Validation Best Practice for a SaaS
Validation Best Practice for SaaS

Validation Definition:

Establishing documented evidence which provides a high degree of assurance that a specific computerized process or operation will consistently produce a quality result meeting its predetermined specifications.

- Source: GAMP 5-A Risk-Based Approach to Compliant GxP Computerized Systems, pg 335, appendix G2
Validation Best Practice for SaaS

2.1.5 Leveraging Supplier Involvement

Regulated companies should seek to maximize supplier involvement throughout the system life cycle in order to leverage knowledge, experience, and documentation, subject to satisfactory supplier assessment.

Source: GAMP 5-A Risk-Based Approach to Compliant GxP Computerized Systems, pg 21
Validation Best Practice for SaaS

2.1.5 Leveraging Supplier Involvement (cont’d)

- Planning should determine how best to use supplier documentation, including existing test documentation, to avoid wasted effort and duplication. Justification for the use of supplier documentation should be provided by the satisfactory outcome of supplier assessments, which may include supplier audits.

- Vendor documentation should be assessed for suitability, accuracy, and completeness. There should be flexibility regarding acceptable format, structure, and documentation practices.

Source: GAMP 5-A Risk-Based Approach to Compliant GxP Computerized Systems, pg 21
Validation Best Practice for SaaS

One of the appeals of the SaaS application is that a company can shift some of the validation effort to the SaaS vendor.

- This enables the company’s validation team to focus initially on an audit of the vendor’s data center, as well as the vendor’s QA and validation methodology, to ensure these activities are performed at the same standard as would be performed by the client’s own QA and validation teams.
- Typically, the time spent auditing the SaaS vendor can dramatically reduce the time spent validating the system.
Validation Best Practice for SaaS

Vendor Quality Process should include:
- SDLC Methodology
- Project Planning
- Personnel Qualifications
- Documentation Standards & Procedures
- Methods for review & approval
- Design Standards
- Programming Standards
- Configuration Management
- Testing Standards & Procedures
- Separation of Development, Test and Production Environments
Validation Best Practice for SaaS

Vendor Quality Process should include:

- Move to Production Process
- Clearly defined responsibilities
- Involvement of:
  - Customer/User
  - Quality Assurance professionals
  - Technology Professionals
  - Change Management
  - Training process
  - Process for continuous evaluation, incident monitoring, error correction
  - Processes and procedures for physical & logical security of system and data
Validation Best Practice for SaaS

Audit results may then be incorporated into a risk assessment to leverage vendor supplied documentation. In many cases, following an audit of the data center and software development lifecycle (SDLC) methodology, a client’s audit and validation team will then develop only the core validation documents:

- Validation Plan
- User Requirements Specification
- User Acceptance Test Scripts (including testing for customizations, integrations)
- Validation Report
- System Governance
System Governance Best Practice for SaaS

Define Your Governance Model (System)

• Standardize Nomenclature and Other Meta Data
• Create Role Based Training Curricula
• Create Targeted Security Roles
• Define Integrations with other systems (HRIS, EDMS)
• Train Your Administrators and End Users
• Decentralize System Administration Appropriately
• Monitor the System Through Standard Reporting
• Practice Continuous Improvement
System Governance Best Practice for SaaS

Define Your Governance Model (Procedures)

- **Use and Operation Procedures**, including general Use and Operations for Users and User esignature certification

- **System Administration Procedures**, including security roles, system admin roles and responsibilities, maintenance (including system releases), configuration changes requiring change control

- **Computer System Change Control**, including standard operation procedures for system configuration changes, addition of new functionality, handling system releases
System Release Notifications

Notification to System Admin- **30 Days prior to System Release**

Platform Release Notes:
- Enhancement List
- System Availability
- Regression Test Script Access Information
- Preview Testing Details
- Standard Enhancement Demos

Notification to System Admin- **21 Days prior to System Release:**
- Platform Release Guide
- Enhancement Details
- Elective Enhancement Demos

Notification to System Admin- **14 Days prior to System Release:**
- Final Release Details
- Premium Enhancement Demos
System Release-Enhancement Categories

**Standard Enhancements** - A platform impacting enhancement that affects ComplianceWire functionality for all Clients.
- Does not result in additional cost to existing ComplianceWire Clients.
- Changes to the ComplianceWire platform that are considered ‘Standard’ are not configurable for individual instances and cannot be turned off.
- Documentation of changes and impacts will be provided with Release Communication.
System Release-Enhancement Categories

**Elective Enhancements** · A change to ComplianceWire platform functionality that is not defaulted to be ‘enabled’ for all Clients and is available without additional cost.

- In many cases, this functionality can be enabled with a request to the Client Services Team at UL EduNeering who will modify a Client’s ComplianceWire configuration.
- Details related to the operability, impact and activation instructions will be provided for Elective Enhancements in Release Communications.
System Release-Enhancement Categories

**Premium Enhancements** - A change to ComplianceWire functionality or tools that require additional cost or subscription.
- These changes will be documented on a high level in Release Communication.

- In many cases, the implementation of such enhancements requires further analysis of a Client’s instance of ComplianceWire with additional implementation and application support.
- Clients who are interested are encouraged to contact their Account Director for more details and pricing.
System Release-Enhancement Categories

**Consultative Enhancements** · Functionality or tools that are being built and may have some components introduced to the infrastructure of ComplianceWire, but are not yet available or purchase.
· The changes will be documented on a high level in the Release Communication.

- In many cases, the implementation of Consultative Enhancements will require further analysis of a Client’s instance of ComplianceWire. It may be necessary to customize changes, reconfigure or require professional services.
- Clients who are interested are encouraged to contact their Account Director for more details and pricing
System Release Example Process Overview

- Organizational administrator reviews the system release notes with appropriate business users, system owner, QA and IT to decide if any non standard enhancements will be utilized.

- Organizational administrator reviews the regression test scripts received for completeness for testing for standard enhancements and non standard enhancements being utilized.

- Organizational administrator completes an impact assessment form and coordinates with QA, IT and System owner to evaluate the impact and identify procedure changes that may require change control (i.e. New system feature being used) and any additional testing required.

Note- most clients choose to use the UL EduNeering regression test scripts that are part of the release to save time and resources.
**System Release Example Impact Assessment Example**

![Impact Assessment Form](image)

### Section 1: Organizational Administrator
- **Name:**
- **Date:**
- **Date of System Release:**

### System Release Enhancements/New Features
(Please add additional sheets as required)

### System Release Impact

**Impact of Change**

- Does this change affect a validated state of ComplianceWire?
  - [ ] Yes
  - [ ] No (if yes initiate change control)

- If change affects a validated state of ComplianceWire is validation testing required?
  - [ ] Yes
  - [ ] No
  - [ ] Partial
  - [ ] N/A

**Existing Affected Documents:**
- [ ] ComplianceWire Application Configuration Specification
- [ ] ComplianceWire User Acceptance Testing
- [ ] ComplianceWire Test Mapping Reference
- [ ] ComplianceWire User Requirements Specification
- [ ] ComplianceWire Validation Plan
- [ ] ComplianceWire SOP General Use and Operation
- [ ] ComplianceWire SOP System Administration

### QA Approval
- **Name:**
- **Signature:**
- **Date:**

### System Owner Approval
- **Name:**
- **Signature:**
- **Date:**
System Release Example Impact Assessment
Example Completed

Appendix 1: Impact Assessment Form (example)

<table>
<thead>
<tr>
<th>Section 1: Organizational Administrator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name: Scott Barnard</td>
</tr>
<tr>
<td>Date of System Release: December 17, 2013</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>System Release Standard Enhancements and/or new functionality being used (Please add additional sheets as required)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard Enhancements:</strong></td>
</tr>
<tr>
<td>• Browser Compatibility- new compatibility requirements</td>
</tr>
<tr>
<td>• Managing Training (Sub) Types- new change the Name, Abbreviation and Description for a Training (Sub) Type</td>
</tr>
<tr>
<td>• Curriculum Enhancements- new field curricula code, curriculum title field has increased to 255 characters (previous 50 characters)</td>
</tr>
<tr>
<td>• Curriculum Keywords- new field that is optional</td>
</tr>
<tr>
<td>• Curriculum History- new history area</td>
</tr>
<tr>
<td>• Curriculum Version- new versioning feature</td>
</tr>
<tr>
<td>• Curriculum Status- new status for curricula, Draft, Pending, Approved, Effective, Retired and Archived</td>
</tr>
<tr>
<td>• Reporting solutions enhancements- new base reports in the reporting tool</td>
</tr>
<tr>
<td>• Instructor Name Field Changes- instructor field is no longer supported, instructor list is how you add and instructor to the class for an ILC.</td>
</tr>
<tr>
<td>• ILC online registration enhancement- instructor now shows when registering for a class</td>
</tr>
<tr>
<td>• Copy and ILC class- new feature to be able to copy and ILC class</td>
</tr>
<tr>
<td>• User Group Membership Activity- new link for users to view group membership activity</td>
</tr>
</tbody>
</table>

**Additional Enhancements to be added:**

- Curriculum Review & Approval
System Release Example Impact Assessment Example Completed

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<tr>
<th>System Release Impact</th>
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<tbody>
<tr>
<td>Impact of Change:</td>
</tr>
<tr>
<td>The standard enhancements and functionality have been tested by UL Eduneering (Audit Report Sept 1, 2013). New features will be reviewed by administrators during the test phase of the release. No formal testing will be required for standard features. Browser requirements document will be reviewed with IT prior to release.</td>
</tr>
<tr>
<td>Documentation Impact:</td>
</tr>
<tr>
<td>- URS (add curriculum review and approval) this will require new tests scripts to be developed for the addition to the URS and amended to the original UAT scripts</td>
</tr>
<tr>
<td>- Administration SOP- add curriculum review and approval process, add curriculum code feature</td>
</tr>
<tr>
<td>- Train Administrators on new processes for curricula</td>
</tr>
<tr>
<td>Does this change affect a validated state of ComplianceWire</td>
</tr>
<tr>
<td>If change affects a validated state of ComplianceWire is validation testing required:</td>
</tr>
<tr>
<td>Existing Affected Documents:</td>
</tr>
</tbody>
</table>
System Release Example Impact Assessment
Example Completed

| ComplianceWire Application Configuration Specification |  |
| ComplianceWire User Acceptance Testing             |  |
| ComplianceWire Test Mapping Reference               |  |
| ComplianceWire User Requirements Specification      |  |
| ComplianceWire Validation Plan                      |  |
| ComplianceWire SOP System Administration            |  |

<table>
<thead>
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Best Practice Tips

• Minimize validation- do an initial audit of vendor to determine if their validation processes are sufficient
• Audit at least every 2-3 years to ensure vendor is still in compliance with your standards
• Share validation responsibility with Vendor, QA, IT, Business owner, Administrators
  - Vendor audit of functional requirements should be referenced in your validation plan to justify why you didn’t do full validation (IQ, OQ, SDS, Backup/restore etc)
  - QA review and approves documentation
  - IT review and approves documentation, sets up user PC environment
  - Business Owner- authors documentation
  - Administrators- Runs any test scripts