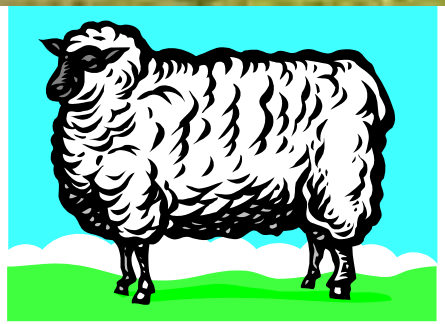
Business & Decision

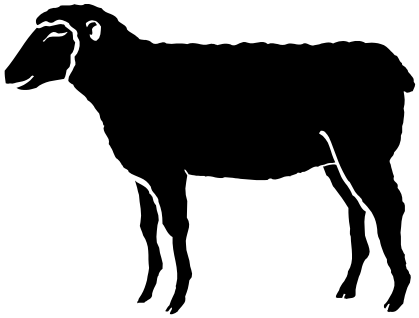
Why are Life Sciences companies scared of “The Cloud”.

Regulatory Affairs Conference
Raleigh. 8Th September 2014.

What have sheep and trains got to do with it?







Life Sciences is A Scientific industry

But that doesn't mean that it has to be impractically purist.



The slow uptake of Cloud system by Life Sciences companies seems more to be about issues that are theoretical rather than practical.

So what is everyone so afraid of?



Are they scared?



Security Professionals Identify IT Risks Associated with Cloud Computing

ESG research points to lack of control, privacy, and lack of security visibility.

CSC

LIFE SCIENCES:

Let's just put everything in the cloud, doesn't (always) work

Cloud computing is the future but not if security problems persist

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. Read more

The Risks Involved in Cloud Computing

MARCH 19, 2013

The 5 cloud risks you have to stop ignoring

Guidance



- GAMP5 is no help
  - Some of the GPGs have a little information particularly the Testing GPG.
- ICH – nothing
- FDA guidance – nothing and no rules that apply to cloud computing.
- ITIL, COBIT, PIC/S etc. not much

There is very little “official” guidance

Quotes from LS companies.

“Cloud is by definition, difficult to pin down, so I don’t feel we can use it.”

“It’s impossible to Validate a cloud system .”



“How can I have confidence in something that is so hard to control?

“I’m not handing my ability to maintain my systems in a state of compliance over to a third party.”

“How do I qualify Infrastructure that I can’t even touch?

“Where is this damn cloud anyway?.”

I don’t use the cloud at all...

According to a Citrix Survey 95% of people that claim they are not using cloud computing are actually doing so. With such things as

- Online Banking
- Social Networking
- Storing personal photos
- Almost all online mail is now cloud-based
  - Office 365
  - Gmail
  - Yahoo Mail
- Remember Outlook Express….?



Are we in denial?



"We're not really using it for anything that would be regulated."



"Office doesn't affect product Quality."



"We're only using it to move things from one place to another."



"It's just the helpdesk. Nothing to do with product. ."

What are the benefits?

- Low or Zero capital cost
- High availability
- Additional capacity can be added rapidly
- Automatic Load balancing
- You get a lot for your money

So What's the problem?



Some myths and strange worries about the cloud 1

- It's vague and undefined
- The NIST provided good definitions several years ago of
  - Infrastructure as a service
  - Platform as a Service
  - Software as a Service
  - Private, public, hybrid cloud



- We'll be putting our systems in the hands of people who know nothing of the Life Sciences Industry
  - True if you choose a service provider who knows nothing of the Life Sciences Industry
  - There are a lot of good ones available.

Some myths and strange worries about the cloud

- Only a handful of Major players can build the massive infrastructure needed. We'll be at the mercy of Google, Microsoft or Amazon.
- How much infrastructure do you need?
- There are a large number of small suppliers that can help out.
- It was never designed for the Life Sciences Industry
- True. Neither was
  - SAP, Oracle E-Business Suite, Microsoft AX ….



Some myths and strange worries about the cloud 2

- Only a handful of Major players can build the massive infrastructure needed. We'll be at the Mercy of Google, Microsoft or Amazon.
- How much infrastructure do you need?
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The most valid questions

The main issues

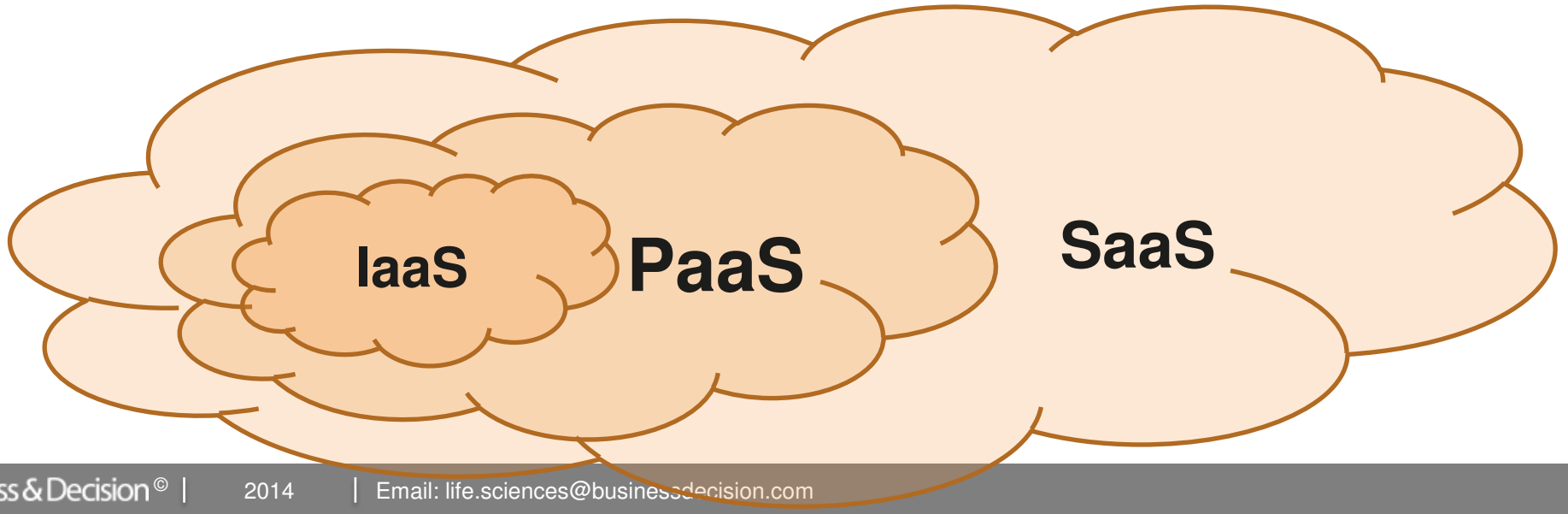
How can we validate and qualify a system when we don't even know where the server is?

How can we deal with frequent changes to the software we might not even find out about?



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



How do you Validate them?

- **Maybe you don't**
- **IaaS and PaaS are infrastructure models**
  - SaaS later.
  - You Qualify infrastructure in the same was as you've always done
  - Qualification of virtual servers has been done for decades
  - Qualification of IaaS and PaaS is only one further level of abstraction further on.
- **Challenges**
  - Lack of guidance and standards
  - Your QMS may not cover IaaS and PaaS
    - Then re-write your QMS!
  - New technology – no change there.

Example – Private cloud provided by an outsourced vendor.

Assume PaaS, you still need to have:

- Electronic Recordkeeping Compliance
- SOPs
- Validation of Applications
- Infrastructure Qualification
- Security
- Training and Training records
- Backup and restore
- Problem reporting
- Business continuity
- Disaster recovery
- Record retention
- Archival
- Configuration Management
- Change Management
  - Risk and impact assessment
  - Back out plans
  - Justification etc.
- Risk Assessment and Management
- Service Level agreements
- Etc.

- What is different with a Cloud based system?
  - Not a lot!

Software as a Service

What is Computerized System Validation?

- **There are different definitions of computerized systems validation and they are interpreted differently by different organizations**
  - Only your organization can definitively state whether it's possible to validate SaaS applications in accordance with your own Policies and Procedures
- **Generally, validation**
  - Is a process of verifying requirements, specifications, design and functionality
    - The latter usually by testing
  - Relies on the qualification of the underlying IT infrastructure

SaaS requires a different approach

The traditional methodology depends on a "frozen" system, and its functions.

It's necessary to move away from the idea that this is a fixed entity like a packaging machine that can be validated in the same way. It a *service*, not an entity.

Similar changes in thinking have occurred before – e.g. GAMP4 to GAMP 5. From IQ/OQ/PQ to a more flexible approach.

Possible time to start thinking things through from the start again . Scary and hard work!

What are we actually trying to achieve?

Regulatory authorities are usually looking for very simple things:

- **That the product does not harm the patient**
- **That the product actually works**
- **That you make it to the correct standard consistently**
- **That you identify it properly.**

- **That you can demonstrate that your systems are under control**

Can this be achieved with software as a service?

Some Life Sciences companies think not because:

- Their QMS can't handle it
  - Then Critically examine the QMS
- There is no history of inspections, warning letters, etc. to which to refer
  - Nor was there for the first ERP systems but it didn't stop companies using them.
- There is very little guidance around
  - No but the regulations are available and that is what you need to satisfy.
  - Decide for yourself what is good practice

Can this be achieved with software as a service?

- The IT people work for a different company?
  - Have a service level agreement that says that they work to your QMS.
  - They don't have the training
  - Give them it.
- Generalist cloud providers don't have the training, and knowledge of Life Sciences that we expect in our industry
  - Look at a specialist company, then.

All these issues can be tackled.

To conclude:

- Life Sciences companies need to stop fooling telling them selves that their industry is unique and nobody works to the same quality standards.
- Use of cloud services is an industry norm. LS companies should not be missing out on the benefits because of outdated notions of how validation should be done.
  - It needs to be thought through according to the real requirements, and not just be referring to existing SOPs.
  - We need to get away from the idea of validating a fixed thing and embrace the idea of having control of a service.
- Life Sciences companies should stop being cowardly and use every means of improving their services, including the “The cloud” It will be uncomfortable but it will be worth it.