Validating ‘Cloud’

June 2012

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Agenda

Validation of Cloud

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

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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

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Celerion

- 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

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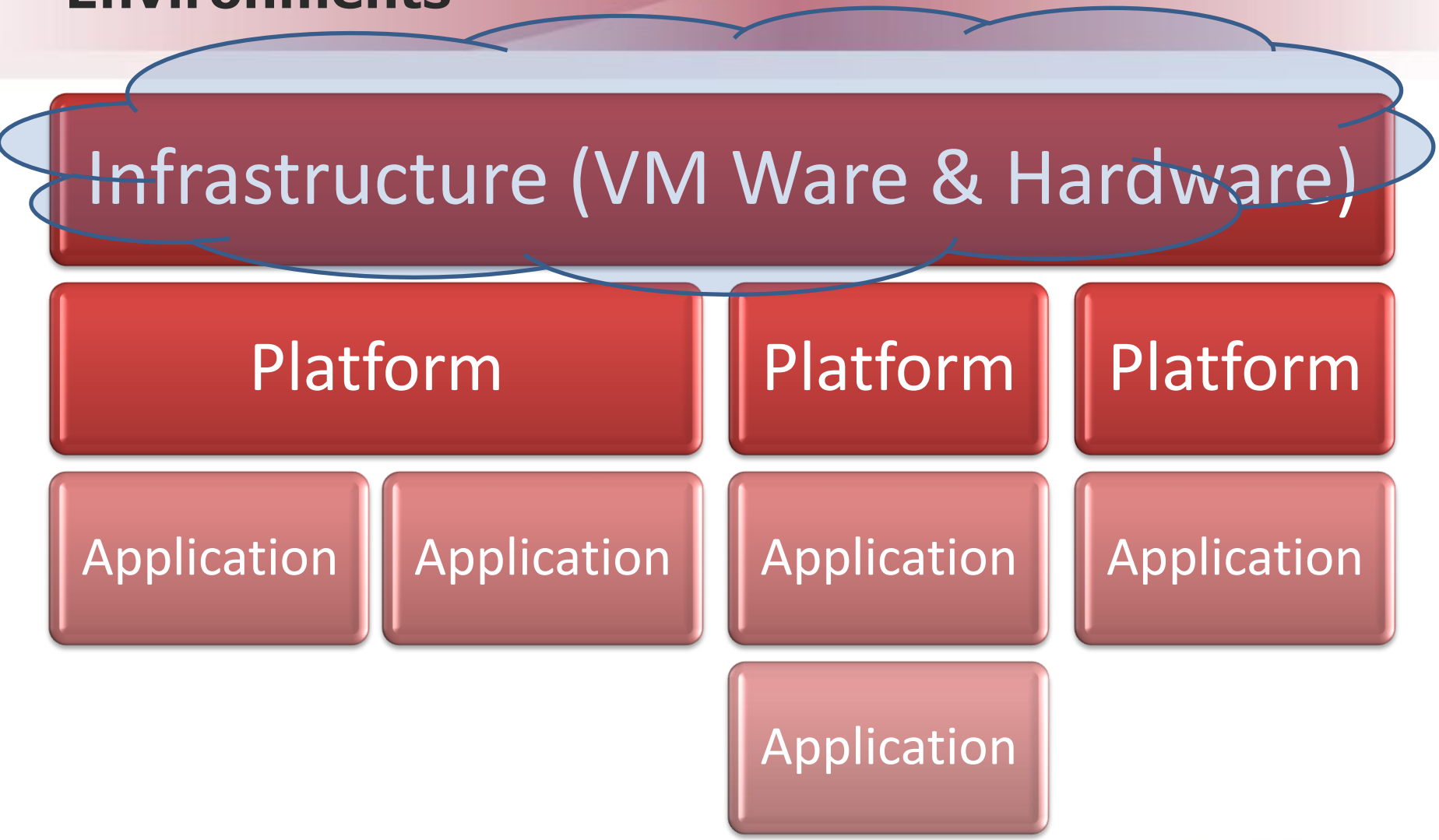
Environments



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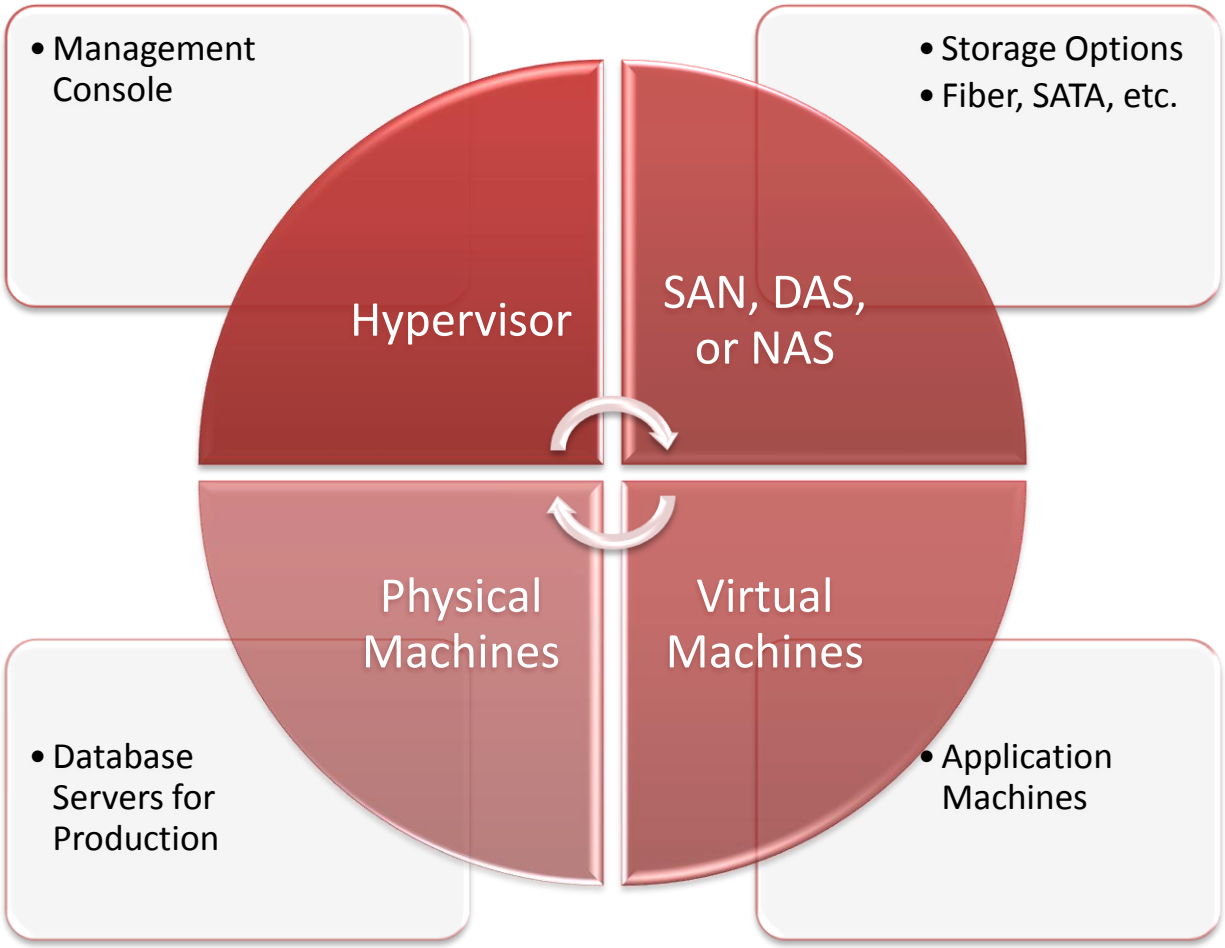
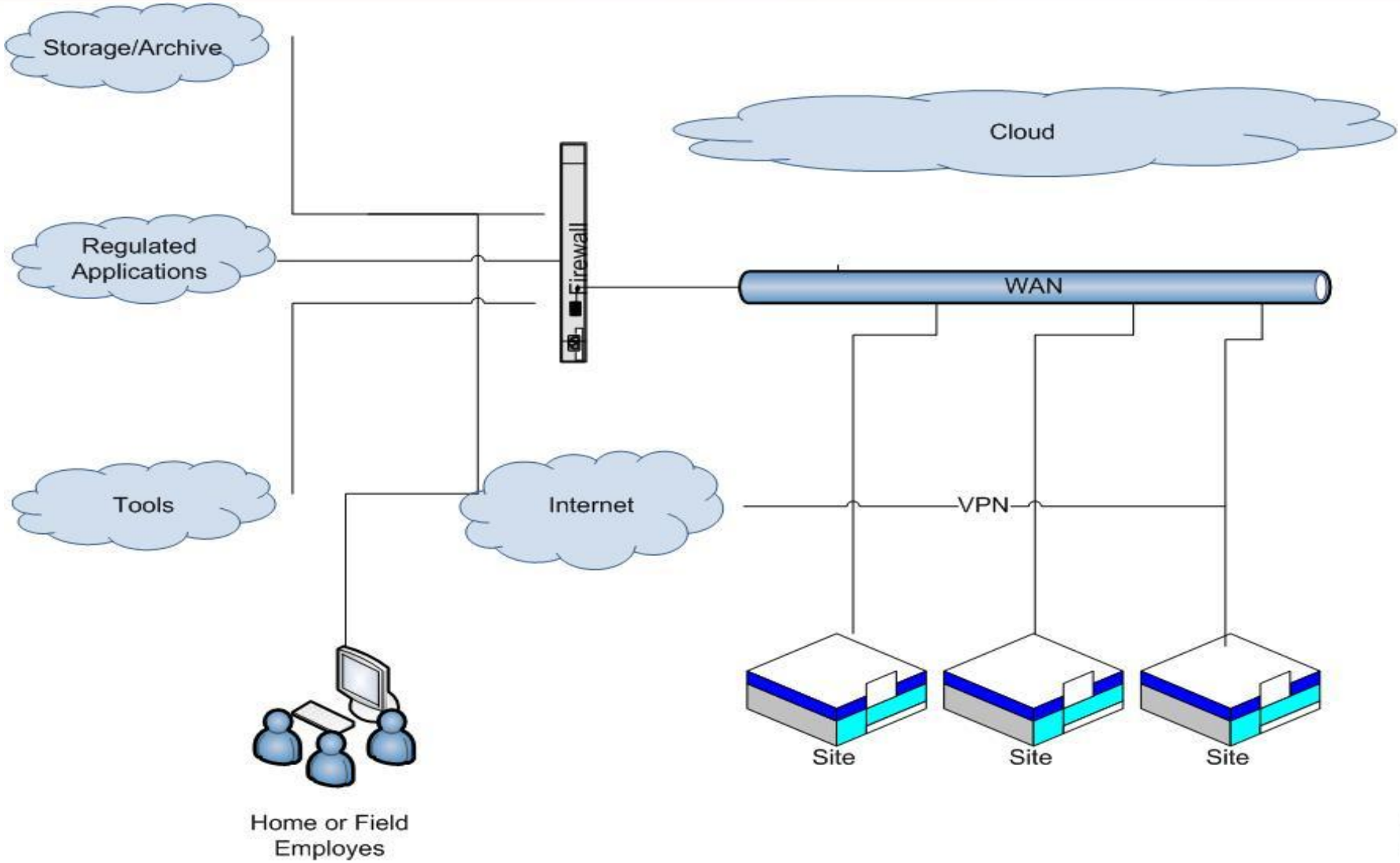
Components of Cloud Computing



Environments



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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.

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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

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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.

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Manage Risk by Designation of Systems

- 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).

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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.

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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

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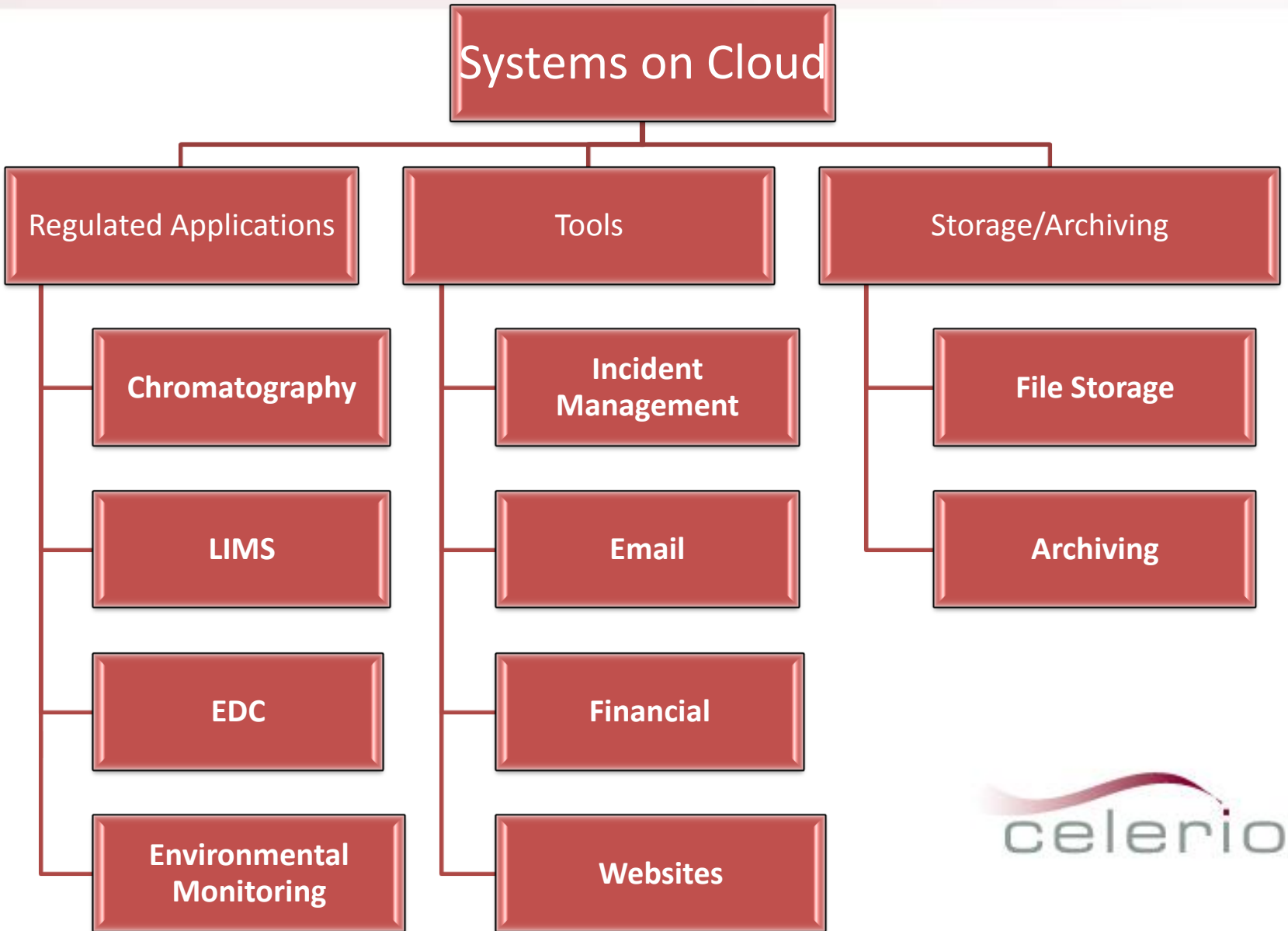
Manage Risk by Designation of Applications



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Why "Go Cloud"

- Cost
  - Provides flexible pricing options
  - Reduces IT headcount required 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

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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

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‘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

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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)

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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

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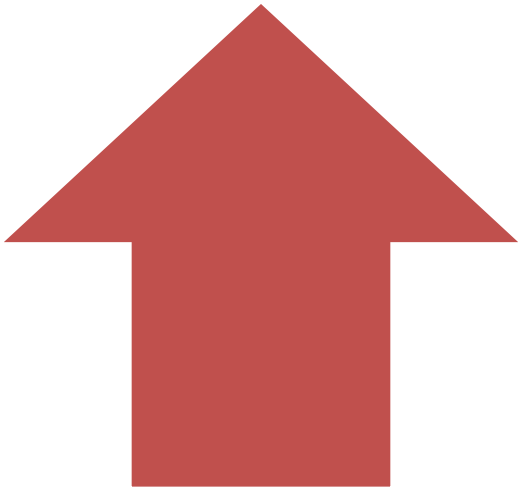
Validation – of VMs Risk Based Approach



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
- Hyperviser Performance

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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 (hyperviser installation)
  - ‘Baseline’ information included in ‘regulated application’ diagram,documentation

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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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IQ/OQ Example

1				
2	**Post-Provision Worksheet for Windows Servers**			
3		Customer:	Celerion	
5				
6	Created by	Verified by	Items/Configuration Tasks	
8				
9	Network Identity			
15	CPU/RAM/Disk			
20	VM Priority Groups			
24	Operating System			
32				
33	DNS Settings			
41	WINS Settings			
45	Registry Changes for MS Networking and NetBIOS			
50	Service Principle Names			
54	Removal of Rackspace Desktop Background Updater			
58	DC01-IAD DNS Checks/Updates			
62	DC01-IAD Active Directory Group Creation			
66	DC01-IAD Active Directory UO Membership			
67		NY	Move server to appropriate Organizational Unit	Admin\Servers\Rackspace\Virtual Machines
69	Local Group Updates			
73	End of Document			
74				
75				
76				

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

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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

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Personal Experience

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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)

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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

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Personal Experience – the ugly

- Nothing – as long as the right partners are selected

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Contact Info & Questions

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