Computer System Validation Overview
Topics

- What is validation and why do we do it?
- What does the validation process look like?
- What do I have to do?
- Helpful references and training info
What is validation?

- Computer systems installed in the corporation are validated to assure that they are of high quality, meet business needs, and are designed, implemented and managed in compliance with appropriate regulatory requirements to perform in a manner consistent with their intended functions.

The intent of validation is to ensure that regulated systems meet the criteria listed below.

- Systems are developed according to quality software engineering principles.
- Systems meet the business needs of their users and
- Continue to operate correctly and reliably throughout their life cycle.
What is validation?

- Validation is mostly just good software engineering practice in a formal setting
  - Making sure the system is built right
  - Making sure the right system is built
  - Managing change
What is validation?

- Validation is a formal (i.e., documented) process:
  - plan
  - execute
  - summarize

- Documentation provides evidence of execution & management involvement
Why do we do it?

- Because we have to
  - Regulatory requirements, both US and international
- Because it makes good business sense
  - Quality is built in to the system
  - The system does what it needs to do
  - Less effort needed for system maintenance
  - Reduction in business & regulatory risk
  - Cost savings
Why do we do it?

Phase during which a defect is discovered

Software Engineering Economics
B.W. Boehm, 1981
What does the validation process look like?

**Life Cycle**

An approach to computer system development that begins with identification of the user’s requirements, continues through design, coding, integration, testing, qualification, control, and maintenance, and ends only when production use of the system is discontinued.
“Custom” System Life Cycle Model

*Initiation*  "whether"

- Project Approved

*Analysis*  "what"

- Requirements Approved

*Design*  "how"

- Design Approved

*Implementation*  "do it"

- System Accepted (UAT Approved)

*Deployment*  "install it"

- System Deployed

*Operations*  "support it"

- System Used in Production

**DEFINE/APPROVE:**
- Drivers
- Goals
- Risks
- Assumptions
- Customers
- Measures of Success
- Project Plan

**DESIGN:**
- Functionality
- Interfaces
- System Architecture
- Screens & Reports
- Test Strategy
- IQ/OQ Strategy

**IMPLEMENT:**
- Build Process
- Infrastructure
- Software Coding
- Unit/Integration Test
- System Test
- User Acceptance Test
- Deployment Plan
- Training Plan
- SOPs

**OPERATE:**
- Maintain Application
- Maintain Infrastructure
- Ongoing Training
- Retire System

**DEPLOY:**
- Train Users & Support
- Finalize SOPs
- Deploy to Production
- Hand off to Support
- Close Out Project

**ANALYZE:**
- Existing and New Process
- Integration Points
- Infrastructure
“Custom” System Life Cycle Model

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**DEFINE/APPROVE:**
- Drivers
- Goals
- Risks
- Assumptions
- Customers
- Measures of Success
- Project Plan/Charter

**QA Role**
- Assign IQA Team Member(s)
- Establish Project Document Management Process
- Begin Project Team CV / Training Records Capture

**Validation Deliverables**
- Approved Project Plan/Charter
“Custom” System Life Cycle Model

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**ANALYZE:**
- Existing and New Process
- Integration Points
- Infrastructure

**QA Role**
- Review Requirements Specification for testability, P11 coverage etc.
- Begin Traceability Matrix
- Author Validation Plan

**Validation Deliverables**
- Approved Requirements Specification
- Draft Traceability Matrix
- Approved Validation Plan

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**Synchronisys**
Synchronizing Systems with Business
“Custom” System Life Cycle Model

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DESIGN:
- Functionality
- Interfaces
- System Architecture
- Screens & Reports
- Test Strategy
- IQ/OQ Strategy

QA Role
- Author Test Plans
- Author Test Scripts/checklists (w/developers & business)
- Update Trace Matrix for System Test & UAT
- Write IQ/OQ Plan

Validation Deliverables
- Approved Design
- Design review documentation
- Approved Test Plans
- Finalized Test Scripts/Checklists
- Trace Matrix
- Approved IQ/OQ Plan
“Custom” System Life Cycle Model

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- Requirements Approved

**Design**
- "how"
- Design Approved
- System Approved (UAT Approved)

**Implementation**
- "do it"
- System Accepted
- System Deployed
- System Used in Production

**Deployment**
- "install it"
- Validation Deliverables
- **QA Role**
  - Review Unit/Integration Test evidence
  - Review IQ/OQ evidence
  - Execute System Test
  - Author System Test Summary Report
  - Coordinate UAT execution
  - Manage TIRs to resolution
  - Author UAT Summary Report
  - Review Deployment & Training Plans, SOPs

**Operations**
- "support it"

**IMPLEMENT:**
- Build Process
- Infrastructure
- Software Coding
- Unit/Integration Test
- System Test
- User Acceptance Test
- Deployment Plan
- Training Plan
- SOPs

**Validation Deliverables**
- Code review documentation
- Unit/Integration Test evidence & Summary
- System Test evidence & Summary
- UAT evidence & Summary
- Completed IQ/OQs for system test & UAT
- Approved Deployment & Training Plans
“Custom” System Life Cycle Model

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QA Role
- Review production IQ/OQ evidence
- Author IQ/OQ Summary
- Author Validation Summary
- Complete CV/Training Record Capture
- Package Formal CSV Documents and Archive

DEPLOY:
- Train Users & Support
- Finalize SOPs
- Deploy to Production
- Hand off to Support
- Close Out Project

Validation Deliverables
- Production IQ/OQ evidence
- IQ/OQ Summary
- System SOPs / Work Instructions
- CVs/Training Records
- Production Deployment Memo
- Validation Summary Report
“Custom” System Life Cycle Model

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IQA Role
- Ensure compliance with Change Management SOP
- Review change documentation
- Support validation work on maintenance releases

Validation Deliverables
- Documentation supporting system changes

Operations:
- Change Management
- Periodic Review
- Ongoing Training
- System Use in accordance with SOPs

Synchronising Systems with Business
Roles & Responsibilities

- **System Owner/Business Management**
  - Overall responsibility for system validation
  - Review and approval of key deliverables
  - Provide business resources to the project
  - Deployment approval
  - Support ongoing use of the system in a compliant manner
Roles & Responsibilities

- Development Team
  - Project management (shared with business)
  - Hardware and software implementation
  - Testing
  - Installation/Operational Qualification
  - Technical documentation
  - Deployment
  - Support Model
Roles & Responsibilities

- Business Team
  - Project management (shared with Informatics)
  - Requirements Definition
  - User Acceptance Testing
  - Standard Operating Procedures for system use and administration
  - Training (often shared with Informatics)
Roles & Responsibilities

- Quality Assurance
  - Validation approach/oversight
  - Vendor audits (as needed)
  - Validation documentation
  - System testing (sometimes shared with Development Team)
  - UAT coordination (shared with Business Team)
  - Organization and archiving of validation package
  - Ensure compliance with Corporate validation policy and SOPs
Roles & Responsibilities

- Regulatory Compliance
  - Advise on regulations
  - May review and approve key deliverables
  - Perform systems and documentation audits
Summary

- Validation makes good business sense (and it’s a regulatory requirement)
- Validation looks a lot like good software development practices
- Keeping a system validated requires activity over the life of the system
- A successful validation project requires involvement from the business, Informatics and Regulatory Compliance.
References & Resources

- ISPE’s GAMP4 Guide for Validation of Automated Systems (start/specialized applications)
- FDA Web Site
  - 21 CFR Part 11; Electronic Records & Signatures
  - Guidance for General Principles of Software Validation (CDRH)
  - Guidance for Computerized Systems used in Clinical Trials