What are the issues from a regulated point of view in relation to use Cloud solutions?

Pharmaceutical Users Software Exchange
Copenhagen, Denmark, June 11th 2014

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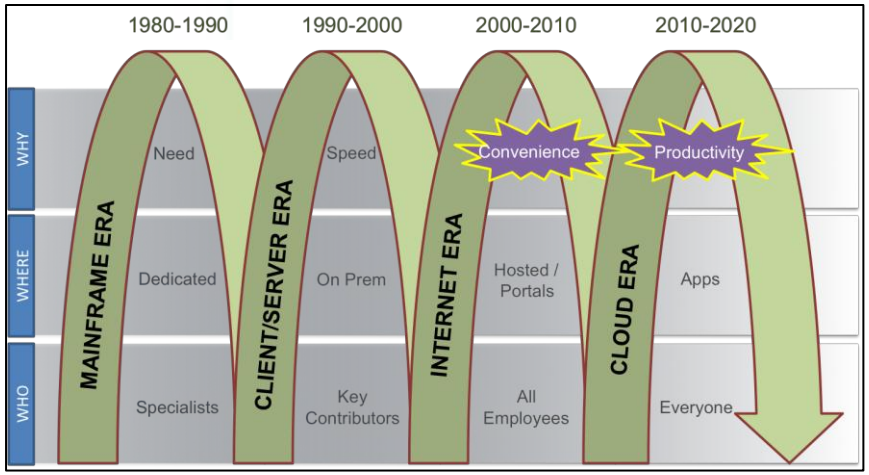
NNIT

Agenda

- Status on Phuse group
- Issues from a regulated point of view in relation to use Cloud solutions.



Barriers

- NOT technology
- Mindset, terminology, understanding
- Diversified controls – client, supplier, sub-suppliers
- Absence of standards
- SIMT apps
- QMS fitness for purpose

Our Draft Framework

- Intro
- Background
- Definitions
- Scope
- Regulatory Interpretation
- Cloud Service Provider - procurement
- Appendices
    - Quality Responsibility Matrix
        - Buildings and Facilities
        - Equipment and physical infrastructure
        - Software - physical infrastructure
        - Software – virtualization services
        - Equipment – virtual infrastructure
        - Software – application platform
        - Software – GxP apps
        - Organization and personnel
        - Privacy and Security
        - Quality Systems
        - Record Keeping
        - Validation and Qualification
    - Quality Amendment Considerations
    - System Security Plan
    - FAQ
- Acknowledgements
- References

The regulatory perspective

- FDA has proposed guidance entitled "GXP Consideration for Outsourced IT (**Cloud Computing**) Systems in Medical Product Manufacturing and Clinical Study Environments".

- The working group has gived input to this guidance.
  - Krishna Ghosh, CDER/OC/OMPQ/DGMPA
  - Crystal Allard, CDER/CSC

- Debate with EMA also in progress via working group

The regulatory expectations

- FDA will exercise enforcement discretion in regard to certain part 11 requirements.
- FDA will continue to enforce all predicate rule requirements, including requirements for record and recordkeeping.
- Cloud computing and 21 CFR part 11 controls, including requirements for validation

  - Accurate and complete copies of records
  - Protection of records
  - Limiting system access
  - Operational system check
  - Authority checks
  - Device checks
  - Policy for accountability
  - System documentation
  - Integrity of electronic records
  - Electronic signature controls
  - Password controls
  - Training

The regulatory expectations

- Challenges to data integrity
  - Sponsors loss of control
    - Data, applications, resources are located with cloud providers
    - User identity management is handled by the provider
    - User access control rules, security policies and enforcement are managed by the cloud provider
  - Unclear roles and responsibilities
    - Cloud providers may have limited FDA regulatory knowledge. It is expected they must comply with technical and regulatory requirements.
    - Require careful risk assessment and mitigations.
    - The regulated company is ultimately responsible for data security and integrity and meet the regulatory requirements
- Possible Mitigations
  - Robust Quality/Service level agreements to address all the challenges above.

In practice

- EMA and FDA requirements for IT systems
- Highly regulated applications
- Highly regulated data
- Typical implementation cost +20-25% for GxP vs Enterprise
  - Impacts design and implementation time equally
- Internal audit every 1-2 years
- External audits by FDA: High (perceived) business risk: Non-compliance can eventually lead to closing down of businesses
- High requirements on process and quality management (QM system in place)

Cloud – Quality, Security and Compliance

Life Sciences

- EMA/FDA Requirements
- GxP Qualified Platform
- Quality & Validation Resources

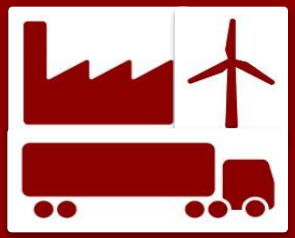
Public

- Act on Processing of Personal Data
- RS3402(*)

Finance

- Financial Business Act
- RS3402(*)

Enterprise



- Quality Management System
- ISO 9001
- ISO 27001(*)
- ITIL
- Tier 3+ Data Center
- Audits
- Partner Certifications
- Data Location
- Customization
- Integration
- Sourcing
- Customer Intimacy

(*) In Progress