Compliant Computer System Validation

in an "as-a-Service" World

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Royal Sonesta
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- 10+ years experience in biotech Quality, Validation, and IT
- Consulting, full-time experience at Genzyme, Shire
- Currently at bluebird bio, a gene therapy company based in Cambridge, MA, with ~1,200 employees and growing, preparing for commercial launch of our gene therapy platform in 2020.
- bluebird is operating in >95% hosted/cloud/SaaS systems

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Agenda

What will we cover today?

- Context
- How are things changing in CSV?
- How are things changing in technology?
- Life Cycle Approach – what's needed for SaaS systems?
- Concept, Project, Operation, Retirement
- Organizational Needs
- Whose support do you need to operate in the cloud?

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Context

Previous/Recent Guidance

- New FDA guidance in 2020?
- FDA's upcoming Guidance on Computer Software **Assurance** for Manufacturing, Operations, and Quality System Software
- ICH Q7 (10Nov2000)

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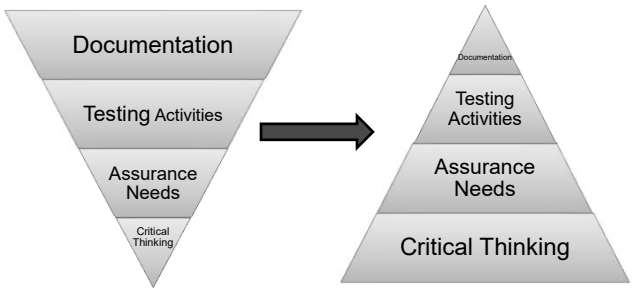
Context

Previous/Recent Guidance

- Regulations haven't changed, but guidance needs to change with technologies
- Move from CSV -> CSA in industry aligns with what is needed for cloud technology



Adapted from: "Computer System Assurance for Manufacturing, Operations, and Quality System Software" F. Vicenty, D. Matlis (source)

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Context

What isn't changing?

We still need to:

- Demonstrate that we're meeting regulations
  - Evidence that the system is meeting intended use
  - Documented controls
- Manage risk
  - Understanding impact to product/patient, understanding high-risk features

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Context

What are we trying to achieve?

- What are we trying to achieve through CSV?
- Data Integrity
- Risk Management
- Adherence to regulations
- Security
- Knowledge / awareness
- Confidence in our systems, and consequently confidence in running our businesses through automated electronic systems
- And yes… some proof/evidence… documentation

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SaaS Systems

Also IaaS, PaaS…

- What are talking about?
- SaaS – Software as a Service (Veeva)
- IaaS – Infrastructure as a Service (Amazon Web Services, AWS)
- PaaS – Platform as a Service (Salesforce Health Cloud)
- Most applications that we're working with are SaaS sitting on their own contracted IaaS

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SaaS Systems

Roles and Responsibilities

- Traditional IT responsibilities change moving to cloud

On - Premises	IaaS	PaaS	SaaS
Users	Users	Users	Users
Data	Data	Data	Data
App Administration	App Administration	App Administration	App Administration
Application	Application	Application	Application
Operating System	Operating System	Operating System	Operating System
Virtualization	Virtualization	Virtualization	Virtualization
Hardware	Hardware	Hardware	Hardware
Network	Network	Network	Network

Source: "SaaS applications: A new division of responsibilities between vendor and IT" Spanning

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ISPE GAMP Guidance

Good Practice Guide: IT Infrastructure Control and Compliance

18 Appendix 11 – Traditional versus XaaS Model Comparison

Appendix 11

In the following Sections characteristics of the three XaaS types are listed. For a definition of the three types see the definition provided by NIST (NIST Special Publication 800-145: The NIST Definition of Cloud Computing [12]).

18.1 Infrastructure as a Service

Infrastructure as a Service (IaaS)	How is it different?	Positives	Risks	Mitigation Strategies
IT Infrastructure Elements				
Platforms	Physical access to servers no longer possible	• Reduces redundancy – buy only the space you need • The user's peak load capacity increases and efficiency of the user's in-house systems (which are usually underutilized), is improved	• No access to physical hardware • Potential for down time out with control of Platform Owner • Compatibility of IaaS and internal legacy infrastructure	• Audit datacenter, enforce quality practices • SLA • System/process audit
Processes	Change and configuration management under third party control	Requirement for hardware Change Control (CC) outsourced	Limited visibility to hardware changes	• Audit datacenter, enforce quality practices • SLA • System/process audit
Personnel	Hardware personnel under third party	• Reduced labor cost • Costs and resources are shared by IaaS users and the infrastructure is centralized by the provider	No direct supervisory control of key personnel	• SLA • Require up to date training records • Clear definition of responsibilities

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ISPE GAMP Guidance

Good Practice Guide: IT Infrastructure Control and Compliance

- Good practice guide discusses XaaS Infrastructure in-depth
- Appendix 11, “Traditional versus XaaS Mode Comparison” discusses:
- Differences between traditional/on-premise
- Positives
- Risks
- Mitigation Strategies
- Many mitigation strategies are procedural and rely on strong SLA with your vendor

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Life Cycle Approach

What are we worried about in the cloud?

- Regular patching/releases
- Previously, upgrades would happen on user-controlled basis, now patching can happen even daily
- Validation
- Does your SaaS vendor understand your life science needs?
- Ownership of responsibilities
- Traditional concepts change
- Infrastructure Qualification
- Backup and restore
- How do you truly test this in the cloud?
- Data storage
- Where you operate and where you store your data matters!

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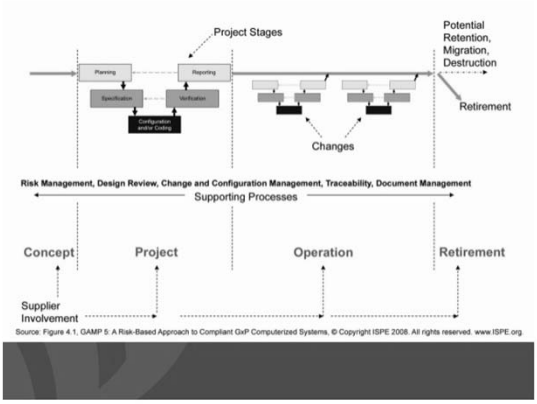
Life Cycle Approach

What are we worried about in the cloud?

- This model still applies, but faster!



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Life Cycle Approach

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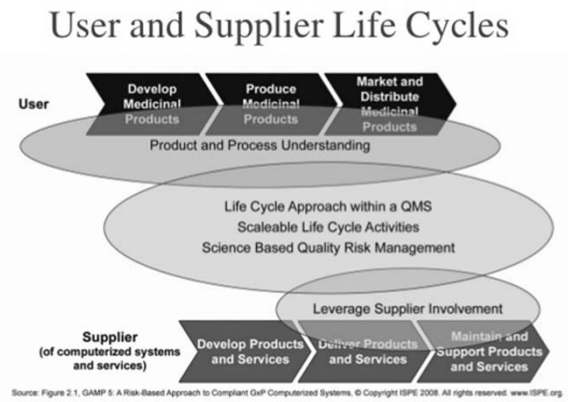

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Life Cycle
Concept

- Intended Use
- What will the system be used for?
- Critical thinking!
- Regulatory Applicability
- Based on intended use, which regulations will apply to the system you'll be working on? Who should be involved in decision-making early in the project?
  - **GxP? 21 CFR Part 11, 210, 211, Annex 11**
  - **Financial? SOX**
  - **HIPAA, PHI, GDPR, etc.**

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Life Cycle
Concept

- Procurement
- Work with finance to implement IT purchasing controls
- Vendor Assessment / Audit
- Working with your quality team, assess your vendor's software development practices, ITSM, and QMS
- Assessment depends on your organization – assessments, questionnaires, interviews, audits
- Partner with your quality team – initial assessment is only the beginning of the relationship between your two companies

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Life Cycle
Project

- Requirements Definition
- Important to understand your requirements in the context of the system
- Functional requirements and configuration specifications start to look very similar – define a tool that's useful to your org/team
- Informal Testing
- For highly configurable SaaS systems, informal testing becomes more important than formal when it comes to ensuring your users get what they want
  - **Highly configurable workflows should be tested**
- Risk Assessment
- Focus on process risks, but also learn by using the system
- Use RA to inform your Change Management process

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Life Cycle
Operation

- Change Management
- Determine ahead of time how your will generally accommodate:
- Configuration Changes
  - **Scheduled upgrades**
  - **Regular bug fixes**
  - **Integrations**
- Periodic Review
- ITSM – Access management, Incident, Break/fix
- Data Management
- Define "what's ok?" for your application
- By building a framework for validation and system life cycle at your organization, application owners/administrators can maintain compliance efficiently

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Life Cycle

Retirement

- Data Migration
- Track where you're moving your data and what is the "source of truth"
- Retirement
- Industry is constantly shifting – what do you do when your SaaS provider is purchased?
- Considerations when moving to a new application
  - **Data security**
  - **APIs**
  - **Compatibility**

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Organizational Needs

What do you need from your org?

- Foundation
- Standardizing Language – make sure everyone is on the same page!
- Understanding risk in the cloud – training and education
- Trust between IT and Quality
- Leadership Buy-In
- Scaling work with company over time
- Risk-based approach
- Cross-functional operations
- Quality Compliance/Operations
  - **Vendor Assessments, Vendor Audits, Quality Agreements**
- Buy-in on key concepts / language
  - **Get everyone on the same page up front, save time, money, effort and improve Quality down the line!**

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Questions?

Please use the microphone indicated so our recording includes audio of your question

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