Validating ‘Cloud’

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Validation of Cloud

Introduction

- Environments
- Definitions
- Manage Risk by Designation of Systems
- Why Go ‘Cloud’
- Success Dependencies
- Validation
- Personal Experience
Introduction

- My background includes implementation and support of various laboratory, clinical, statistical and environmental applications including:
  - Cloud Applications (SaaS)
    - COTS
  - Cloud Infrastructure
    - In-House COTS
    - In-House Customized
    - In-House Developed
    - Integrated Websites
  - Internal Non-Cloud Infrastructure
    - In-House COTS
    - In-House Customized
    - In-House Developed
Celerion is a CRO that provides clinical research solutions with the following services:

- Clinical Conduct Over 730 Beds in clinics in US and Northern Ireland
- Bioanalytical Services in US and Zurich, Switzerland
- Clinical Pharmacology Sciences
- Drug Development/Regulatory Services
Agenda

Validation of Cloud

Introduction

Environments

Definitions
Manage Risk by Designation of Systems
Why Go ‘Cloud’
Success Dependencies
Validation
Personal Experience
Environments

Infrastructure (VMWare & Hardware)

Platform

Application

Application

Platform

Application

Platform

Application

Platform

Application

Application
Components of Cloud Computing

- Management Console
- Database Servers for Production
- Storage Options
  - Fiber, SATA, etc.
- Application Machines
- Physical Machines
- Hypervisor
- SAN, DAS, or NAS
- Virtual Machines
- Fiber, SATA, etc.
Validation of Cloud

Introduction

Environments

Definitions

Manage Risk by Designation of Systems

Why Go ‘Cloud’

Success Dependencies

Validation

Personal Experience
Definitions

- **Cloud computing** is the distribution of computing infrastructure, applications, or services – internally or externally
  - Infrastructure – routers, hardware, firewalls, security (physical and logical), disaster recovery, HVAC, fire suppression, environmental monitoring
  - Applications – hosting software, upgrades, installation qualification, operational qualification, logical security, backups,
  - Services – helpdesk, hardware/software monitoring,
- NIST Defines Cloud computing is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be **rapidly provisioned and released with minimal management effort or service provider interaction**.
Definitions: Different type of Clouds

- **Private cloud**: Here, the cloud hardware is provided solely for a single organization. The private cloud can be owned, managed, and operated by either the organization or a third-party provider and can be located on-site or off-site.

- **Public cloud**: Access to the cloud infrastructure is for any customer willing to pay the fees. Because of the open access, this delivery model requires careful consideration due to security requirements.

- **Hybrid cloud**: combination of different hardware/software options
Validation of Cloud

- Introduction
- Environments
- Definitions
- Manage Risk by Designation of Systems
  - Why Go ‘Cloud’
  - Success Dependencies
  - Validation
  - Personal Experience
Manage Risk by Designation of Systems

- **Computerized System**
  - A combination of computer hardware, firmware, operating system(s) and utilities, application software, databases, networking component(s) and interface(s), equipment, instrument or instrumentation supported by operating procedures, methods and work or business processes used by trained personnel. This includes Commercial Off-the-Shelf System (COTS) systems and software bought from an external vendor, developed internally, or by a third party for specific purposes.
Tools

- A program or application used to create, debug, maintain, or otherwise support or automate other computerized programs and applications. Tools may also be applications used to support GxP activities (such as incident management).
Manage Risk by Designation of Systems

- Regulated Application
  - A computerized system used to generate, produce and report data generated for or in support of GxP studies.
Manage Risk by Designation of Systems

- **Storage or Archiving** –
  - A storage area network (SAN) in various speeds with different special-purposes that interconnects different kinds of data storage devices with associated data platforms on behalf of a larger network of users.
  - May be local to the hardware and computerized systems, but may also extend to remote locations for backup and/or archival storage.
Validation of Cloud

Introduction
Environments
Definitions
Manage Risk by Designation of Systems

Why Go ‘Cloud’
Success Dependencies
Validation
Personal Experience
Why “Go Cloud”

- Cost
  - Provides flexible pricing options
  - Reduces IT headcount required to support and monitor server(s)
- Provides flexible growth options
- Single Point of Touch (reduces workstations and servers at sites)
- Single Point of Software (upgrades, configuration, etc.)
- Only Web Access Required
- No re-installation required to change hardware
Why “Go Cloud”

- Storage Capacity
- **Physical and Logical** Security
- Power consumption and ventilation (HVAC)
- Availability
- Competence
- Location independent
- Shortened Installation Cycle
- Pay As You Go – easy to forecast
- Hardware Upgrades ‘easy’
- Disaster Recovery/Business Continuity Options
‘Cloud’ Concerns

- Cost
- Flexibility
- Privacy/security (transparency, proprietary)
- Important to understand data ownership
- Record retention
- Bandwidth
- Maintaining Validated Status
- Patching
- Automating – not proper change control
- Application configuration
- Employees and other Contractors
- Upgrade ‘forcing’
- Web Availability
Success depends on...

- Vendor Audits - Use Risk Based Approach
  - Quality Program
  - Hiring Process
  - Security Policy
  - Training
  - How is access managed
  - Disaster Recovery capabilities & testing
  - Privileged Logical Access
  - Security on VMs
  - Security from Internet Threats
  - Certifications (Sas-70-SSAE-16, SOC Reports, ISO Standards, or other security standards)
Success depends on…

- Have they worked with other clients in the regulated industry – what type?
- Approach for Account Managers, Team
- Managing Vendors
- Training Program
- SOPs for Outsourced Vendor
- Approach to Risk Management
- Reporting
- Understanding Access
- Security Audit (3rd Party)
- Regular Status Meetings
- Understand your current level of business risk & theirs
## Validation of Cloud

### Agenda

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- Validation
- Personal Experience
Validation – of VMs Risk Based Approach

High Risk
- Maintaining Change Control (VMs can proliferate)
- VM Images – Asset Inventory
- Logical Access
- Performance (depending on app)

Low Risk
- Hardware they reside on
- New Hardware they ‘might’ reside on
- Hypervisor Performance
Qualification – Risk Based Approach

- Installation Qualification
  - Any hardware that is put into the data center is qualified according to your existing process - as if it was put it one of your sites
    - Configuration, Asset Management, Diagrams, Etc.
  - Any software or configuration done should be in the IQ documentation (hypervisor installation)
  - ‘Baseline’ information included in ‘regulated application’ diagram, documentation
Qualification– Risk Based Approach

- Operational Qualification
  - Can be a little more tricky – again refer to your risk assessment for your VMs
  - May Require vendor to complete some testing
  - As long as HypverViser software remains the same does not need to be tested on multiple VMs
  - Does it work as intended according to the specs
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<th>Verified by</th>
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</tr>
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<tr>
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<td></td>
<td>Network Identity</td>
</tr>
<tr>
<td></td>
<td></td>
<td>CPU/RAM/Disk</td>
</tr>
<tr>
<td></td>
<td></td>
<td>VM Priority Groups</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Operating System</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DNS Settings</td>
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<td></td>
<td>WINS Settings</td>
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<tr>
<td></td>
<td></td>
<td>Registry Changes for MS Networking and NetBIOS</td>
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<tr>
<td></td>
<td></td>
<td>Service Principle Names</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Removal of Rackspace Desktop Background Updater</td>
</tr>
<tr>
<td></td>
<td></td>
<td>DC01-IAD DNS Checks/Updates</td>
</tr>
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<td>DC01-IAD Active Directory Group Creation</td>
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<td>DC01-IAD Active Directory OU Membership</td>
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<td>Move server to appropriate Organizational Unit</td>
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Qualified VM Environment – now what?

- Perform Application IQ/OQ/UAT according to normal procedures – relating to the application criticality, regulatory requirements, or other designation
- ‘Baseline’ information included in ‘regulated application’ diagram, documentation
Validation – Risk Based Approach

- **SOPs**
  - Procedures or Policy for Managing your Cloud Providers (may need specific ones depending on how many and what type of providers you have)
  - Procedure or Robust Audit Program (Regulatory Training and Awareness, Security, Compliance to Procedures)
  - Responsibility designed for data reliability, integrity, security
  - Execute regular security assessments
  - Designate ‘Server Owners’ or ‘Application Owners’ for clear responsibility
Agenda

Validation of Cloud

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- Definitions
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- Success Dependencies
- Validation

Personal Experience
Personal Experience – the Good

- Great Support Models (24 x 7 x 365)
- Experience of Staff exceeds internal staff
- Robust Monitoring & Reporting (firewalls, internet infiltration, server performance, troubleshooting, alerting, preventative maintenance)
Personal Experience – the Bad

- Team Changes
- Privacy Policies between Companies
- IQ/OQ Sometimes takes ‘reminders’
- It does take time to manage your vendor
- Maintaining up to date diagrams
Personal Experience – the ugly

- Nothing – as long as the right partners are selected
Contact Info & Questions

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