Cloud Computing and Virtualization in Pharmaceutical Manufacturing

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Agenda

Cloud Computing for Pharma Manufacturing

Virtualization for Test/Dev from Both Sides

Virtualization for Production

Buckle Up and Hang On

The Cloud

NIST Definition of Cloud

"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."

NIST Special Publication 800-145

Redneck Definition of Cloud

Don't care about the details

+

Connection to the Interwebs

+

$$

=

New 'puter somewhere on the other end that somebody else worries about
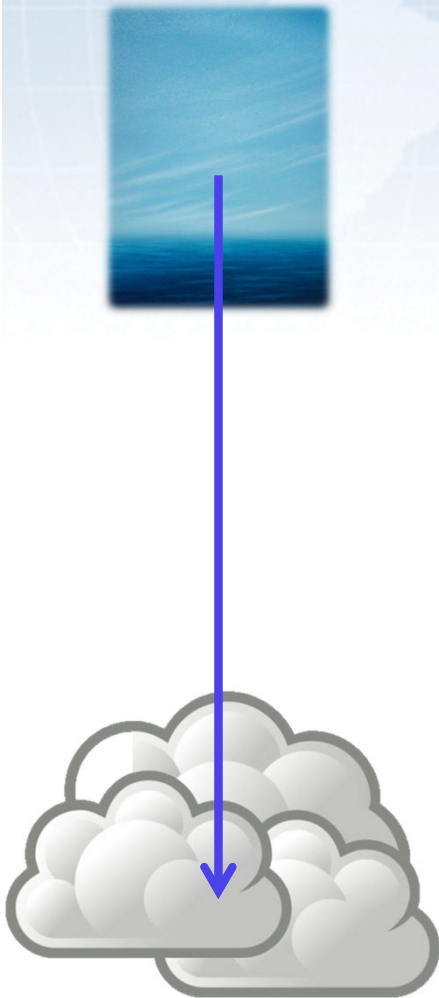
What the Cloud is NOT/What is NOT Cloud
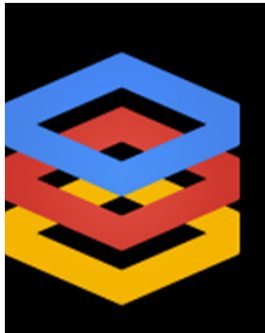
Colocation

IAAS

SAAS

Hosted Solutions
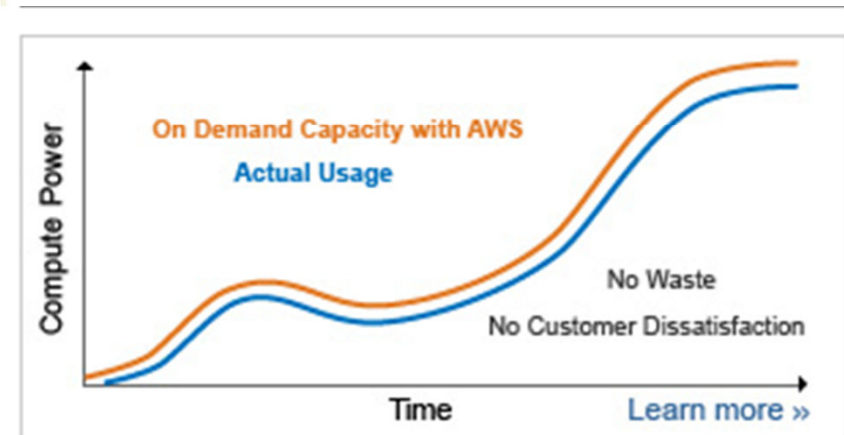
What is Cloud

Pricing and Delivery Model

Pricing

On-Demand Instances

On-Demand Instances let you pay for compute capacity by the hour with no long-term commitments. This frees you from the costs and complexities of planning, purchasing, and maintaining hardware and transforms what are commonly large fixed costs into much smaller variable costs.

The pricing below includes the cost to run private and public AMIs on the specified operating system ("Windows Usage" prices apply to Windows Server® 2003 R2, 2008, 2008 R2 and 2012). Amazon also provides you with additional instances for Amazon EC2 running Microsoft Windows with SQL Server, Amazon EC2 running SUSE Linux Enterprise Server, Amazon EC2 running Red Hat Enterprise Linux and Amazon EC2 running IBM that are priced differently.

Region: US East (N. Virginia)

	Linux/UNIX Usage	Windows Usage
Standard On-Demand Instances		
Small (Default)	$0.065 per Hour	$0.115 per Hour
Medium	$0.130 per Hour	$0.230 per Hour
Large	$0.260 per Hour	$0.460 per Hour
Extra Large	$0.520 per Hour	$0.920 per Hour

On Demand Capacity with AWS
Actual Usage
No Waste
No Customer Dissatisfaction
Compute Power
Time
Learn more »

Pharma <u>Manufacturing</u> Applications

A Few Go/No Go Checkpoints

"If I lose it for X days can I still make product and it out the door?"

"If someone else sees the data am I in big trouble, have I lost a lot of IP?"

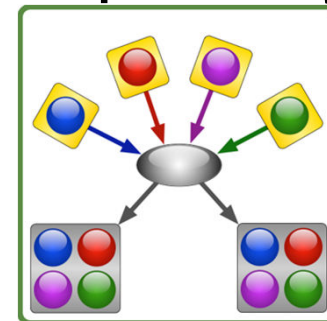**ISPE**

Potential Good Applications
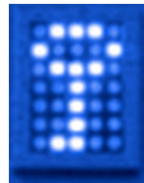
- Second Tier Historians

- Enterprise Reporting Platforms

- Centralized Configuration Repository

- Offsite Backup
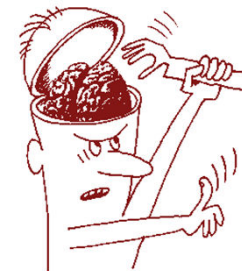
Probably Bad Ideas

- First Tier Historians

- Data and/or HMI Servers
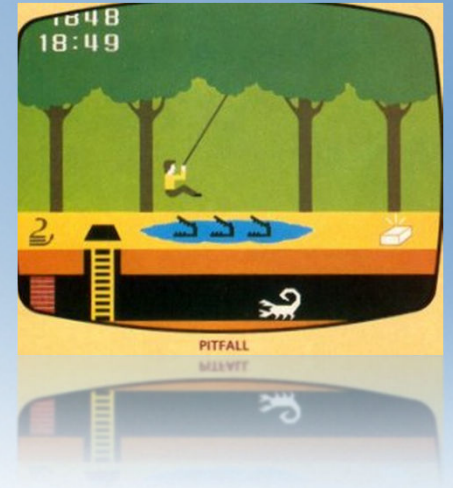
- Research Data

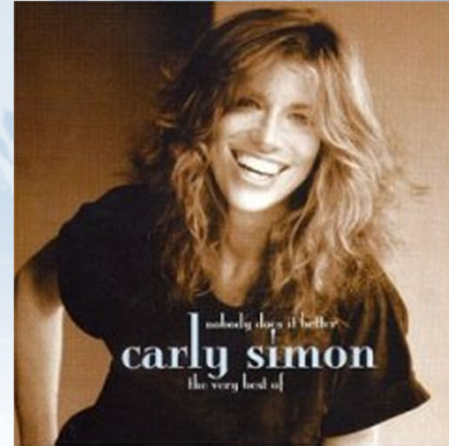- Detailed Batch Records with IP

Pitfalls

- No Connectivity = No Application

- $$ for everything you do

- Jurisdiction/Legal Issues

- Validating Upgrades

Benefits

- These folks are Pros

- Always up to date

- Disaster Here <> Disaster Everywhere

- Geographic Resilience

Virtualization for Test/Dev

- The Integrator Perspective

- The Owner Perspective

Virtualization for Test/Dev – The Integrator

- Replicate Production Environment (as close as possible)

- SOP's for Transfers To/From

- Strict Control of Environment

- No Sandbox!

- Run GMP Quality testing; leveraged to reduce production downtime during installation.

Virtualization for Test/Dev – The Owner

- Facilitates the future addition of new products into the production system

- Changes and modifications can be fully tested and validated before rolling into production

- Reduces production shutdown time due to testing and qualification of modifications

- There is no risk to current production system since Development System is independent and isolated

Virtualization for Test/Dev – The Owner

- Facilitates training of new employees by exposing them to an "offline" copy of the production system before they step into the "online" system

- Provides current technicians and operators with an informal "training" automation environment

ISPE

Virtualization for Test/Dev – The Keys

- Replicate production as closely as possible

- Make QA/Validation key team members from the beginning to get buy-in

- Good URS is key to making sure everyone understands what you're getting and what you're not