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
"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

Gmail

Hotmail

Office 365

Netflix
What is Cloud

Amazon Web Services

OpenStack

Compute | Networking | Storage
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.

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<th>Region: US East (N. Virginia)</th>
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<td>Linux/UNIX Usage</td>
</tr>
<tr>
<td>Small (Default)</td>
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<tr>
<td>Medium</td>
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<td>Large</td>
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On Demand Capacity with AWS

- Actual Usage
- No Waste
- No Customer Dissatisfaction

Learn more »
Pharma Manufacturing 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?”
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.
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