

Validation of a Cloud-Based ERP system, in practice.

**Regulatory Affairs Conference
Raleigh. 8Th September 2014**

What is the "The Cloud"

Identifying And Remediating Security Vulnerabilities In The Cloud

online education / online learning

Rosetta Stone looks to the cloud with \$8.5M acquisition of language learning site

by Ki Mae Heussner APR. 2, 2013 - 6:31 AM PDT
2 Comments

SUMMARY: *Language learning giant Rosetta Stone has acquired Seattle-based Livemocha to shift its products to the cloud.*

tweet this



Data Center

Building the private cloud: Prepare the fabric in System Center VMM

When is the Cloud not the right tactic?

As with every tool, there's a time and a purpose and the Cloud is no exception. Here are some suggestions as to when to avoid Cloud and SaaS.

The Cloud: The Gift That Keeps On Printing...

HOME > STORAGE & NETWORKING > CLOUD > THE CLOUD FOR BROADCAST: MORE CONTENT FOR CONSUMERS

The cloud for broadcast: more content for consumers

Cloud storage serves the demand for interactive content.

Aldo Cugnini | Broadcast Engineering

Apr. 1, 2013

Posted: Wednesday, 03 April 2013 4:54AM

The cloud has already saved ity



Some Definitions

The NIST Definition of Cloud computing

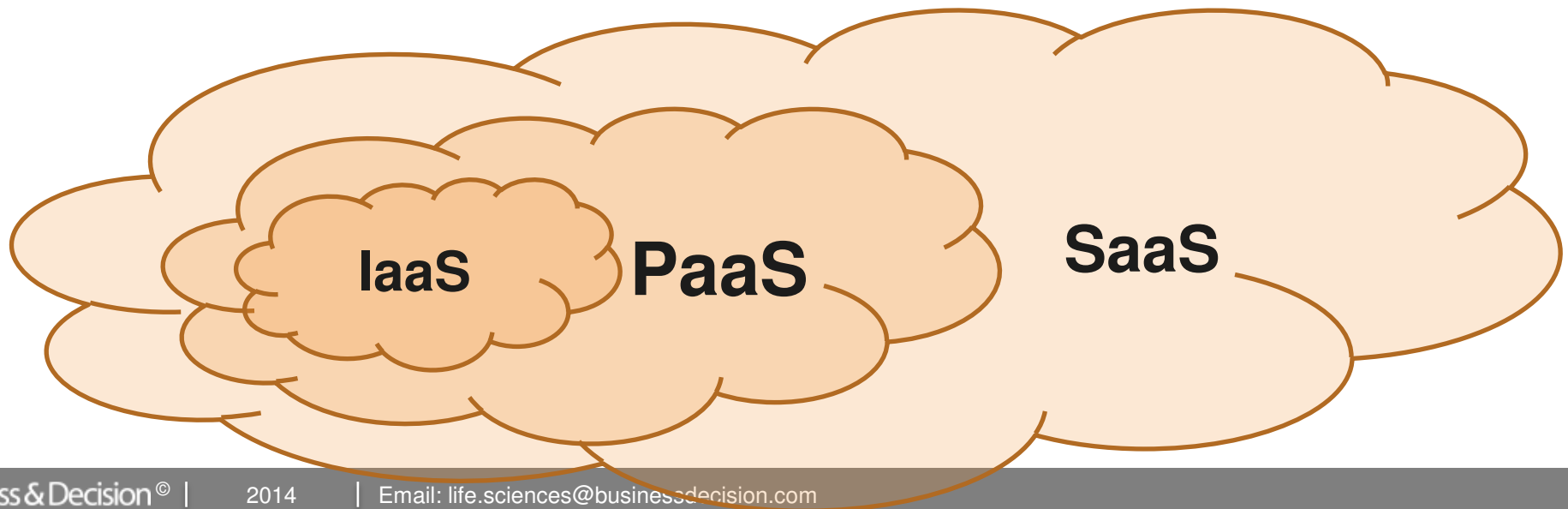
“Cloud computing is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g., networks, servers, storage, applications, and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction”.



The Main Types of Cloud Models

■ Service Models

- ▶ Cloud Infrastructure as a Service (IaaS)
 - Software and operating system still controlled by the User
- ▶ Cloud Platform as a Service (PaaS)
 - Software still controlled by the User
- ▶ Cloud Software as a Service (SaaS)
 - Software NOT controlled by the User



Infrastructure as a Service

- **Infrastructure as a Service (IaaS)**
- The capability provided to the consumer is to provision processing, storage, networks, and other fundamental computing resources where the consumer is able to deploy and run arbitrary software, which can include operating systems and applications. The consumer does not manage or control the underlying cloud infrastructure but has control over operating systems, storage, deployed applications, and possibly limited control of select networking components (e.g., host firewalls).



Platform as a Service

■ Platform as a Services (PaaS)

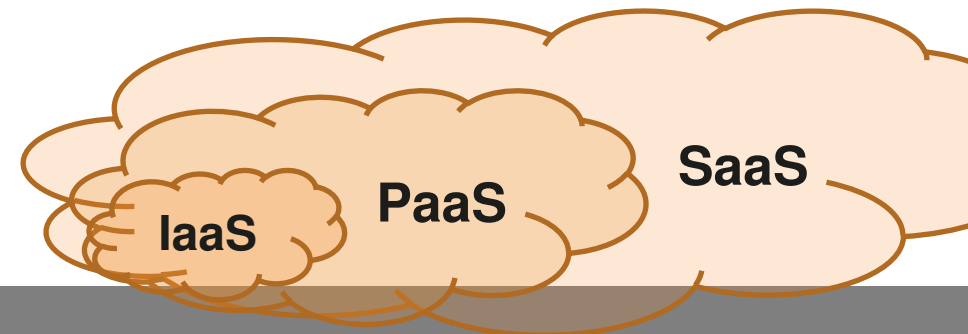
- The capability provided to the consumer is to deploy onto the cloud infrastructure consumer-created or acquired applications created using programming languages and tools supported by the provider. The consumer does not manage or control the underlying cloud infrastructure including network, servers, operating systems, or storage, but has control over the deployed applications and possibly application hosting environment configurations.



Platform as a Service

■ Software as a Service (SaaS)

- The capability provided to the consumer is to use the **provider's applications** running on a cloud infrastructure. The applications are accessible from various client devices through a thin client interface such as a web browser (e.g., web-based email). **The consumer does not manage or control the underlying cloud infrastructure including network, servers, operating systems, storage, or even individual application capabilities,** with the possible exception of limited user-specific application configuration settings.



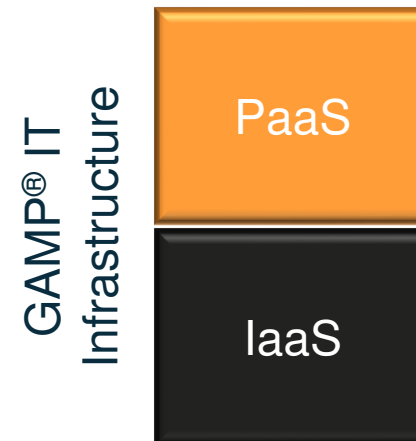
GAMP® and IaaS

■ The GAMP model of Infrastructure.

- Note that GAMP defines IT infrastructure as *including* the operating system (and associated utilities)

- ▶ This is *excluded* in the NIST model
- ▶ Care needs to be taken to distinguish between IaaS and PaaS

- The NIST model distinguishes between ‘management’ and ‘control’

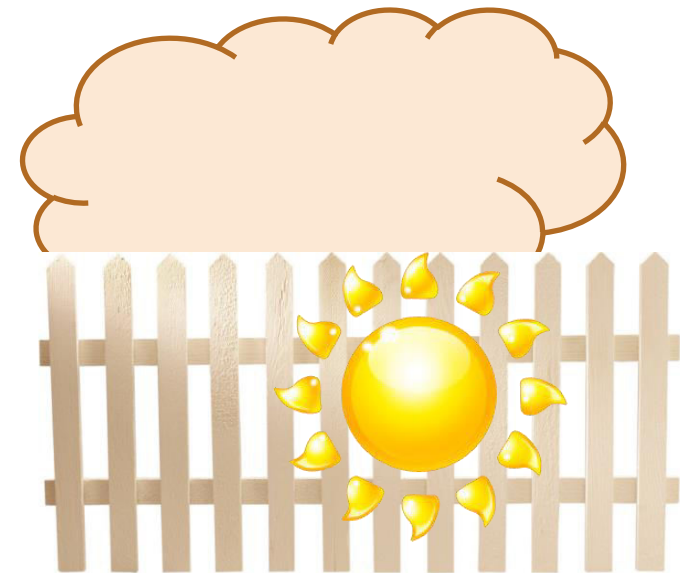


Yet more kinds of cloud

■ Deployment Models

- ▶ Private Cloud
 - On-premise OR off-premise
- ▶ Community Cloud
 - On-premise OR off-premise
- ▶ Public Cloud
- ▶ Hybrid Cloud

On-Premise?



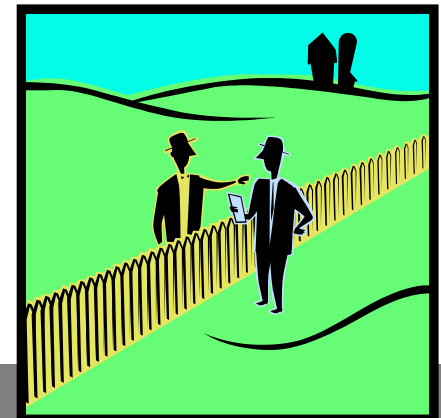
Off-Premise?

■ Private cloud

- ▶ The cloud infrastructure is operated solely for an organization. It may be managed by the organization or a third party and may exist on-premise or off-premise

■ Community Cloud

- ▶ The cloud infrastructure is shared by several organizations and supports a specific community that has shared concerns (e.g., mission, security requirements, policy, and compliance considerations). It may be managed by the organizations or a third party and may exist on-premise or off-premise



■ Public cloud

- ▶ The cloud infrastructure is made available to the general public or a large industry group and is owned by an organization selling cloud services.

■ Hybrid cloud

- ▶ The cloud infrastructure is a composition of two or more clouds (private, community, or public) that remain unique entities but are bound together by standardized or proprietary technology that enables data and application portability (e.g., cloud bursting for load-balancing between clouds).



What happened to “The Cloud”?

- In short it's a pretty poor description...

Private

Public

Community

Hybrid

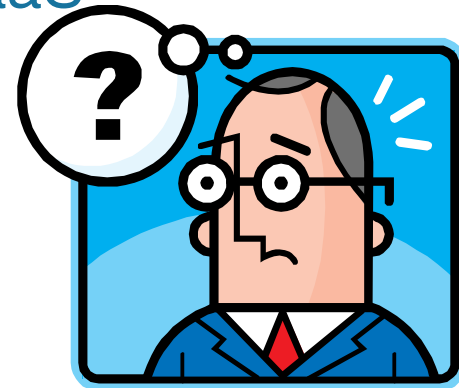
IaaS

PaaS

SaaS

Qualification of PaaS and IaaS

- ▶ Qualification is the same as any other infrastructure.
- ▶ It can be Specified, installed, built and verified
- ▶ Controlled using support and maintenance processes and procedures
- ▶ Understanding- What is provisioned, where it is provisioned Who provisions what
- ▶ Understanding who manages the Platform for PaaS
- ▶ Whose DBAs for PaaS
- ▶ Whose Quality Management System
- ▶ Formal qualification and control of the Infrastructure/Platform by whom
- ▶ Training and education of service providers staff



Validation of an SaaS ERP system



- FPE produces components for Class 2 Medical devices
- They had been using Plex as their ERP system for some years before moving on the medical device market.
- ISO 13485 Audits highlighted the fact that Plex was not validated.

Software as a Service

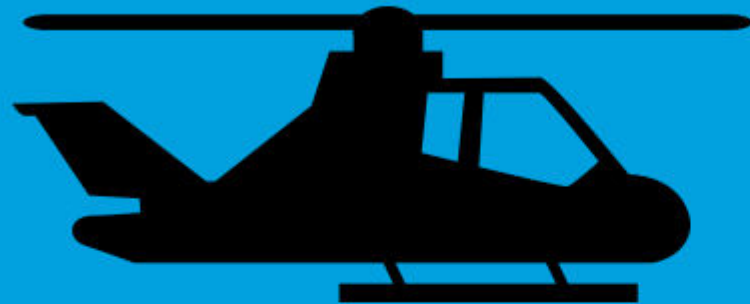


248.391.8001



- Why Plex Cloud ▾
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- Services ▾
- Customers ▾
- Company ▾
- Knowledge Center ▾
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Plex by the Numbers

+1,200
Manufacturing Operations



20
Countries

100%
Cloud

0
Upgrades Required

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News

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■ Plex Systems



- ▶ Is true Software as a Service
 - ▶ Fully functional ERP system
 - ▶ Client companies requires only a machine with a browser
- ## ■ There are no version numbers for the software
- ▶ The version is what is in use right now.
 - ▶ All tenant companies use the same base code
 - ▶ All client data is in the same database.
- ## ■ Under Part 11 it is an *Open System*
- ▶ No issue - encryption is standard



- Customization is not offered
 - ▶ Any development of the software is done by Plex Systems and may then be offered to other clients.
- Development of Plex is continuous.
- Updates to the system occur several times a day
- Tenants may or may not have the option to accept the update
 - ▶ (depending on whether it is configurable)

The Approach, FPE side - 1



- First Validation of the Plex System as used at FPE can be done the same as any other ERP system.
- As the system had been in use for some time this was a retrospective validation.
- Begin with requirements, which can be based on current practice, verify that these work, test and ensure that governance procedures are in place etc.

The Approach, FPE side - 2



- It was clear from the start that an IQ/OQ/PQ approach would not work.
 - ▶ Can IQ minor Infrastructure at FPE
 - ▶ Clients Browsers switches
 - Follow the methodology of
 - ▶ Plan
 - ▶ Specify
 - ▶ Configure
 - ▶ Verify
 - ▶ Report
- All as Per GAMP5

The Approach, FPE side - 3



- User Requirements
 - ▶ Based on current use
 - ▶ Risk assessment
- Functional Requirements
 - ▶ Not used – make little sense for the tenant company in an SaaS system
- Testing
 - ▶ As normal using the Plex test system
 - ▶ Same software as live system
 - ▶ Overwritten with live environment data overnight.



- Reporting
 - ▶ Test Report
 - ▶ Validation Report
- Maintenance of Validated state
 - ▶ Procedures are required of course
 - ▶ Change and Config management
 - Limit to what FPE can actually change.

The Approach, Plex side – 1

- Analysis of Plex internal procedures. What was found:
 - ▶ SDLC is formal, rigorous and well documented.
 - ▶ Changes are assessed for risk, impact and allocated to an appropriate level of testing.
 - ▶ Formal standards are followed for coding, development, based on various ISO standards, ITIL, COBIT and others.
 - ▶ There is a formal CAPA system
 - ▶ SLAs are comprehensive

The Approach, Plex side – 2

- There are formal documented procedures for:
 - ▶ Change and config management
 - ▶ Risk Management
 - ▶ Development
 - ▶ Helpdesk
 - ▶ Infrastructure Qualification (they don't call it that)
 - ▶ Testing
 - ▶ Support Services
 - ▶ Performance monitoring
 - ▶ Incident Management
 - ▶ CAPA
 - ▶ Periodic Review
 - ▶ Back and Restore
 - ▶ Disaster Recovery
 - ▶ Business Continuity Management
 - ▶ Security
 - ▶ User Access
 - ▶ Data Migration
 - ▶ Training

The Approach, Plex side – 3

- Plex's IT QMS is as good as most Life Sciences companies, better than some.
- Plex were aware that Life Sciences companies required validation, but were not really sure what it was.
- Were surprised to learn that they were doing most of it already.
- Some gaps were identified:
 - ▶ Regulatory Compliance Training
 - ▶ Change control system looks at business risk only, not risk to public health.
 - ▶ Technical issues with some part 11 requirements.
 - (Audit trail and multiple signature functions)



The Approach, Plex side – 4

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The model that was developed



- Plex are acting as the IT department of the life Sciences company, similar to a conventional outsourcing model.
- Therefore they need to work in the same way and under a Quality Management System Suitable for a Life Sciences Company. (They already are – almost)
- This needs to be integrated with the QMS of the Client LS Company
- Given these concepts:
 - ▶ Plex can assess the risk and impact of changes in exactly the same way that an IT department in a Life Sciences company does.

Risk assessment of changes



- There are multiple changes per day.
- If these are all rigorously assessed for risk, tested and verified then the frequency is irrelevant.
- Only minor changes in the way Plex functions at different tenants is possible.
 - ▶ Therefore the tenants may need to do regression testing on such changes that may affect these functions.
 - ▶ Therefore they need to know about such changes very close to the time at which they are deployed.

The operational model

PLEX

Plex QMS

Config Management

Change Control

Testing – All changes



Life Sciences
Company QMS

Config Management

Change Control

Testing – some
changes

Understanding of Regulations

Some surprising advantages .

Advantages over a standards ERP project (some surprising!)

- It's SaaS – low capital cost , flexible, fast, etc. etc.
- There is no temporary project team.
 - ▶ No group of (third party) integration consultants, who disband after the project is finished.
 - ▶ Software developers are permanent.
 - ▶ Issues can be referred to the people who wrote the software
 - ▶ No customizations (can be paid for)
 - ▶ Service and response levels are set in a SLA.

Tackling the gaps – in progress

- Regulatory Compliance training of Plex Software development team.
 - ▶ Completed earlier this year.
 - ▶ Developers to CEO level
- Change and configuration management procedures
 - ▶ In change process now, to incorporate patient risk
- Part 11 issues
 - ▶ Audit trail not available on all transactions – being fixed
 - ▶ Multiple signatures on one session – being fixed.
- Completion of FPE pilot project planned for Nov 2014
- Will then work with other LS customers.