Welcome

Cloud Computing – New Challenges in Data Integrity and Security
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Panel

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How Did We Get to The Cloud?
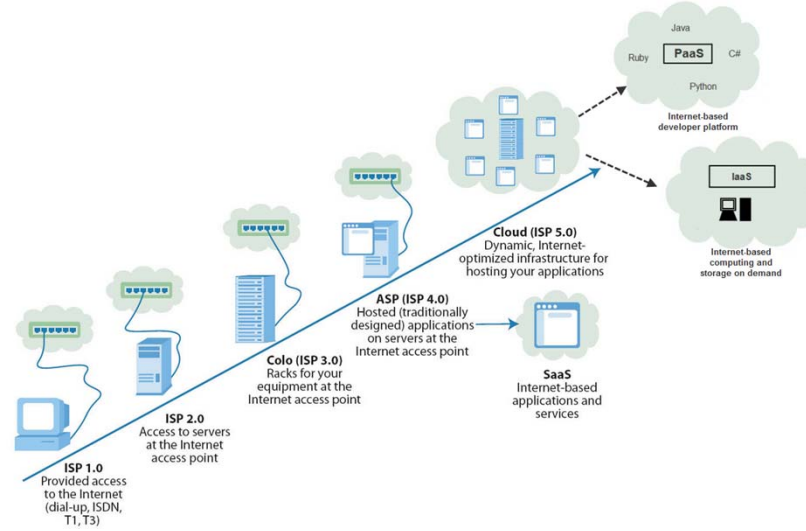
Source: Cloud Security and Privacy: An Enterprise Perspective on Risks and Compliance (Theory in Practice), Tim Mather

Why Cloud?

- Agility
- Scalability
- Redundancy
- Elasticity
- Cost effective?

Control Considerations

- Know your data
  - Data Classification
  - Risk Assessment
- Encryption
  - Transmission
  - At rest
- DevOps and DevOps tools
  - Chef
  - Puppet
  - Jenkins

Strong Procurement & Vendor Management Policies & Practices

- External – The Vendor
  - Be sure they can meet your needs (Security & Privacy)
  - Know how to get your data back
  - Establish appropriate controls (e.g. Change & Access Control) and regular oversight
  - SLAs
- Internal – Your users
  - Avoid Shadow IT
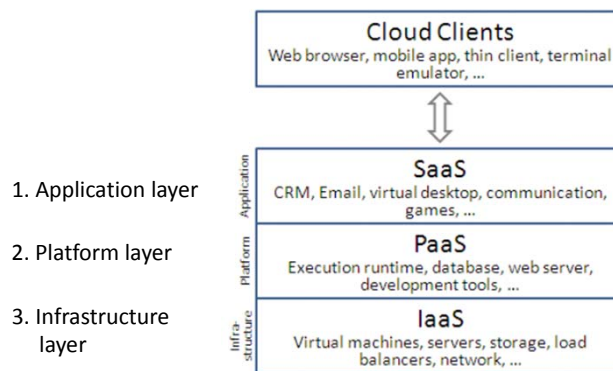 - Know the implications of Commercial Cloud Use – e.g. Google Docs

Cloud computing?

"Cloud" based computing – Interesting facts:

- The popularization of the term can be traced to 2006 when Amazon.com introduced the Elastic Compute
- Cloud computing is the result of evolution and adoption of existing technologies and paradigms.
- The goal of cloud computing is to allow users to take benefit from all of these technologies, without the need for deep knowledge about or expertise with each one of them.
- The cloud aims to cut costs, and help the users focus on their core business instead of being impeded by IT obstacles

[*Source - Wikipedia].

Cloud – technology stack

Cloud Clients
Web browser, mobile app, thin client, terminal emulator, ...

1. Application layer

Application

SaaS
CRM, Email, virtual desktop, communication, games, ...

2. Platform layer

Platform

PaaS
Execution runtime, database, web server, development tools, ...

3. Infrastructure layer

Infra-structure

IaaS
Virtual machines, servers, storage, load balancers, network, ...

[*Source - Wikipedia].

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Software as a Service

SaaS – Software as a Service

– is a software licensing and delivery model in which software is licensed on a subscription basis and is centrally hosted

– It is sometimes referred to as "on-demand software".

– SaaS is typically accessed by users using a thin client via a web browser. SaaS has become a common delivery model for many business applications

Platform as a Service

PaaS – Platform as a Service

– In the PaaS models, cloud providers deliver a computing platform, typically including operating system, programming language execution environment, database, and web server.

– Application developers can develop and run their software solutions on a cloud platform without the cost and complexity of buying and managing the underlying hardware and software layers.

– With some PaaS offers like Microsoft Azure and Google App Engine, the underlying computer and storage resources scale automatically to match application demand so that the cloud user does not have to allocate resources manually.

Infrastructure as a Service

IaaS – Infrastructure as a Service

– providers of IaaS offer computers – physical or (more often) virtual machines – and other resources. (A hypervisor, such as Xen, Oracle VirtualBox, KVM, VMware ESX/ESXi, or Hyper-V runs the virtual machines as guests.

– Pools of hypervisors within the cloud operational support-system can support large numbers of virtual machines and the ability to scale services up and down according to customers' varying requirements.)

– IaaS clouds often offer additional resources such as a virtual-machine disk image library, raw block storage, and file or object storage, firewalls, load balancers, IP addresses, virtual local area networks (VLANs), and software bundles.

[*Source - Wikipedia].

Typical Systems that are hosted

- SaaS Solutions
  - NetSuite (ERP), Salesforce.com   (CRM), ADP (Payroll / benefits)
- PaaS Solutions
  - Amazon , Google, Microsoft
- IaaS Solutions
  - Amazon – AWS and EC2, AT&T Synaptic Cloud, Rackspace

Basic Premise

- Annex 11

The application should be validated; IT infrastructure should be qualified

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Key Question

If you build a virtual environment in your own data center, FDA expects validation and qualification of the system…..

How does this expectation change by putting that system in somebody else's building?

Cloud Provider Responsibilities

- Auditing
- Data Integrity and Security
- Procedures
- Training
- Managing multiple clients
- Quality Agreements
- SLAs

Cloud Provider Certifications

- ISO 27000, 27001
- ISO 9000
- SSAE-16 & ISAE 3402
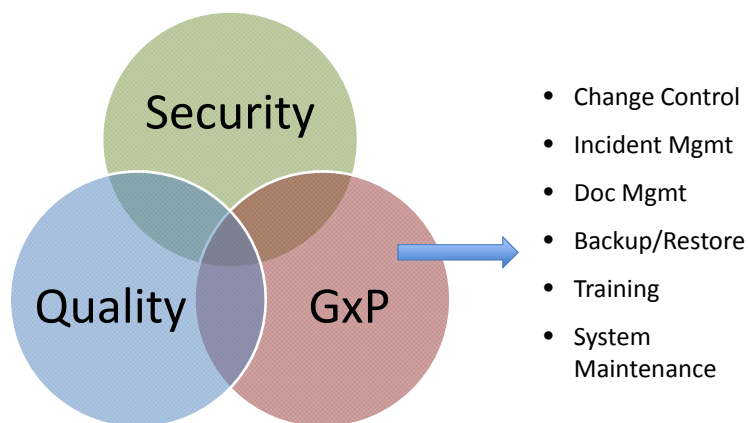- FedRamp
- PCI DSS

Malware Hosting

- In Q3 2014, U.S. percentage of global malware hosting increased from 56% to 63% (*proportional to the overall number of hosted websites*).

- Top ISPs Hosting Malware
    - GoDaddy   44% Q3 *(+42% Q2)*
    - Amazon   17% Q3 (+24% Q2)
    - Google   14% Q3 (+5% Q2)

Source: Q3 2014, Security Engineering Research Team (SERT), Quarterly Threat Intelligence Report, http://www.solutionary.com/research/threat-reports/quarterly-threat-reports/sert-threat-intelligence-q3-2014/

Overlap

Security

Quality

GxP

- Change Control
- Incident Mgmt
- Doc Mgmt
- Backup/Restore
- Training
- System Maintenance

IaaS Vendors – Not all the same

Capability/Enabler	Life Sciences Targeted	Life Sciences Aware	Life Sciences Aware (Low)
Qualification Documents	✓		
Customer Specific Change Agreement	✓		
Qualification Assistance		✓	
Permits Onsite Audit	✓	✓ (may charge a fee)	Some
Enterprise Scale		✓	✓
Service/Deployment Models	Private Cloud, IaaS, PaaS, some SaaS	IaaS, PaaS	Iaas, some PaaS
Cost Profile	$$$	$$	$

Validation – Objectives

- Achieving a state of control over the computerized system
- Data must be accurate, reliable and maintain integrity
- Validation documentation is necessary to provide evidence of the above
  - The same as any other similar GxP system

cGMP Computers Needing Validation

- Inventory control & Management
- Laboratory Information Management
- Building/Warehouse/EM Management
- Documentation (SOPs, etc.)
- Bill of Materials & Materials Weigh-out
- eMPR/eBPR
- Process Supervision and Control

- Statistical Process Control
- Deviations/Investigations Management
- Product complaints Management
- Maintenance/calibration Management
- Change Control Management
- Labeling Control
- Recalls

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Validation – Strategy

GAMP 5 Approach

- Life Cycle
- Risk-Based = QRM
- Effective Governance
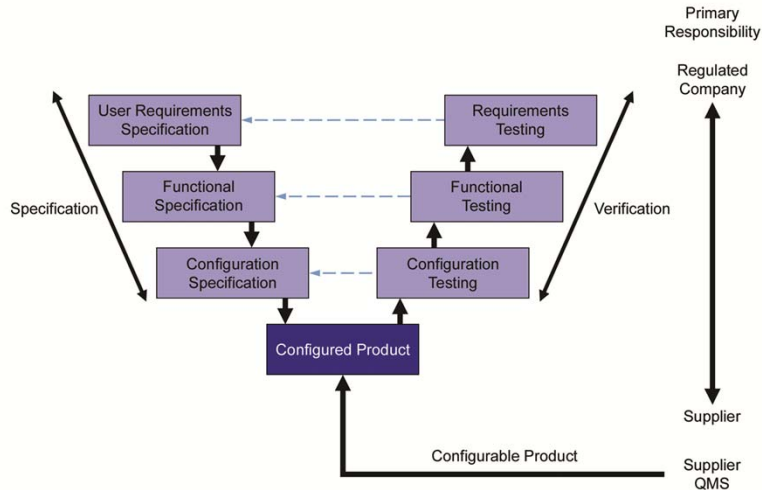- Supplier Good Practices

Qualify* & Validate:

- Architecture
- Software
- Configuration
- Functionality
- Archival/Retention

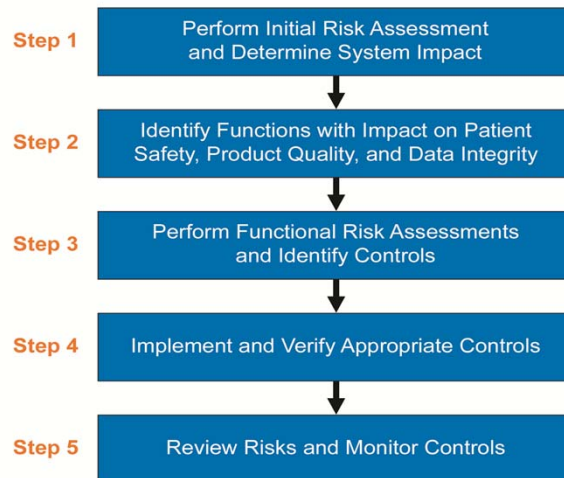**Audit / Certify any supplier qualifications*

GAMP 5 – Primary Responsibility

Source: Figure 4.3, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008. All rights reserved. www.ISPE.org.

GAMP 5 – Risk-Based Approach

Source: Figure M3.1, GAMP 5: A Risk-Based Approach to Compliant GxP Computerized Systems, © Copyright ISPE 2008.
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Validation – Realization

- A Cloud-based GxP computerized system requires the same validation documentation as any internal system:
  - Where the documentation resides may differ
  - Key aspect to validate:
    - Security and user access
    - Functionality and calculations
    - Audit Trails for Security & Data Changes
    - Back-up and Recovery

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Validation – Other Considerations

- Maintaining the state of control
  - Does the cloud have sufficient environments (e.g., development, pre-test, validation, and Production) for change control?
  - SLA &/or Quality Agreement should have a defined list of types of HW/SW changes and the notification requirements for each type of change
  - Disaster Recovery (Supplier)
  - Business Continuity (you)

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FDA Perspectives on Cloud

- FDA is already in the Cloud
  - Information Computing Technologies for the Twenty-First Century (**ICT21 Initiative**)
  - **Cloud First** policy: use cloud computing technologies by 2013 to:
    - Maximize data capacity
    - Reduce computing to a utility
    - Access simplified, rapid, on-demand resources.

Source:
http://www.fda.gov/aboutfda/reportsmanualsforms/reports/ucm274442.htm
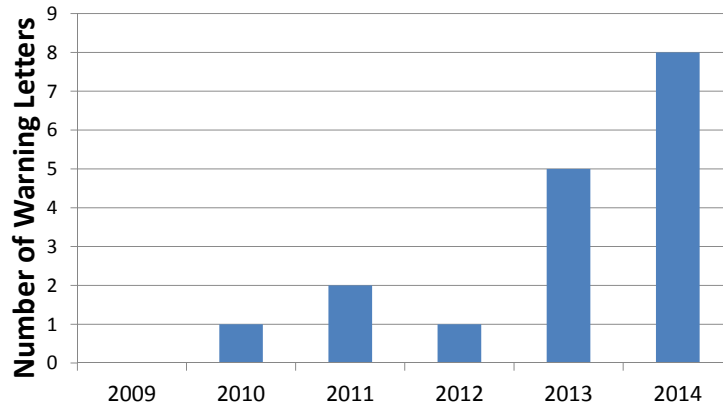
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FDA Perspectives on Data Integrity

- Old issue with a renewed focus
- Focus area for recent inspections
- Application Integrity Policy
- BioResearch Monitoring (BIMO) Program
- Preapproval Inspections
- Stand-alone computers
- What this means for cloud-based systems...

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FDA Perspectives on Data Integrity

cGMP Data Integrity Warning Letters

FDA Perspectives on Data Integrity

Various Concerns Extracted From WLs

- Modified raw data
- Omissions in data
- Missing raw data or Deleted raw data files
- Lack of security & Lack of adequate controls
- Non-documented testing
- Failure to maintain complete data