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# The Future is Cloud

Qualifying Microsoft Azure for  
Regulated Applications in the Life  
Sciences



# Overview

- **Informative Webinar** that aims to provide an overview of how Azure can be qualified for use with regulated applications within **the Life Sciences**
- Slides can be distributed upon request. Details on how to request slides will be distributed to attendees following the webinar
- Feel free to ask questions in the **questions panel**
- Thank you for your interest!



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# Speakers



**Gabor Fari** - Director, Business Development & Strategy  
Health & Life Sciences - Microsoft



**Paul Fenton** - President & Chief Executive Officer -  
Montrium



**Michael Zwetkow** - Vice President, Operations -  
Montrium



# Agenda

- Microsoft's Cloud Story and Vision
- Introduction to the Regulated Cloud
- The Cloud Qualification Paradigm
- Opportunities for Industry
- Proposed Qualification Approach
- Step-by-Step Overview of Azure Qualification Process
- Conclusion and Recommendations
- Regulated Cloud Q&A



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# 1 Microsofts Cloud Story & Vision

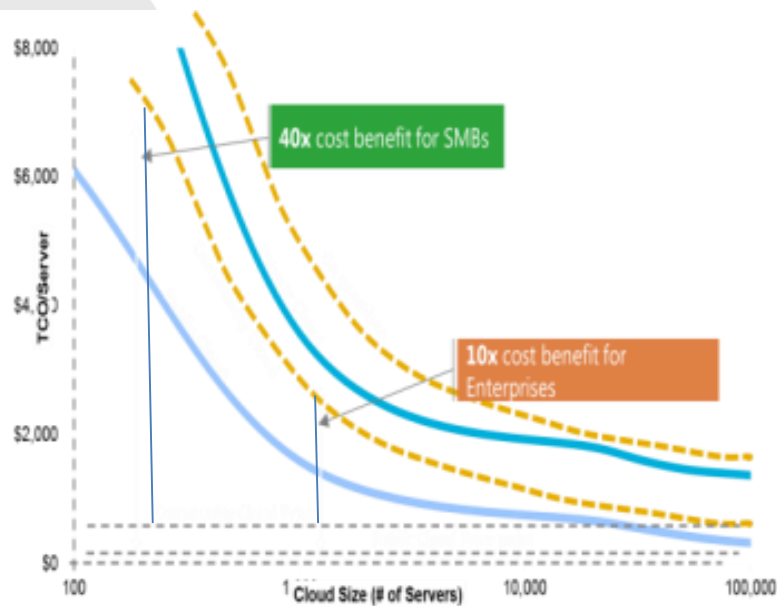
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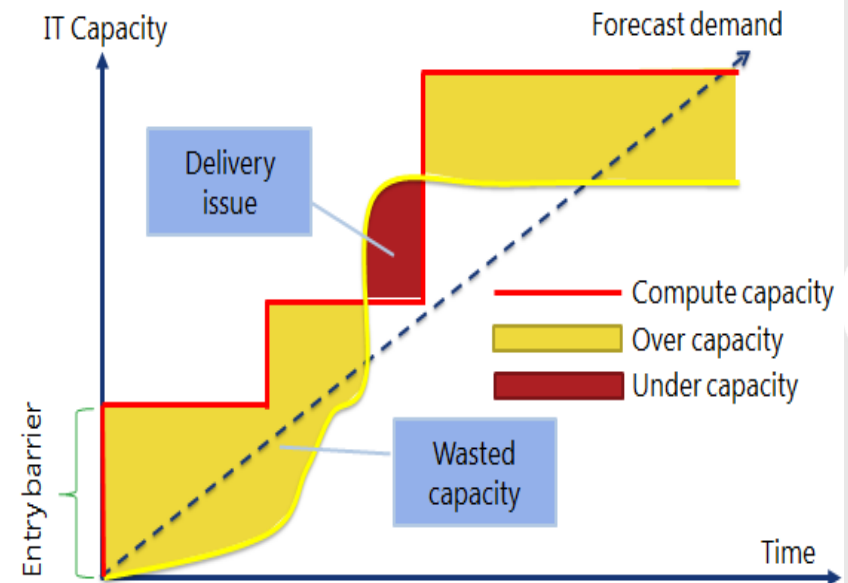


# The Cloud Is Changing The IT Conversation

## ECONOMICS



## AGILITY





# The Cloud is Built on massive Data Centers

Microsoft Globally Distributed Data Centers

Range in size from "edge" facilities to megascale (100K to 1M servers)



Quincy, WA



Chicago, IL



San Antonio, TX



Dublin, Ireland



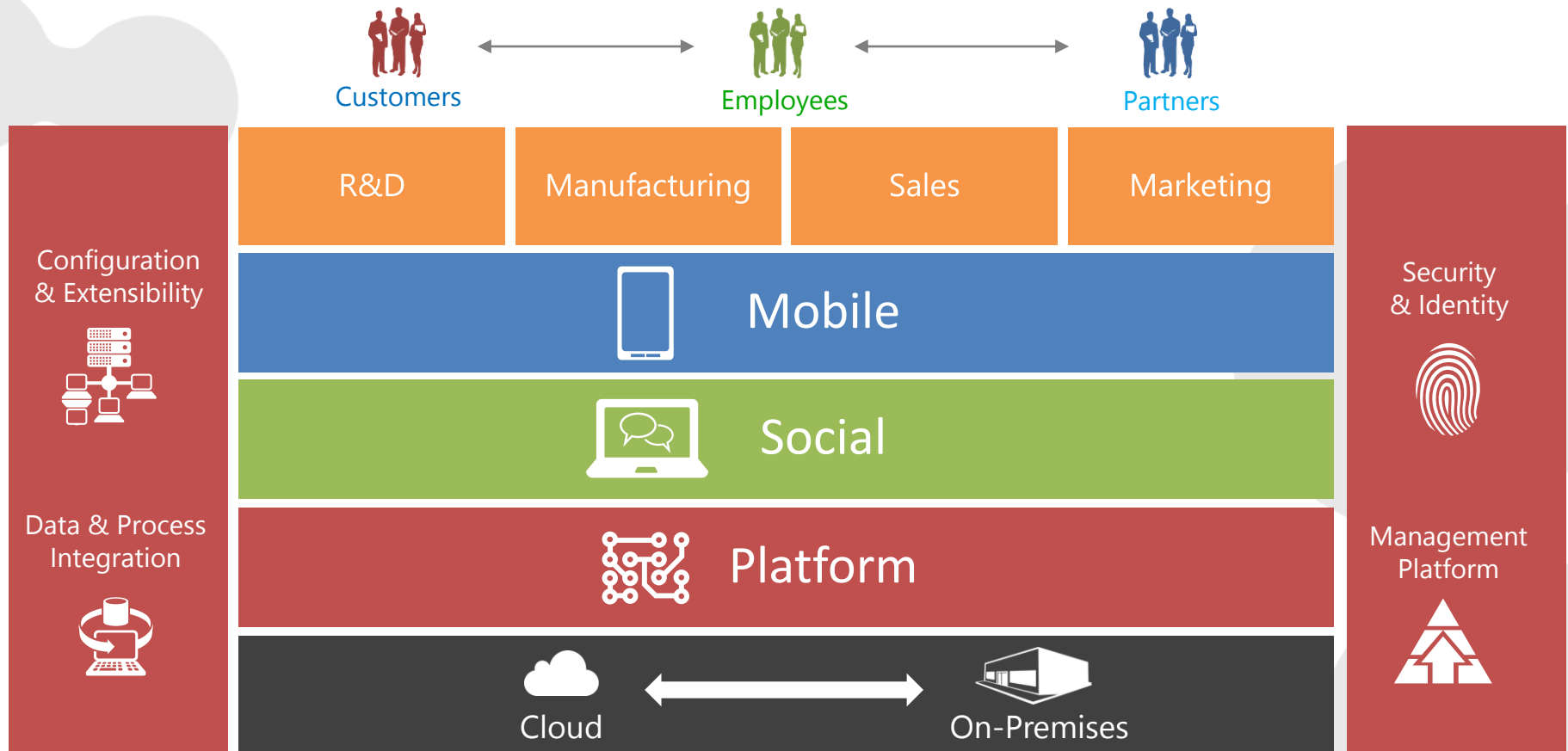
Generation 4 DCs



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# End-to-end Solution Platform powered by Microsoft



# Anywhere, Any Device Access Enterprise-class Productivity





# Cloud principles

Maintain  
an evergreen  
service



Provide a platform  
built on security,  
privacy, and trust



Offer highly  
configurable and  
scalable services



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# Key decision factors when selecting a cloud Platform

- Capabilities (IaaS, PaaS, SaaS, Hybrid scenarios)
- Cost
- Performance
- SLA's
- Scale
- Integrated management tools
- And most importantly: TRUST!

## Whose Cloud can you trust?

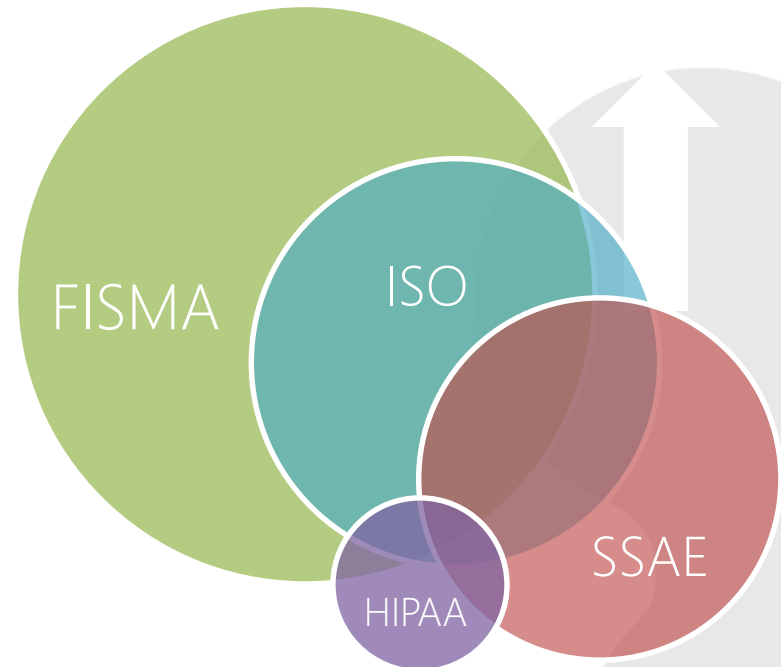


# Microsoft Azure Compliance Capabilities

SSAE 16  
SOC 1 Type 2  
ISO 27001  
EU Model  
HIPAA BAA

## Microsoft Azure feature

Microsoft Azure feature	SSAE 16	SOC 1 Type 2	ISO 27001	EU Model	HIPAA BAA
Websites	✓	✓	✓	✓	✓
Virtual Machines	✓	✓	✓	✓	✓
Cloud Services	✓	✓	✓	✓	✓
Storage	✓	✓	✓	✓	✓
SQL Database	✓	✓	✓	✓	✓
Mobile Services	✓	✓	✓	✓	✓
BizTalk Services	✓	✓	✓	✓	✓
Networking	✓	✓	✓	✓	✓
Active Directory	✓	✓	✓	✓	✓
Service Bus	✓	✓	✓	✓	✓
Media Services	✓	✓	✓	✓	✓



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# 2 Introduction to the regulated cloud

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# Introduction to the regulated cloud

- Many factors are pushing the pharma industry to adopt new strategies for computerized systems
- The need to maintain quality, compliance, agility and flexibility is still there
- Cloud computing = New IT paradigm
- Cheaper, Faster, More scalable, High availability, Better DR
- No clear regulatory guidance (yet)
- Dilemma: Innovation versus Compliance



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# Compliance challenges

- Pharma industry has typically been conservative and risk averse in relation to computerized systems compliance
- Pharma has very specific requirements around quality and compliance – cloud providers may not be pharma specific
- Traditional qualification focused on individual machines and specific hardware/software
- How to clearly identify and document system components
- Shared resources – unclear ownership
- Who is responsible for what
- Change control



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# 3 Cloud Qualification Paradigm

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# Cloud qualification Paradigm

- Need to visualize the vendors cloud as one environment
- Need to clearly identify roles and responsibilities between cloud vendor and sponsor
- Need to map vendor controls to compliance requirements
- Need to perform and document due diligence in some form to ensure compliance
- Need to implement processes to ensure qualified / validated state of regulated applications running on the cloud



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# GAMP Cloud SIG

- GAMP has established a special interest group to address the challenges posed by the cloud paradigm
- GAMP has reached out to FDA, pharma companies and cloud providers to collaborate on the subject of compliant cloud
- Goal is to establish a framework which satisfies the needs of the regulators, sponsors and cloud service providers
- This framework would be based on existing best practices and differences between traditional IT infrastructure and cloud infrastructure



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# Opportunities for Industry

- Reduced time and cost to implement GxP applications
- Better performance, redundancy and lower cost
- Ability to focus on core business and reduce IT burden
- Better geographical distribution and redundancy of applications
- New data and application models based on cloud principles

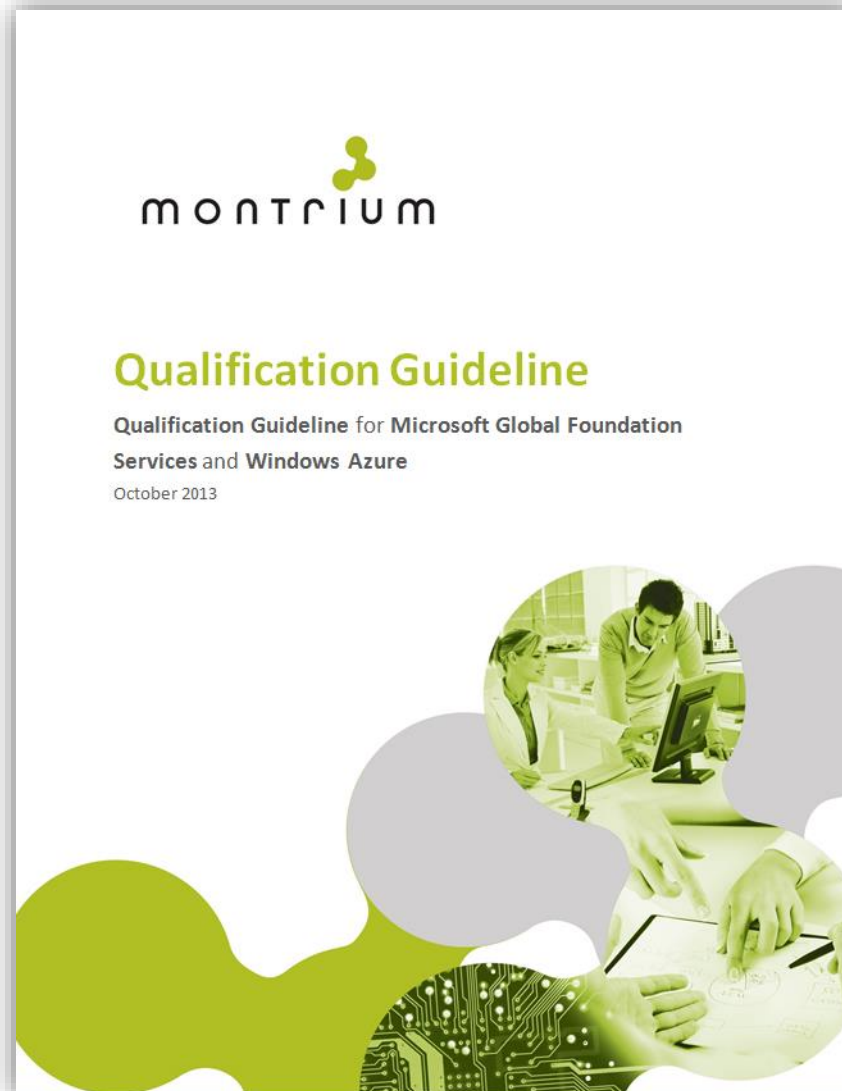
# 4 Proposed Qualification Approach

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# Azure Qualification Guideline



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# What are the key concerns?

- What is the **impact on compliance**?
- Which **controls** need to be in place?
- Who is **responsible** for what?
- What needs to be verified when performing **qualification**?



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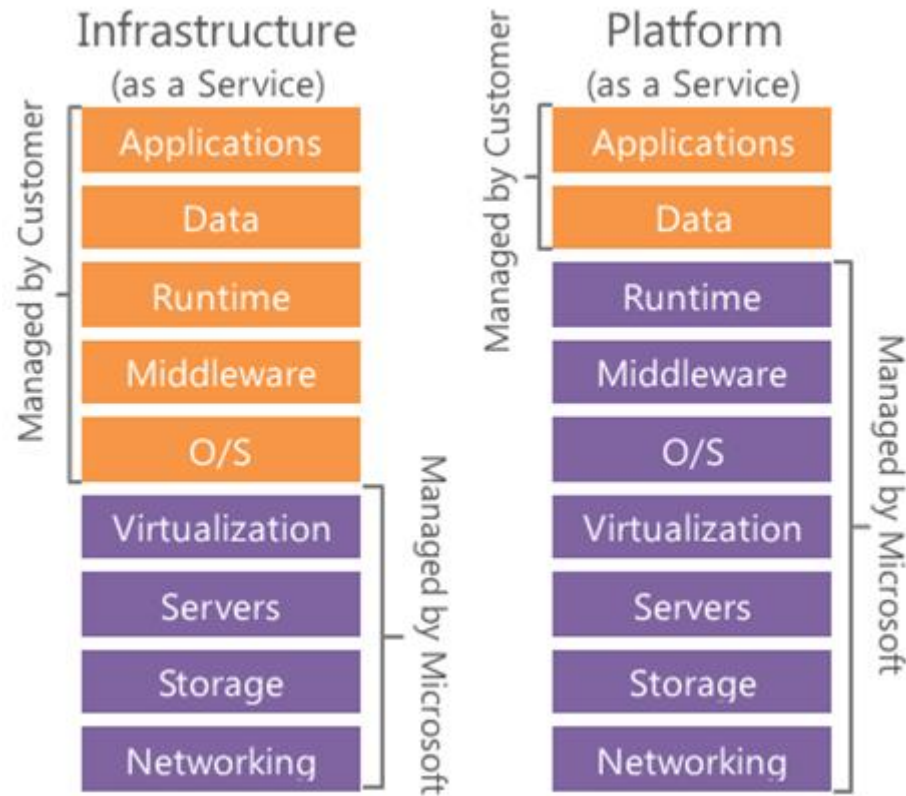


# What is Azure?

- Public, off-premise cloud computing platform, created by Microsoft, for building, deploying and managing applications and services through a global network of Microsoft-managed datacenters.
- Administered by Microsoft's Global Foundation Services (GFS) group which manages the core infrastructure and foundation technologies.
- Provides both IaaS and PaaS service delivery models.

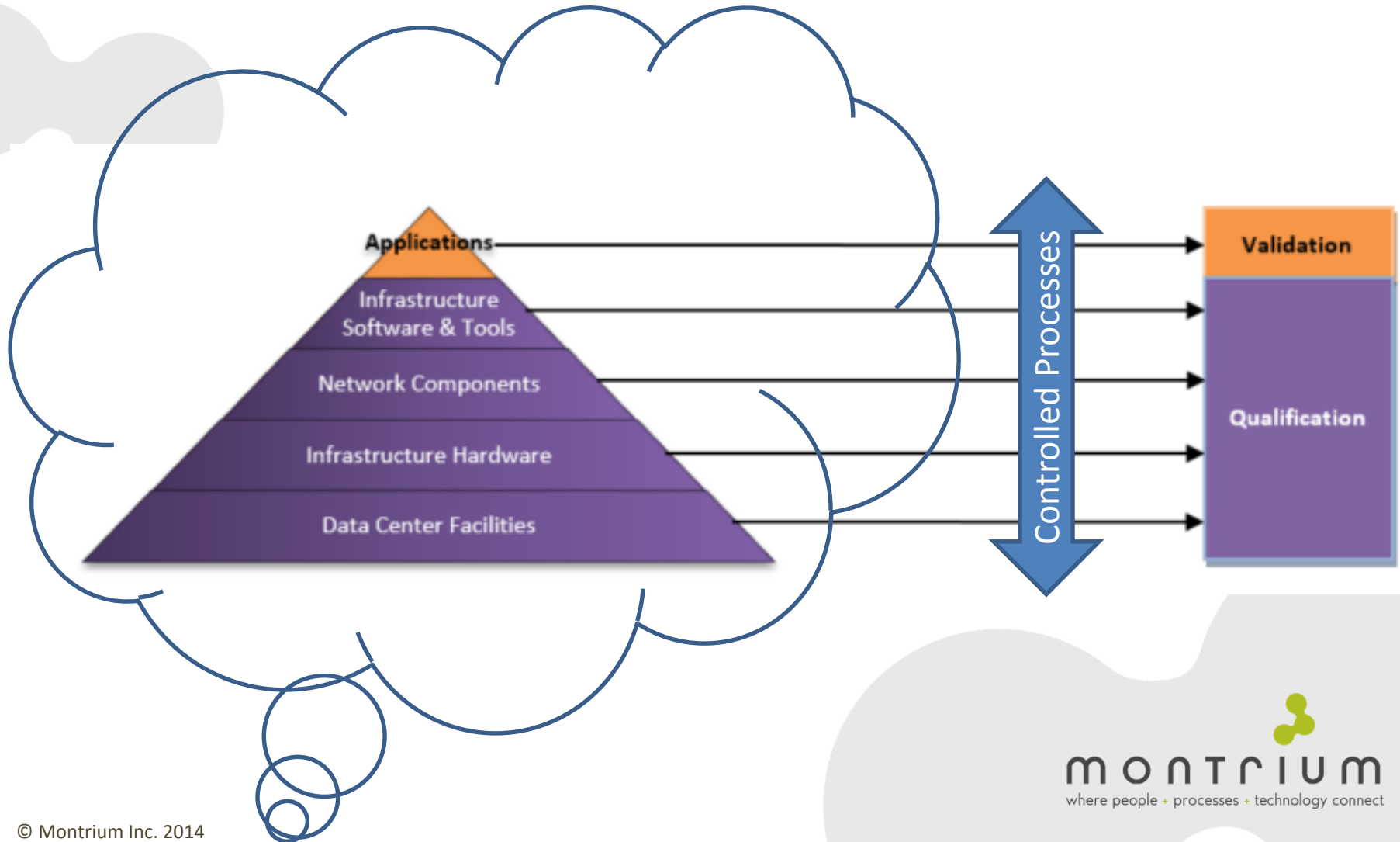


# IaaS & PaaS Delivery Models





# What are we qualifying?





# Azure Qualification Guideline

## Overview

### Purpose

- Assist life science customers in establishing a qualification strategy for the Azure platform.

### Target Audience

- Any regulated customer within the life sciences industry, aiming to use Azure to host GxP regulated computerized systems.

### Regulatory Scope

- FDA 21 CFR Part 11 Electronic Records; (21 CFR Part 11)
- EudraLex Volume 4 - Annex 11 Computerised Systems (Annex 11).



# Qualification Guideline Objectives

1. Identify Microsoft's **procedural** and **technical** controls which can be leveraged by the regulated user (customer) to **demonstrate compliance**.
2. Identify **activities** and **controls** that should be established by customers in order to **qualify** and **maintain control** over the **GxP application**.
3. Identify **key deliverables** which should be produced as part of the qualification effort.
4. Identify the **responsibilities** shared by Microsoft and its customers for meeting **regulatory requirements**





# Summary of Microsoft Responsibilities

- Ensure Azure is managed in a controlled and secured manner, so as to provide the following key elements:
  - Confidentiality
  - Integrity
  - Availability
- Ensure the virtual machines deployed within the Azure fabric meet the specifications.
- Ensure the Azure service meets the terms defined within the governing Service Level Agreements (SLA).





# Microsoft's Controls

- Security Policy and Procedures
- Physical and Environmental Security
- Logical Security
- System Monitoring and Maintenance
- Data Backup, Recovery and Retention
- Confidentiality
- Software Development / Change Management
- Incident Management
- Service Level Agreements
- Risk Assessment
- Documentation / Asset Management
- Training Management
- Disaster Recovery
- Vendor Management



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# Audit Reports

- ISO/IEC 27001:2005
- SOC 1 Type II / SSAE 16
- SOC 2 Type II



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# Summary of Customer Responsibilities

- Evaluate risks associated with using the cloud environment
- Evaluate Microsoft's processes and controls in relation to regulatory requirements
- Qualify virtual machines and validate GxP application(s) deployed within the Azure platform
- Establish procedures governing the operation and maintenance of the controlled environment



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# Customer Procedural Controls

- Computer Systems Validation
- Physical Security
- Logical Security
- System Monitoring
- Records Retention and Archiving
- System Administration and Maintenance
- User Access Management
- Backup and Restoration
- Training Management
- Documentation Management
- Incident and Problem Management (Helpdesk)
- Change / Configuration Management
- Vendor Management
- Disaster Recovery and Business Continuity



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# Regulatory Compliance Assessment

- A detailed assessment was performed on each regulatory requirement to interpret how compliance could be achieved within the context of a hosted GxP computerized system installed on the Azure platform.
- The assessment described the responsibilities of the customer and Microsoft, as well as the activities, documentation and controls (technical/procedural) that are required to meet the regulatory requirement.



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# 21 CFR Part 11 - Electronic Records Compliance Assessment

## 11.10 (d)

### *Limiting system access to authorized individuals.*

#### Customer – Regulated User

The customer is responsible for ensuring that an individual must have a valid user account in order to access both the Azure platform and any relevant GxP computerized system. Within the Azure platform and GxP computerized system, user permissions must be managed by the System Administrator to specify what areas of the computerized system are accessible to authorized users.

#### *Description of activities, documentation and controls:*

- Windows Azure customers register for the service by creating a subscription through the Windows Azure Portal web site. Customers manage applications and storage through their subscription using the Windows Azure management portal;
- Ensure proper procedures are established to govern logical and physical security over the terminal devices (e.g. workstations, laptops, etc.) used to access the Azure platform. The procedure should clearly describe how access to the system is managed, as well as how user system access is documented;
- Appropriate System Administration practices are followed for GxP computerized systems installed on the Azure platform based on predefined system administration procedures.

#### Microsoft – Cloud service provider

Microsoft is responsible for ensuring adequate controls are established to ensure access to the Azure platform is restricted to authorized individuals.

#### *Microsoft meets these requirements through the following controls:*

- Security Policies and Procedures (see Section 2.5.1)
- Physical Security (see Section 2.5.2)
- Logical Security (see Section 2.5.3)



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# Qualification Approach

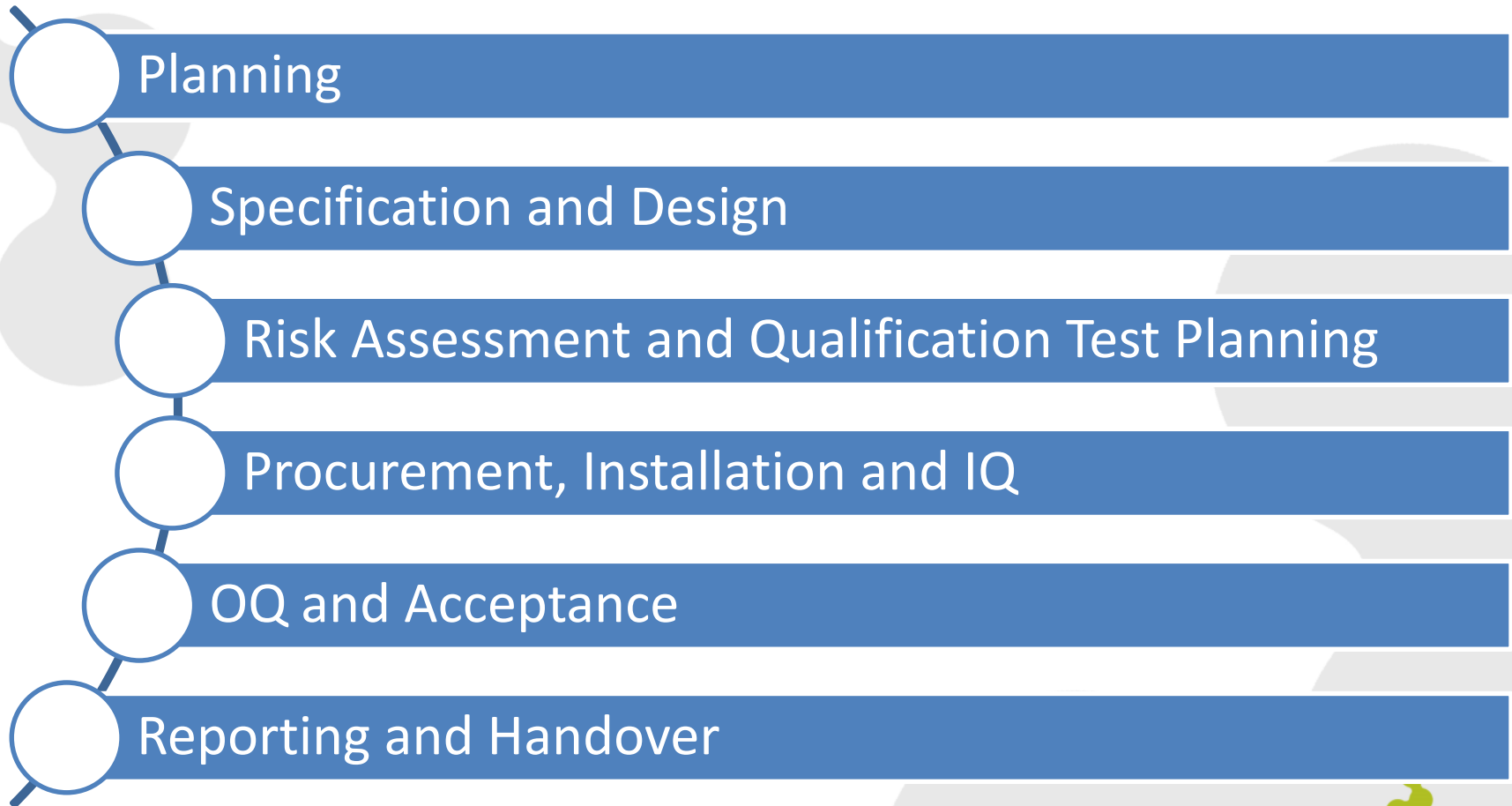
- ISPE's GAMP® series of Good Practice Guides:
  - ISPE, GAMP 5 - A Risk-Based Approach to Compliant GxP computerized systems, 2008
  - ISPE, GAMP Good Practice Guide: IT Infrastructure Control and Compliance, 2005
- PIC/S PI 011-3 Good Practices for Computerized Systems in Regulated 'GxP' Environments, 2007



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# IT Infrastructure Qualification Phases



**Reference:** ISPE, GAMP Good Practice Guide: IT Infrastructure Control and Compliance



# Elements verified during IT Infrastructure Qualification

		Microsoft (Physical)	Customer (Virtual)
	<b>Facility</b> <ul style="list-style-type: none"><li>• Environmental controls</li><li>• Power redundancy</li><li>• Physical security</li></ul>	✓ ✓ ✓	
	<b>Network</b> <ul style="list-style-type: none"><li>• Cabling, connectors, routers, switches, etc.</li><li>• Network inventory</li><li>• Topology</li><li>• Key configuration settings</li></ul>	✓ ✓ ✓ ✓	✓ ✓
	<b>Servers</b> <ul style="list-style-type: none"><li>• Server specifications</li><li>• Server inventory</li><li>• Key configuration settings</li></ul>	✓ ✓ ✓	✓ ✓ ✓



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# Key items to be verified in IQ

- Virtual Machines are deployed and configured according the specifications
- Network topology and server landscape diagrams are accurate
- Minimum software / hardware (virtual) requirements for the GxP application are met. These typically included:
  - amount of memory and disk space
  - number of CPUs
  - operating system (service packs, hot fixes, and security patches)
  - other software dependencies or service programs



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# Considerations when using Azure

## System Architecture

- Determine appropriate server specification and architecture taking into consideration scalability and performance needs (i.e. Availability Sets & Affinity Groups)

## VM Deployment

- Use of automated scripts to deploy VMs within Azure

## User Access Management

- User Account and Password Management
- Procedural controls for use of Microsoft IDs and passwords

## Configuration and Change Management

- Configuration and change management of virtual machines deployed within Azure

## Data Backup and Restoration

- Implementation of technical controls to manage server and application level data backup

## Security Monitoring

- Implementation of technical controls to protect applications and data from external threats

## Data Encryption

- Planning and implementation of data encryption requirements

## OS Patch and Upgrade

- Procedural controls for assessing Azure security and OS patch updates

## Incident Management

- Procedural controls for incident and alert reporting to Microsoft when those are specific to customer systems and Azure

# 5 Conclusions & Recommendations

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# Summary of Recommended Approach

Identify which regulations apply based on the intended use and the controls needed to achieve compliance

Review independent audits to determine acceptability of Microsoft's controls

Map individual controls to regulatory requirements to demonstrate compliance and identify responsibilities shared between Microsoft and the internal system owners (IT)

Develop qualification plan and perform verification activities



# Conclusion

- There is significant value to be had from leveraging cloud technology
- It is important to define a clear qualification process for the organization which will ensure that you collectively meet regulatory requirements
- This process should document activities performed by Microsoft and the sponsor in the form of a compliance assessment
- Regular re-evaluation of controls will ensure ongoing compliance



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