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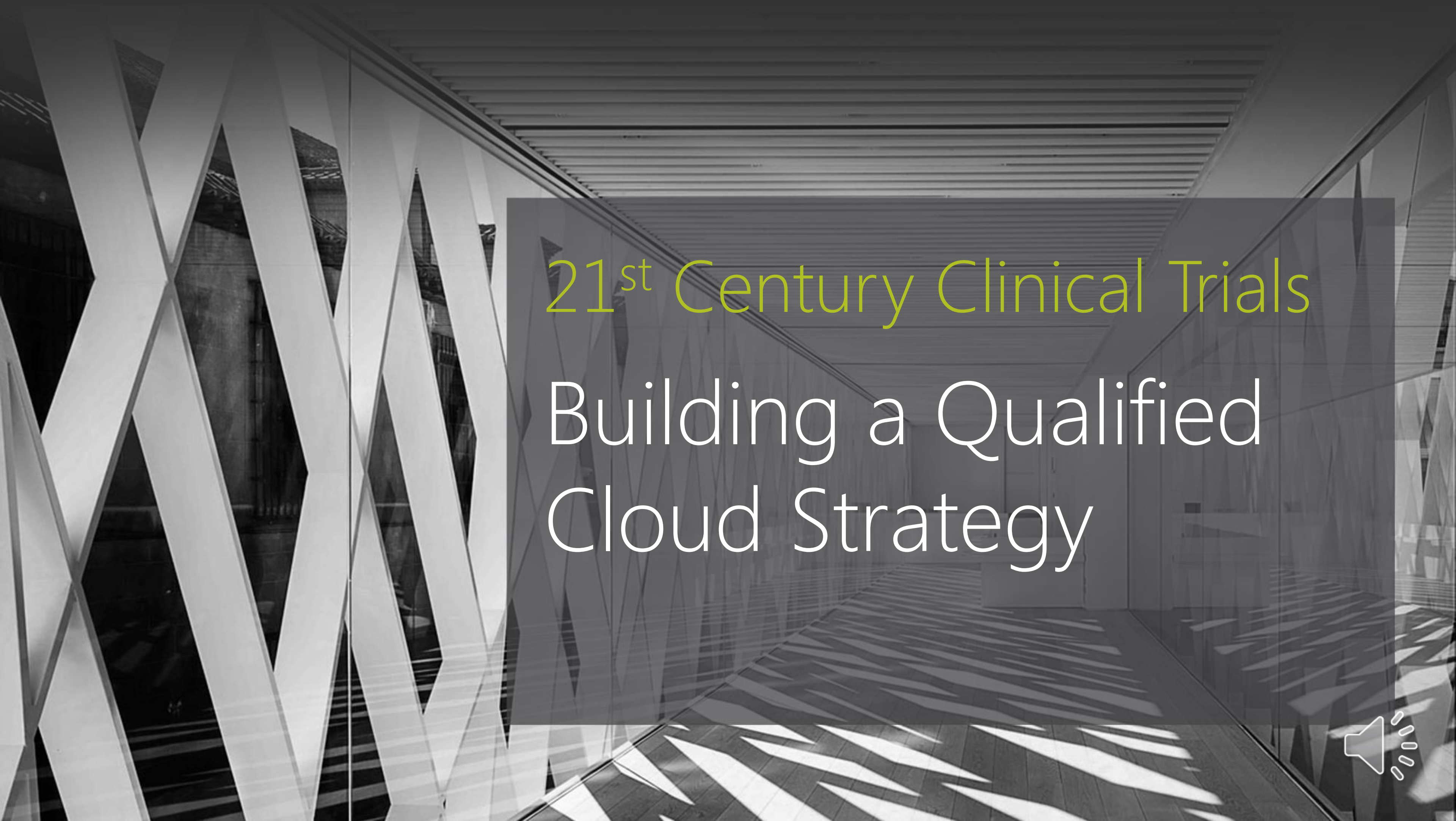

21st Century Clinical Trials

Building a Qualified Cloud Strategy

Speakers

Paul Fenton - President & Chief Executive Officer - Montrium

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Webinar Series

- Aims to look at technological trends and new organizational models in clinical trials
- Special focus on cloud based solutions and content management
- Participants should gain a good grounding on how these technologies are enabling change in how we work
- Aims to be practical also and give you criteria and decision making tools to implement technology and change
- For more info go to: www.montrium.com/webinars

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Housekeeping

- Slides can be distributed upon request. Details on how to request slides will be distributed to attendees following the webinar
- Details on **future webinars** will also be distributed
- Feel free to ask questions in the **questions panel**
- You can also **Tweet** me at **@paulkfenton**
- Thank you for your interest!

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Agenda

- What is cloud computing and how is it being used in Pharma
- What are the regulatory barriers and how can these be overcome
- Common questions and concerns regarding cloud applications in life sciences
- Implementing a cloud qualification strategy
- Key differences between on-premise vs. cloud application qualification
- Strategies for migrating systems and data into the cloud

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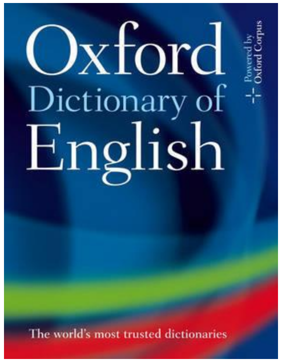
What is cloud computing and how is it being used in Pharma?

1

What is cloud computing?

Definition: **Cloud computing** is the delivery of computing as a service rather than a product, whereby shared resources, software, and information are provided to computers and other devices as a utility (like the electricity grid) over a network (typically the Internet) – *Wikipedia*



Definition: The practice of using a network of remote servers hosted on the Internet to store, manage, and process data, rather than a local server or a personal computer – *English Oxford Dictionary*

Required Characteristics

- On-Demand Service: Self-Service
- Broad Network Access: Multi-Device
- Resource Pooling: Multi-Tenant Model
- Rapid Elasticity: Scalability
- Measured Service: Pay for what you need, monitoring and reporting

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Cloud Advantages

- Can be deployed quickly
- Flexible pricing models
- Allow for significant scaling
- Allow for operational efficiencies
- Reduces Capex
- Alleviates internal IT burden
- Improves availability and disaster recovery

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Key Drivers for Cloud Adoption

- Patent cliff
- Personalized medicine
- Need to do more with less
- Need to be more agile
- Ever increasing outsourcing of R&D activities
- Complexity and globalization of clinical R&D
- More and bigger data
- New virtual organizational models
- Improved collaboration and access to information
- Cost of ownership
- Vendor offerings

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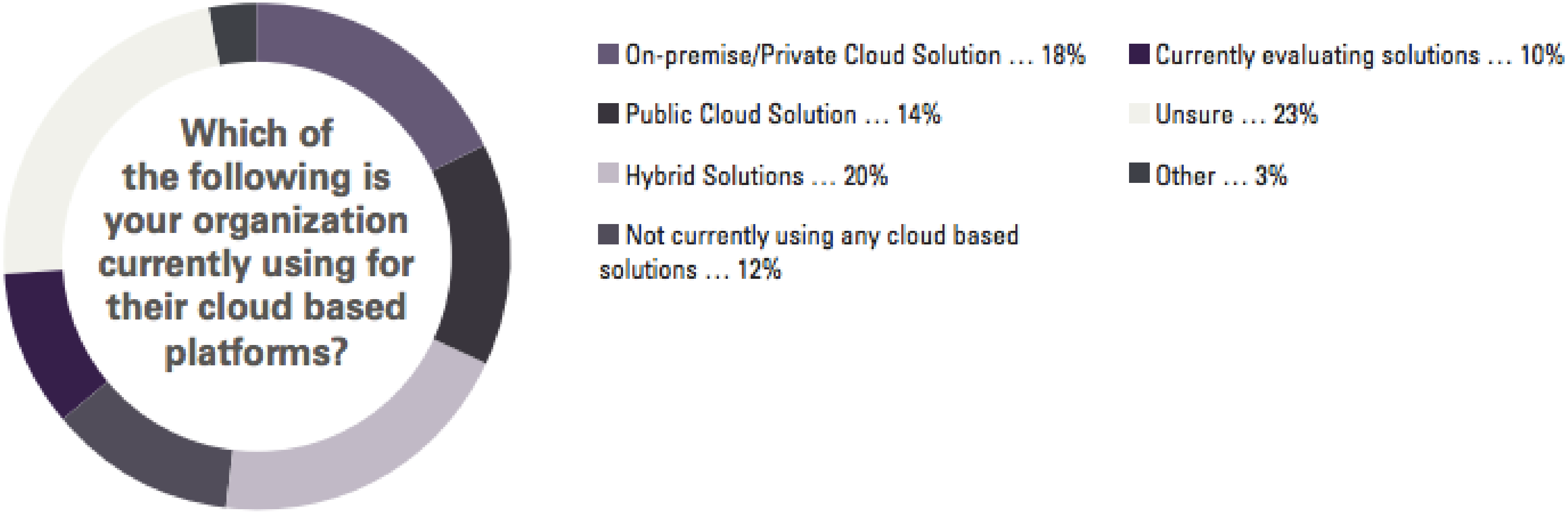
Trends

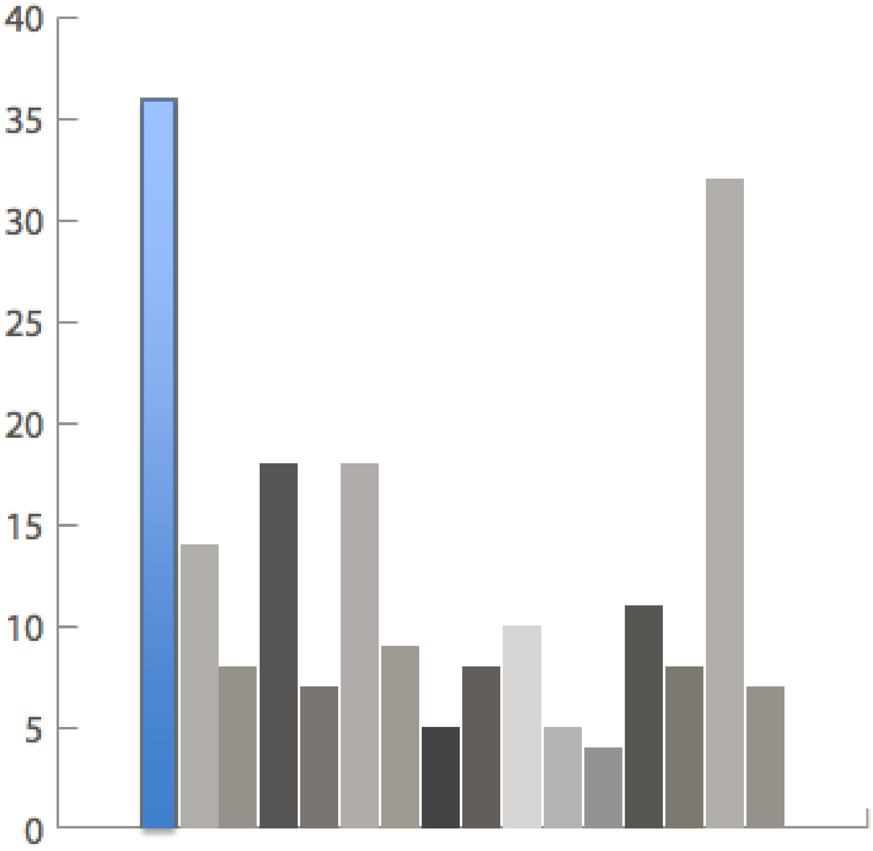


Source: BioIT World, 2014 Annual Life Sciences Survey

Trends

Which applications have you already migrated to the cloud?*

- 🟦 Email... 36%
- ■ Intranet ... 14%
- ■ ERP ... 8%
- ■ CRM ... 18%
- ■ HR ... 7%
- ■ Marketing/Sales ... 18%
- ■ Customer Service ... 9%
- ■ Inventory Management ... 5%
- ■ Lab Information Management Systems ... 8%
- ■ Next Generation Sequencing ... 10%
- ■ CTMS ... 5%
- ■ EDC ... 4%
- ■ Other Core Business Applications ... 11%
- ■ Other Non-Essential Business Applications ... 8%
- ■ None of the above ... 32%
- ■ Other ... 7%



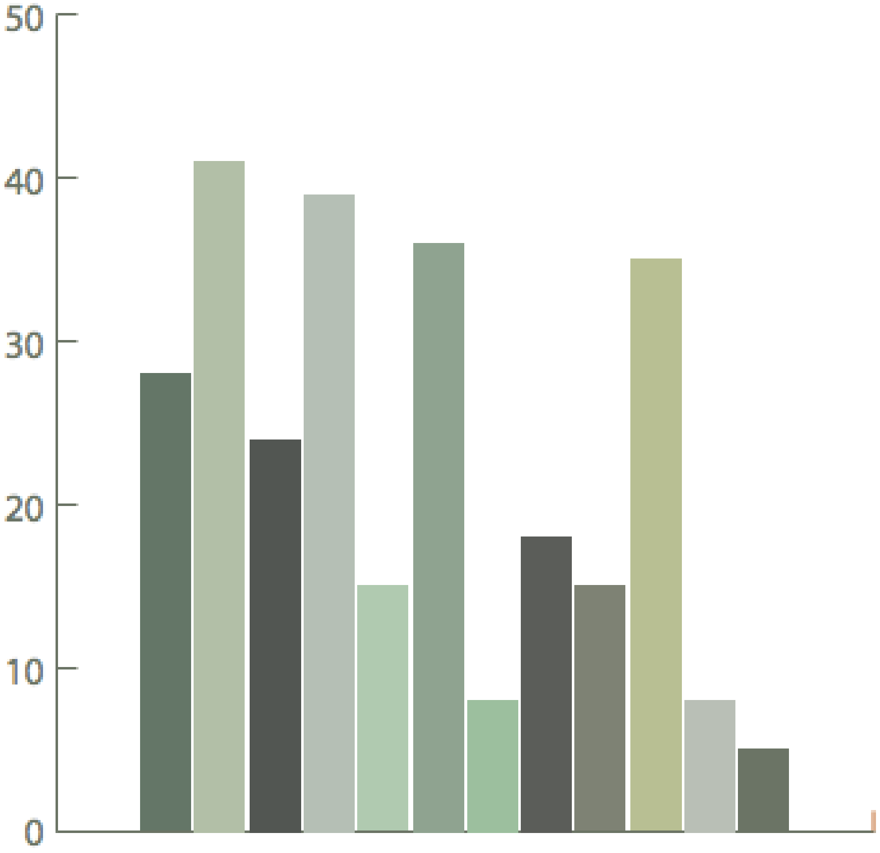
Source: BioIT World, 2014 Annual Life Sciences Survey

*Respondents were able to choose multiple responses

Trends

Which of the following do you see as the biggest benefit of migrating to the cloud?*

- Employee mobility ... 28%
- Cost savings ... 41%
- Ease of use ... 24%
- Data always being accessible ... 39%
- Security ... 15%
- Avoids the need to purchase new hardware ... 36%
- Avoids the need to purchase new bioinformatics staff ... 8%
- Address peaks and troughs in workload ... 18%
- Facilities collaborations with other labs/organizations ... 15%
- Scalability of cloud services ... 35%
- Conversion of capital expenditures to operation costs ... 8%
- Other ... 5%



Source: BioIT World, 2014 Annual Life Sciences Survey

*Respondents were able to choose multiple responses

Regulatory Challenges

2

The Regulations Require….

- That infrastructure is properly qualified
- That technical controls be in place to ensure adequate security and protection of data integrity
- That procedural controls be in place to properly govern systems
- That a quality system be in place
- That individuals have adequate qualification, experience and training to perform their duties

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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Common Concerns

- Maintaining privacy and confidentiality
- Loss of control within the IT function
- Maintaining reliability of key systems and availability of services or data
- Lack of organizational control over services or data
- Legal ramifications (government regulations, compliance and auditing)
- Concerns over cloud vendor lock-in

Ref: Implementing Cloud Computing In Small & Mid-Market Life-Sciences, T. Sommer & R. Subramanian, 2013

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GAMP Cloud SIG

- GAMP has established a special interest group (SIG) 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

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Implementing a Cloud Qualification Strategy

3

Life Science Industry Questions

Compliance

- What is the impact on **regulatory compliance** (i.e. 21 CFR Part 11 and Annexe 11)?
- What should be **verified** when performing **qualification** of an application in the cloud?

Security

- What should be verified to ensure systems are **secure** and that **data** is **confidential**?

Control

- How do we manage **changes** made to the application or underlying infrastructure?
- How do we migrate existing systems into the cloud?

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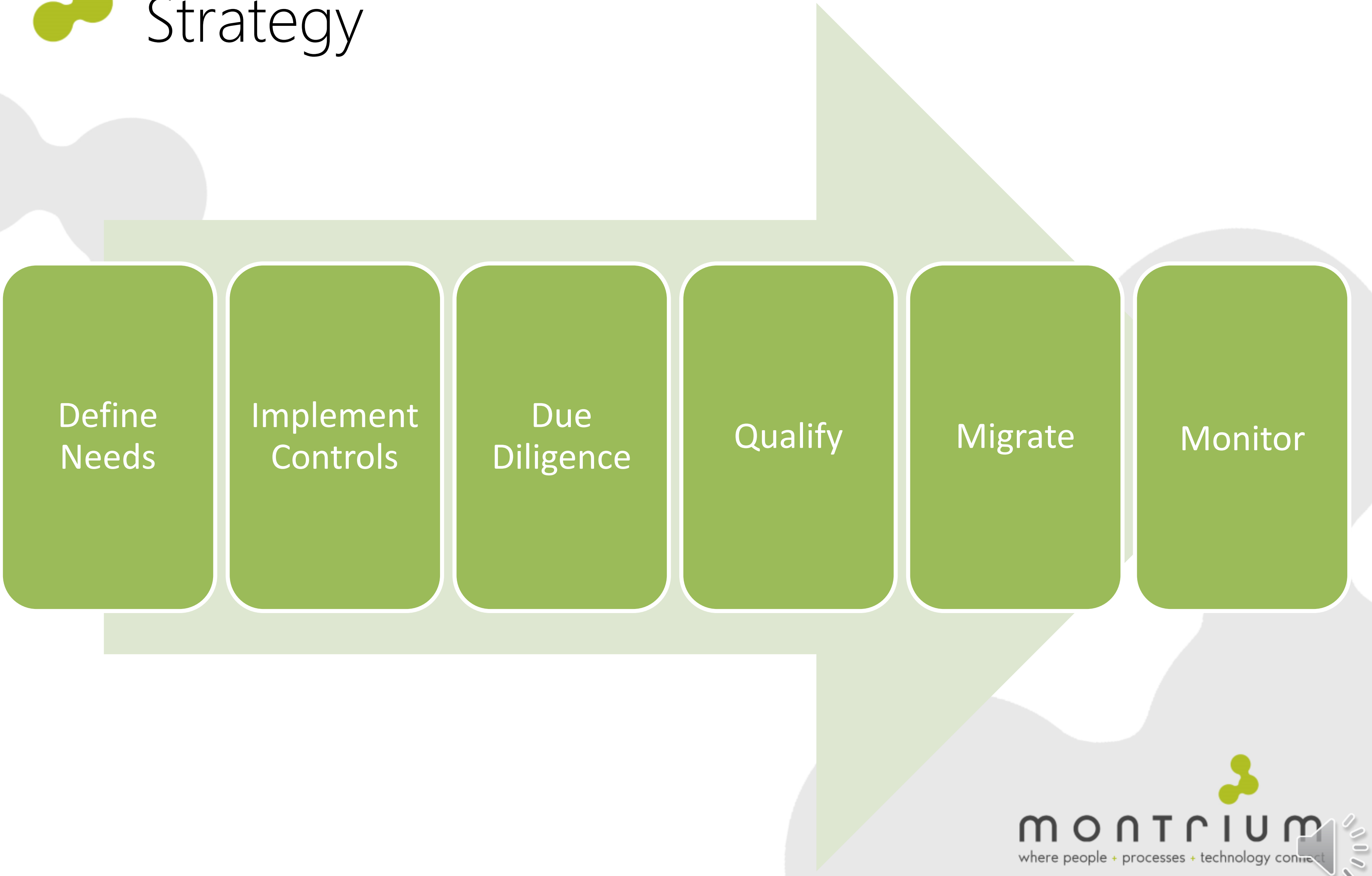
Implementing a Cloud Qualification Strategy



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Implementing a Cloud Qualification Strategy

Step 1 – Define needs, analyse risks and determine service & deployment models

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Cloud Service and Deployment Models*

* Detailed definitions can be found at: The NIST Definition of Cloud Computing (Special Publication 800-145)

Cloud Service Models

- Software as a Service (SaaS)
- Platform as a Service (PaaS)
- Infrastructure as a Service (IaaS)

Cloud Deployment Models

- Private Cloud
- Community Cloud
- Public Cloud
- Hybrid Cloud

Understanding the Risks

Application Type	Service Model	Deployment Model	Risks
Generic Non-Life Science Targeted (i.e. CRM, email)	SaaS	Public	- Application might require configuration to be able to meet all regulatory requirements - Vendor might not have a adequate QMS and be open to audit - Frequent changes to SaaS application could result in regression issues - Data security risks since data is not locally stored
Life Science Targeted GxP application (i.e. eCTD, EDMS, QMS, EDC, CTMS)	SaaS	Community	- System should already have the functionality to address regulatory requirements - Vendor should have a adequate QMS and be open to audit - Changes to SaaS application should be done under change control - Data security risks since data is not locally stored
Custom built GxP application	IaaS	Public	- Risks associated with critical GxP system functionality - Data security risks since data is not locally stored

Implementing a Cloud Qualification Strategy

Step 2 – Implement appropriate internal procedural and technical controls

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Regulated Firm 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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Technical Controls

- Browser / device compatibility management tools
  - Need to ensure that end users are able to access the cloud solutions in consistent manner
- Data Backup and Disaster Recovery Tools
  - Depending on the service and deployment model, data backup and recovery tools might still need to be implemented
- Secure access (i.e. VPN)
  - Need to ensure end users are able to access cloud applications in a secure manner

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Implementing a Cloud Qualification Strategy

Step 3 - Perform cloud provider due diligence

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Summary of Cloud Provider Responsibilities

- Ensure cloud infrastructure / applications are managed in a controlled and secured manner, so as to provide the following key elements:
  - Confidentiality
  - Integrity
  - Availability
- Ensure the solutions deployed within the cloud meet the specifications.
- Ensure the cloud services meet the terms defined within the governing Service Level Agreements (SLA).

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Cloud Provider Due Diligence

- Perform due diligence based on level of risk
  - On-premise audit?
  - Postal audit?
  - Leverage Industry certifications?
    - ISO/IEC 27001 & ISO 27002
    - SOC 1 Type II / SSAE 16
    - SOC 2 Type II
    - HIPAA
    - Safe Harbor Compliance
    - FIPS 200 / SP 800-53
    - WebTrust
    - SysTrust

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Key Security Elements

Security Element	What to verify
Application Security	Strong encryption and authentication controls are used.
Data Security	Auditable security checks and best practice cryptography that prevent breaches implemented.
Infrastructure Security	Physical security measures are in place redundancy of infrastructure and uninterruptible service are tested.
Process Security	Industry best practices are used, and managed by certified security professionals.
Personnel Security	Background checks and strong confidentiality agreements, with all personnel exposed to data
Product Development Security	Secure development lifecycle processes are used, that protect applications in production and in development.

Regulatory Compliance Assessment

- Identify what regulations apply:
  - Primarily 21 CFR Part 11 and Annex 11
  - Other regulations such as GxPs may also have specific requirements
- Perform a detailed assessment on each regulatory requirement to interpret how compliance could be achieved within the context of a hosted GxP computerized system installed on the cloud platform
- Evaluate the responsibilities of the regulated user and cloud provider, as well as the activities, documentation and controls (technical/procedural) that are required to meet the regulatory requirement

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Implementing a Cloud Qualification Strategy

Step 4 - Plan and execute qualification activities

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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 Computerised Systems in Regulated 'GxP' Environments, 2007

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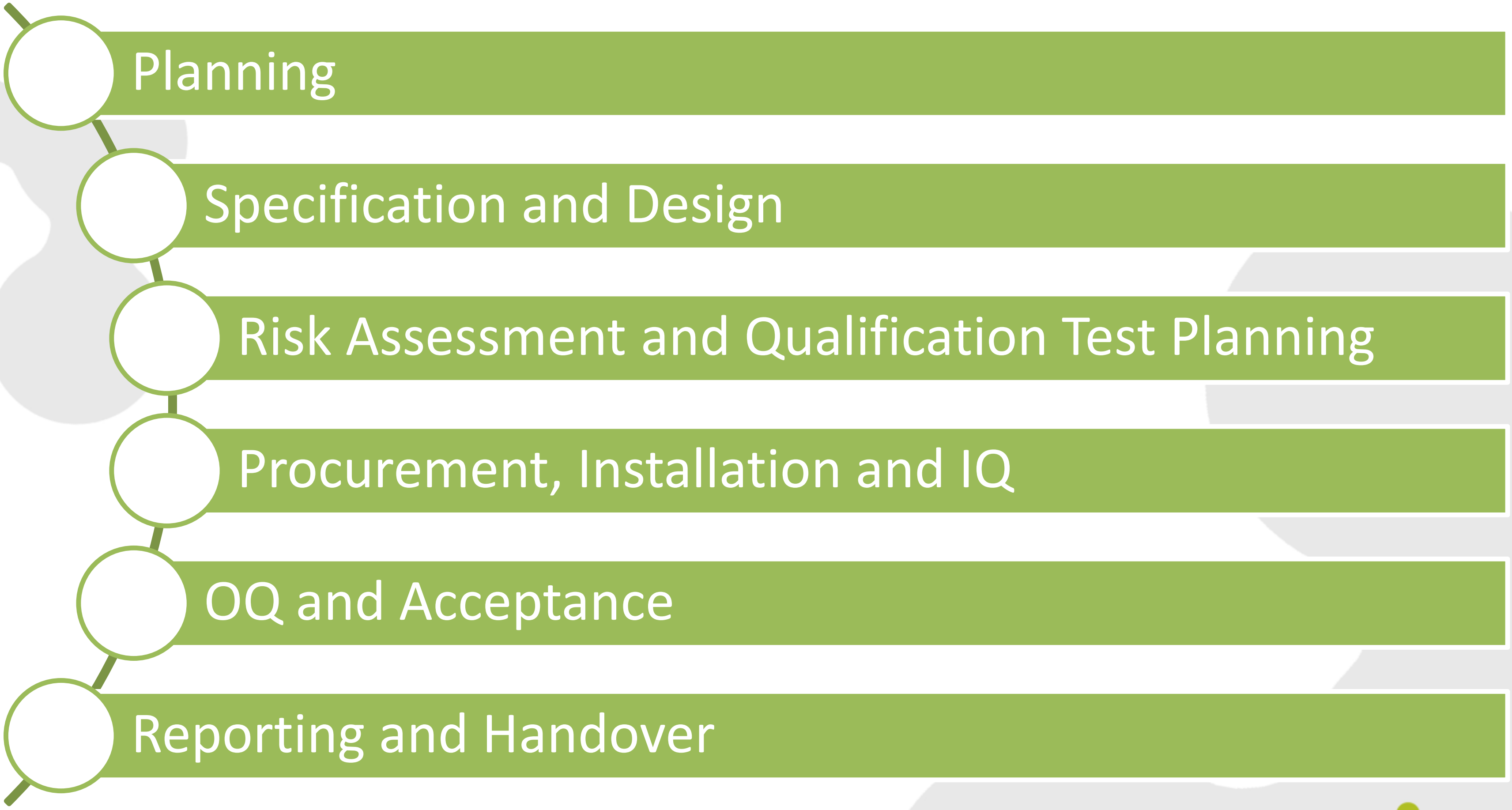
IT Infrastructure Qualification Phases



- Planning
- Specification and Design
- Risk Assessment and Qualification Test Planning
- Procurement, Installation and IQ
- OQ and Acceptance
- Reporting and Handover

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

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Specification and Design

System Description:

- Identifies main system functionality
- Regulatory impact
- System architecture (virtual)
- System interfaces
- System access
- Security features
- Electronic records and signatures

Solutions design should take into consideration:

- High availability in case of hardware failure
- Geographical location of data
- Testing environment

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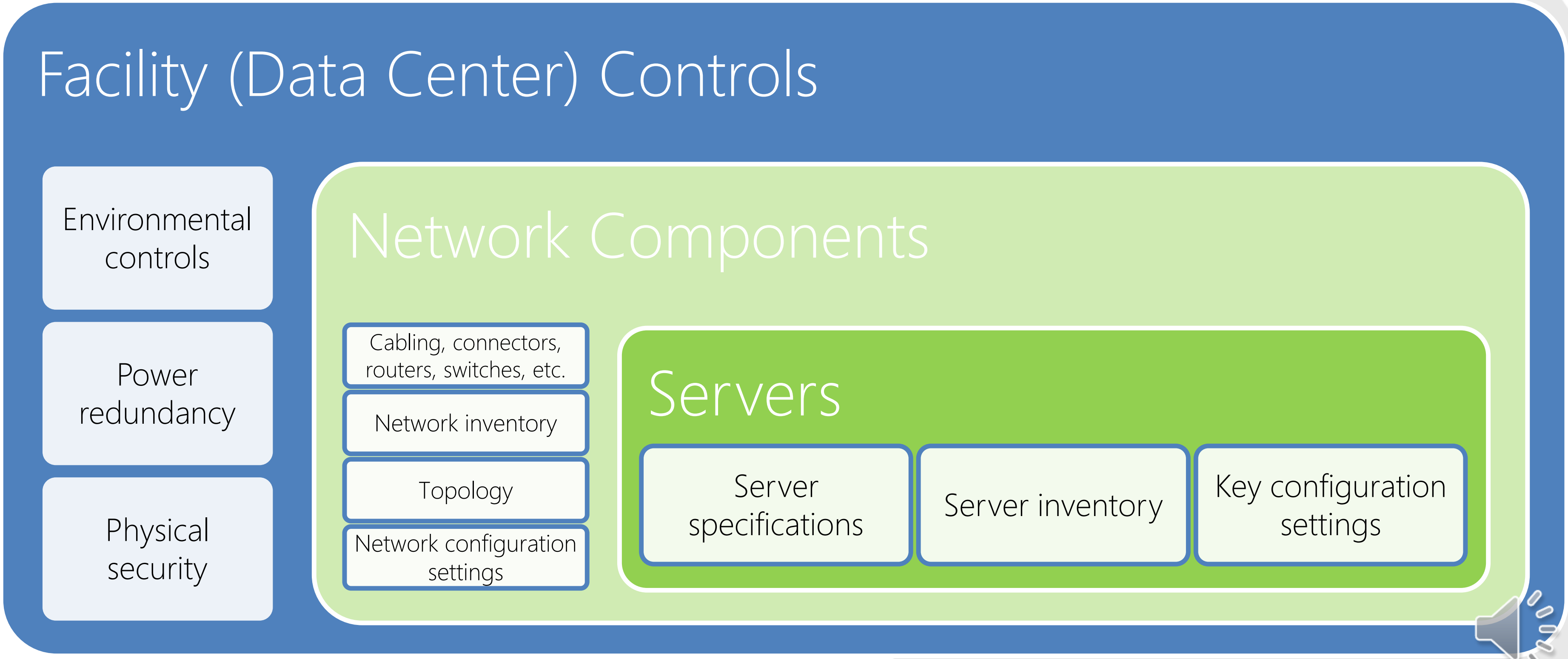
Procurement, Installation and IQ

System Documentation

Client / workstation installation



Facility (Data Center) Controls

Environmental controls

Power redundancy

Physical security

Network Components

Cabling, connectors, routers, switches, etc.

Network inventory

Topology

Network configuration settings

Servers

Server specifications

Server inventory

Key configuration settings

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

Implementing a Cloud Qualification Strategy

Step 5 - Plan and execute migration activities

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Migration Approaches

- Virtual Machine Migration (IaaS)
  - Create a copy of existing virtual environment
  - Upload virtual machines into cloud IaaS
- Data Migration (SaaS)
  - Database detach: typically only works if moving to the same system
  - Data extraction, conversion and upload into new system

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Migration Risks

- Data is moved or transformed incorrectly or incompletely
- Data already residing in the target system is harmed
- Residual data in the source system is adversely affected by the removal of the migrated data
- Not possible to migrate audit trail data

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Data Migration Verification

Migration verification should ensure:

- all data elements are migrated
- all critical data attributes are preserved (e.g., security settings)
- all supporting data are correctly transferred
- no extra data elements are inadvertently introduced
- any specified conversions have consistently produced the expected results

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Implementing a Cloud Qualification Strategy

Step 6 - On-going monitoring and management

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On-Going Monitoring and Management

- Ensure the change management process is well understood. How and when will you be notified if change is coming:
  - What is the process for receiving access to a testing environment, where testing can be performed prior to release in production
  - Define what type routine testing should be performed after the change has been implemented to ensure critical functionality has not been lost
- Setup controls to monitor key performance metrics are aligned with SLA
- Perform routine audits

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Implementing a Cloud Qualification Strategy (Summary)

1. Define needs, analyse risks and determine service & deployment models
2. Implement appropriate internal procedural and technical controls
3. Perform cloud provider due diligence
4. Plan and execute qualification activities
5. Plan and execute migration activities
6. On-going monitoring and management

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Conclusion and Recommendations

- 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 the cloud vendor
- Regular re-evaluation of controls will ensure ongoing compliance

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