1 (e)*].

FDA's Title 21 CFR Part 11 also deals with records in electronic form that are created, modified, maintained, archived, retrieved, or transmitted, under any records requirements set forth in agency regulations. This part also applies to electronic records submitted to the agency under requirements of the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, even if such records are not specifically identified in agency regulations. However, this part does not apply to paper records that are, or have been, transmitted by electronic means [*Ref: 21 CFR Part 11, section 11.1 (b)*].

EUDRALEX Annex 11 is a recognized guideline to companies that produce therapeutic products for use in the European Union. This annex applies to all forms of computerized systems used as part of a GMP regulated activities. As per Annex 11, a computerized system is a set of software and hardware components that together fulfill certain functionalities. The application should be validated; IT infrastructure should be qualified. [*Ref: EUDRALEX Annex 11, Principle*].

The major goal for the FDA regulations and Annex 11 guidelines on computer systems is to achieve product and patient safety by ensuring the following:

- Data Integrity, achieved by two methods at application level:
  - By use of electronic signatures
  - By usage of automated audit trails and logs
- Security, to safeguard systems against internal and external threats:
  - Restricting access to authorized personnel
- Data Retention, to ensure data availability whenever required. The data/documents generated is auditable by FDA any time during the life cycle of the therapeutic product. The retention time requirement usually varies from two to 15 years.
  - Retention period is determined by individual organizations. This needs to be communicated to computerized system solution team as data residing in a storage system needs to keep up with technology changes
  - Backup and recovery
  - Disaster Management

The International Society for Pharmaceutical Engineering (ISPE) has published the Good Automated Manufacturing Practices (GAMP) Guideline, Version 5. This guideline stresses the importance of risk based validation/qualification of systems. It also stresses the importance of leveraging vendor-supplied facts and documents to aid in validation/qualification.

3 SECURITY CAPABILITIES OF MICROSOFT

Azure traditional data centers are dedicated to a single organization, and perimeter hardware firewalls provide the organizational boundary. But any organization using a public cloud environment is embracing some form of multitenancy, where services are shared with other organizations using the same public cloud environment. This makes traditional perimeter-based security impractical for each tenant.

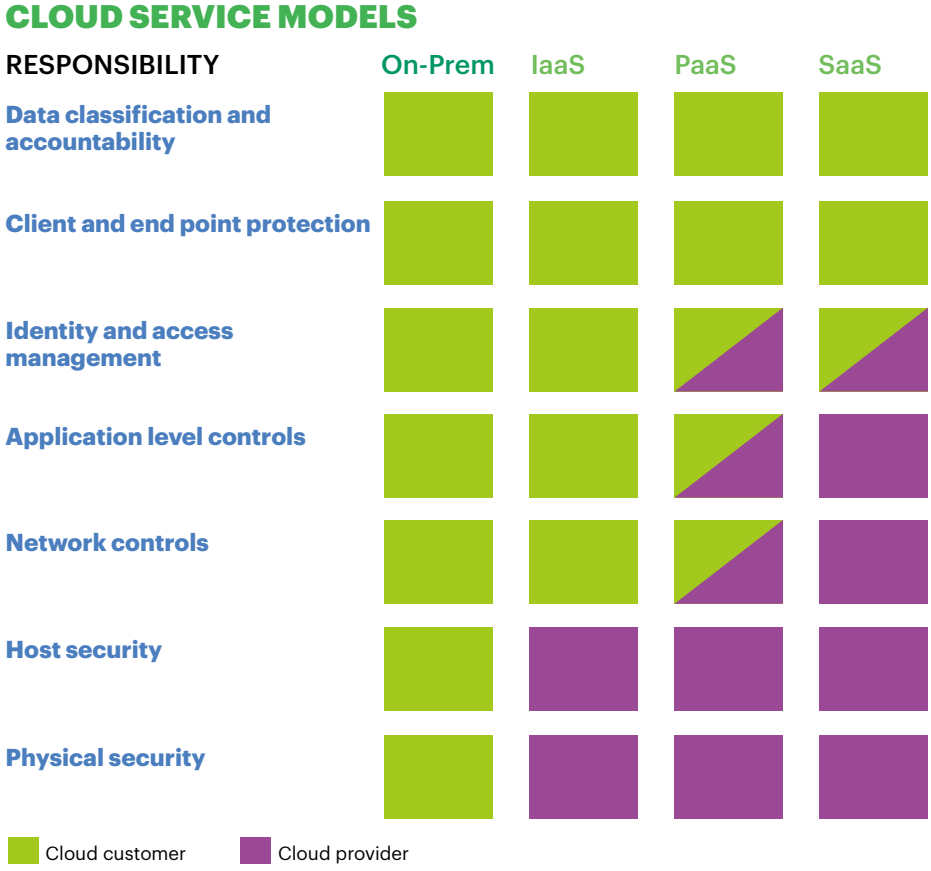
In the last few years there have also been dramatic advances in the nature of security threats. Attacks now come from sophisticated insider threats, organized criminals, even nation states. Like-minded individuals can form effective teams through social networking, and they can use networks of compromised systems, combined with sophisticated malware to conduct their attacks. Threats evolve at an ever-faster rate, and many enterprise IT security organizations are struggling to keep up.

Microsoft takes a multi-layered approach to securing its public cloud environment. They make sure that threats are tracked and combatted in order to protect the data from unauthorized access, regardless of whether the attempted breach is from within or outside of the organization. To ensure that its cloud environment is appropriately protected, Microsoft has invested heavily in threat modeling, prevention, detection, forensics, remediation, and incident response capabilities.

Multiple boundaries are established inside the Microsoft Azure environment and movement is limited across those boundaries. They do this by limiting privileges according to context, and isolating logical networks and identities. The cloud infrastructure and applications in the cloud environment become part of the sensor network designed to determine if an attack is underway. Microsoft also uses its data analytics capabilities to understand how threats are evolving over time.

These defenses are combined with an "assume breach" mindset, and with consistent efforts to test the effectiveness of security measures. To provide maximum protection, Microsoft employs a dedicated team that models emerging threats and uses blended threats to attempt to compromise Microsoft's services, alongside a defensive team designed to thwart them. This allows the company to enumerate risks, and justify the resources necessary to combat them.

FIGURE 1 . Responsibilities for managing applications in on-premises and cloud models



Building secure cloud services is considered to be a dual responsibility of Microsoft and its customers. Microsoft provides the security controls to protect data and applications, and the customers own their data, identities, and responsibility for protecting them. The exact nature of the responsibilities depends on the cloud model used, as shown in the Figure 1.

Any company looking to use public cloud services should consider very carefully the security capabilities of a cloud service provider, but our assessment reveals that the tools and security capabilities of Microsoft Azure are comprehensive, and in many cases will more than match those of internal IT security departments in life sciences companies.

4 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 on pg. 6 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 multitenancy. • 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.
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.

Qualifying the infrastructure underlying Microsoft Azure

Life sciences companies that are looking to validate applications on Microsoft Azure first need to ensure that the underlying infrastructure (servers, storage, network components, firewalls, CPU, memory, anti-virus, etc.) is secure, documented, and maintained in a controlled state. In life sciences, this state is commonly referred to as "qualified."

Qualification is traditionally achieved by following two processes—Installation Qualification (IQ) and Operational Qualification (OQ), but now a life sciences company can achieve this with automated testing and configuration management tools. Once the requirements are determined for any system, one can use automated testing to verify that their minimum-security baseline is met for the underlying cloud infrastructure. When an environment is spun up for a particular application or client, a report can be generated listing out all of the specifications, and this can be maintained via proper change control. This actually increases the quality of the infrastructure documentation and allows one to do hundreds of tests/verifications in minutes versus manually over months.

When an application is deployed in Microsoft Azure, the life sciences company (or its IT partner) maintains the validated application, but Microsoft maintains the underlying infrastructure, using automated testing, proper configuration and change management.

It is worth noting that while there may be some differences to how a life sciences company qualifies the infrastructure underlying public cloud services, application validation does not change. Applications should go through the normal system development life cycle, across development, testing, quality and production environments, with some or all of the environments residing in the public cloud. However, by using Microsoft Azure for all of these environments, one can ensure consistency throughout the development life cycle.

Maintaining the environment in Microsoft Azure relies upon an underlying set of capabilities provided by Microsoft and the client or third party provider, but also on appropriate change control and risk management procedures for the application itself.

5 CHALLENGES IN QUALIFYING THE INFRASTRUCTURE UNDERLYING MICROSOFT AZURE

The biggest challenge that life science companies have with validating cloud applications is in translating the requirements of the regulations to the services offered by public cloud providers. Once the requirements are clearly defined for the public cloud, it becomes easier to document how regulatory requirements are met appropriately.

In a public cloud environment, the FDA still holds individual life sciences companies responsible for compliance to its regulations. This has led pharmaceutical companies to be risk averse due to the very nature of business they operate. However, once more precedents are established for use of the public cloud in the life sciences industry, we expect significantly higher adoption for GxP applications. Another significant challenge for life sciences companies is the lack of familiarity with cloud technologies inside many life sciences compliance teams. Most life sciences companies traditionally rely on GAMP guidelines. Accenture believes that GAMP 5 has not fully addressed qualification of cloud solutions, and has not put forth any guidance in the past seven years for public cloud providers. Fortunately, there are efforts already underway by ISPE to develop more adequate guidelines on the adoption of cloud systems by pharmaceutical companies.

The following steps will help life sciences companies become comfortable with qualifying the infrastructure that underpins Microsoft Azure:

- Establish how to meet regulatory requirements with limited physical access to the data centers and physical systems. The current data centers utilized by Azure are physically secure and under constant guard.
- Establish how to rely on Microsoft Azure documentation to support qualification and validation.
  - An example would be to leverage MSFT's procedures and change management records
- Determine procedures for responding to an audit from a regulator, including gaining access to necessary documentation from Microsoft.
- Gain an understanding how Microsoft performs the following functions for Microsoft Azure:
  - Service management
  - Change management
  - Audit trail requirements and management

- User access control on base systems and storage of access logs
- Incident management and Corrective Action and Preventative Action (CAPA)
- Problem management
- Configuration management
- Training of employees
- Data Segregation
- Data Privacy

Currently, Microsoft Azure is certified by ISO 22301, ISO/IEC 27001 and ISO 27017, ISO/IEC 27018, FedRAMP, SOC 1, SOC 2, SOC 3, NIST 800-171, DOD, and various other regulatory bodies which demonstrate Microsoft's control and rigor with respect to compliance in general.

Accenture's experience and expertise in the field can help life sciences companies gain a more detailed understanding of these areas, and thus prepare them to adopt Microsoft Azure for GxP applications.

6 A STRATEGIC APPROACH FOR ADOPTING MICROSOFT AZURE SERVICES

Life sciences companies that have made the decision to adopt Microsoft Azure for their GxP regulated applications now face the question as to how to go about it in a strategic way. After all, for most life sciences companies, these applications represent a significant part of the overall investment in IT, and are tied directly to the business value the technology provides.

New applications are frequently the easiest way to start, as there is no cost of change. For these applications, it is simply a matter of working with the regulators to address their concerns and identifying and mitigating. It is very important to identify applications that may fall under GxP regulations early in the design phase, as design considerations may affect the ease of the validation process. For example, there is currently more precedent of applications that use infrastructure services being validated than those using higher-level platform services. Note that this not a reflection of the underlying suitability of infrastructure as a service (IaaS) or platform as a service (PaaS) for GxP applications, rather it is more an indication of the time in market for some of these higher-level services. Organizations that are looking to develop new GxP applications should balance the benefits provided by platform services with the risks associated with being a first mover on validation.

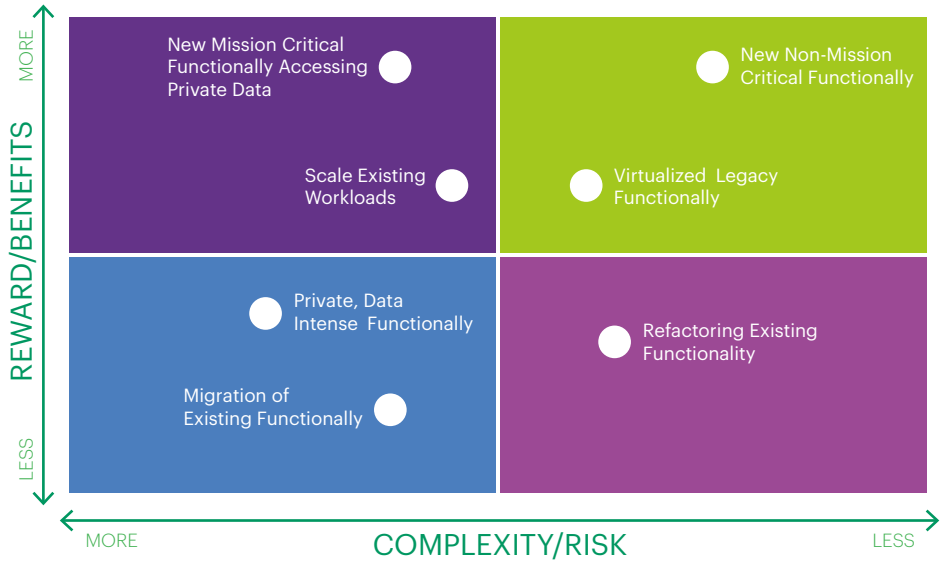
For existing applications, life sciences companies should assess the portfolio to determine which applications are the best candidates to move in part or in full to the public cloud. On the surface, this is a fairly simple exercise in balancing benefits or rewards against risks and complexity (see Figure 2).

However, which applications fit into which quadrant can be somewhat more challenging, particularly once the obvious candidates have been identified. When examining the portfolio of GxP applications one should consider the following factors, comparing the new environment to the old:

- Financial costs and benefits, including the cost of migration
- Usability
- Performance
- Functionality
- Scalability
- Geographical reach
- Operational maintenance
- Security (Confidentiality, Integrity and Availability)
- Flexibility
- Strategic alignment to business and technology strategy

As IT portfolio management is a specialized field, many organizations will find it helpful to work with a partner such as Accenture to analyze their portfolio of GxP applications, and determine which ones to move first, based on overall suitability and on the likely complexity of validation in the new environment.

FIGURE 2 . Evaluating the best GxP applications to move to the cloud

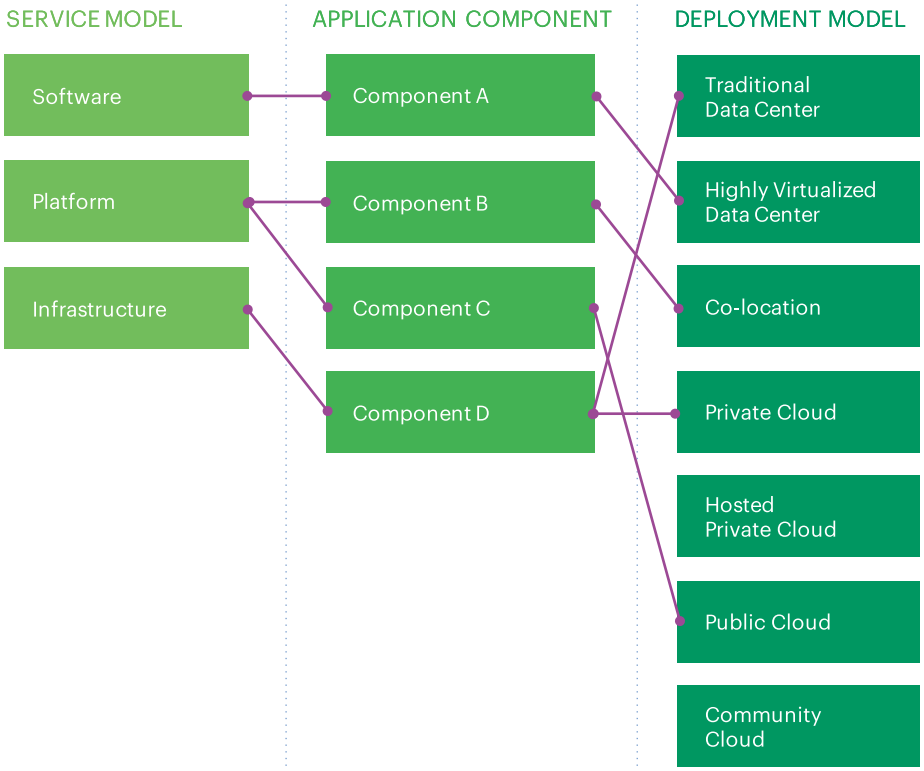


Hybrid computing models—a useful alternative

Applications are no longer monolithic in nature, and frequently components of an application may be distributed across a variety of underlying infrastructures. Microsoft has invested heavily in this area, looking to support customers who not only span their applications and data across on-premises environments, hosted private clouds and public clouds, but also complex individual application deployment scenarios, as illustrated in Figure 3.

In some cases, it may not be desirable to move an entire application to the public cloud, but components of the application may still be good candidates for a shift. Just by moving one part of the application, one may increase the usability, flexibility, scalability or geographical reach of that application, and make validating that application significantly easier.

FIGURE 3 . Hybrid application deployment models



7 OPERATING MODELS FOR GXP VALIDATION

Life sciences companies can choose from three operating models for GxP validation.

In the first model, the life sciences company takes responsibility for both business (functional) and technical aspects of migrating and validating GxP applications. The overall governing control is the Quality Management System of the life sciences company.

In the second model, the life sciences company retains the business aspects but engages a technology partner such as Accenture to assist in validating GxP applications using the company's own Quality Management System. Working with the technology partner, the client would identify candidates for migration. The technology partner would then use its management tools to create a "logical" factory in which planning, coordination, disposition (VMs within Microsoft Azure), and actual execution steps are developed and validated to migrate application and databases including GxP from the client's locations into Microsoft Azure.

Traditionally for new applications, technology providers consider infrastructure qualification along with the validation of the application itself. The underlying infrastructure qualification for Microsoft Azure services should only have to happen once, after which the focus would be on application validation—driven primarily by the client's standards.

The third operating model is where a client engages a technology provider that assumes both business and technical aspects of migrating workloads and validating new GxP application using the partner's Quality Management System by installing and managing another technology layer on top of the existing Microsoft Azure infrastructure.

In this type of model, the life sciences company and the service provider can agree to the level of their support and maintenance functions. 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

8 USING ACCENTURE TO SUPPORT GXP VALIDATION

Most cloud providers do not have a dedicated staff to support the validation and quality services, which are currently provided by internal groups within a life sciences company. Accenture provides validation, quality, and implementation services for a number of top pharmaceutical and medical device companies. In addition, Accenture has partnered with Microsoft to assist clients as they migrate legacy systems to the Microsoft Azure platform and to implement new GxP systems in the cloud. The combination of Accenture consulting services and the Microsoft Azure platform will allow life sciences companies to validate cloud applications.

Accenture is strategically placed to guide/coach clients through the transformation of delivering software in a repeatable stream. As part of our process, we split the software development from its validation activities with quality oversight applied to software development and professional validation engineers. We use the outputs of that software development to create the necessary regulatory documentation to provide a high degree of assurances that the GxP application meets its intended use. This model uses the strength of the organization to deliver functioning/validated software.

Accenture has successfully migrated thousands of GxP and non-GxP applications and databases to the cloud, while ensuring that the application is still working and maintained in a validated state. This process minimizes downtime and risk to the business by ensuring that various tests (both manual and automated) are done prior to migration and post migration. This process uses qualified tools and processes to test the underlying infrastructure as well as the application.

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.

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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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