Title:	CLUWE Web Tool Validation Plan Release 1.0

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TITLE: CLINICAL USERS WORKING ENVIRONMENT (CLUWE) WEB TOOL VALIDATION PLAN RELEASE 1.0

REVIEWERS

Your electronic signature indicates that you have reviewed this document and that for your area of expertise, agree it is accurate and complete.

Business Subject Matter Expert (BSME)

IT Subject Matter Expert (ITSME)

Quality Analyst (QA)

Business Quality Assurance (BQA)

APPROVERS

System Custodian

Your electronic signature attests that

- The appropriate persons involved in the validation process have reviewed the document to ensure that the plan is adequate to properly validate the computer system
- You understand your responsibility to provide the resources necessary to validate the system as described in the plan
- You understand your responsibilities in the validation process.

System Owner

Your electronic signature attests that

- The appropriate persons involved in the validation process have reviewed the document to ensure that the plan is adequate to properly validate the computer system
- You understand your responsibility to provide the resources necessary to validate the system as described in the plan
- You understand your responsibilities in the validation process.

Computer System Quality Assurance Representative

Your electronic signature attests that this document complies with Corporate Computer Systems (CCS) Lilly Quality Standards and Practices.

TITLE: CLINICAL USERS WORKING ENVIRONMENT (CLUWE) WEB TOOL VALIDATION PLAN

PURPOSE

The Web Tool will be validated according to applicable Lilly Quality Standard (LQS) and Lilly Quality Practices (LQPs), IT Common (ITC) SOPs, and local procedures. The Validation Plan (this document) outlines the validation approach and provides the rationale for the extent of validation planned for the system.

This document will become historical at system acceptance. Any departures from this plan will be explained in the Validation Report.

SCOPE

Following are in scope of this validation effort:

- Job Scheduling
- Versioning
- electronic Signature (eSignature)

Following are out of scope of this validation effort:

- SAS Grid/ SAS GSub Commandline tool
- Data Migration
- Data Conversion

ACRONYMS AND DEFINITIONS

The terms and acronyms in this document are defined at their first occurrence.

DOCUMENT REVISION HISTORY

Version	Revision Date	Reason for Revision (Include CR#, if Applicable)	Revised By, Title
0	9-Sep -2015	New document	Zaka Siddiqui, Validation Lead

Table of Contents

1. SYSTEM DESCRIPTION AND SCOPE

Area	Discussion
Description Of System To Be Validated	The system comprises of following functionalities: 1. Job Scheduling – off-line job/program execution including the ability to set execution time,. 2. Versioning – version control of files within repository. 3. eSignature – CFR part 11 compliant Electronic Signature capabilities.
Validation Scope and System Components	The CLUWE Web Tool will: • provide clinical execution environment • provide repository of data, programs and output • be accessible globally with consistent performance The scope of validation will be to validate Job Scheduling, Versioning and eSignature functionalities.
Purchased Components Included In System	Isilon Network Attached Storage by EMC.
Key Interfaces	Key interfaces with this system are: Isilon SAS Grid
Out of Scope	For out of scope please see Scope section above

2. RISK EVALUATION AND REGULATORY STATUS

This validation will be right-sized based on business processes and system risks. Decisions made during discussions where these risks are assessed will be documented throughout the validation package in the applicable validation deliverable, and validation activities will be planned and implemented based on managing and controlling these known risks.

The initial risk assessment for this system provided the following information:

Risk Factor	Discussion
Regulatory Status	The system is designated as GCP and Critical.
Potential Impact	This system has a direct impact to Privacy and Information Classification as the interface to file system and can manipulate file name, properties, and security.
Type of System	The system is custom developed and will be used globally.
System Complexity	This system has high complexity due to the integration with Isilon and SAS-Grid.
Supplier Involvement	There is no vendor involved in the system.

3. VALIDATION PLANNING

The following table includes more validation planning information/activities.

Area	Discussion
System Development Process	Systems development will follow the Lilly Systems Engineering Framework (LSEF).
Software Tools	The following software tools are used in the development and testing of the system. Unless otherwise noted, the tools are compliant with the Enterprise Architecture, supported by infrastructure teams, and appropriately validated based on risk to the system. • Jenkins • Eclipse Java IDE • HP ALM 11.0 – Used for Testing the system and to store requirements, test scripts and code reviews.
Requirements Management Plan (RMP)	Requirements will be stored and managed in HP ALM 11.0. From here on this will be referred to as Quality Center.
Pre-Implementation Change Control Strategy (Configuration Management)	• Approved validation deliverables are version controlled and stored in Regulus. Once a document is approved, proposed changes must be approved by the roles responsible for reviewing and approving the document. • Requirements are managed and controlled using Quality Center. Once requirements are approved, proposed changes are analyzed to determine the impact and agreed upon by System Owner and System Custodian before the changes can be implemented. • Code is managed and controlled using Apache SubVersion (SVN).
Supplier Management	There is no vendor involved in the development of this system
Document Storage	The CLUWE Web Tool validation documents will be managed electronically and stored within Regulus and Quality Center. Please refer to the section on Validation Deliverables to be Produced for location.
Applicable Standard and Practices	The validation of this system will follow the current Corporate Computer System (CCS) Lilly Quality Standard (LQS) and Lilly Quality Practices (LQP) requirements for computer system validation.

4. VALIDATION DOCUMENTATION

4.1 Validation Deliverable Roles

The roles involved in reviewing and approving validation deliverables include:

Role Key	
Role Acronym	**Definition**
BQA	Business Quality Assurance
BSME	Business Subject Matter Expert
CSQA	Computer Systems Quality Assurance
IT SME	IT Subject Matter Expert
QA	Quality Analyst

Role Key	
Role Acronym	**Definition**
SC	System Custodian
SO	System Owner
TL	Test Lead

4.2 Validation Deliverables to Be Produced

The following table provides list and summary of the validation deliverables which will be produced during this effort:

Validation Product	Description/Discussion	Reviewer(s)	Approver(s)	Deliverable Location (Regulus, QC etc)
Validation Planning				
Validation Plan	This document satisfies the Validation Plan expectations of LQS 302.	• BSME • IT SME • QA • BQA	• SC • SO • CSQA	Regulus
Validation Report	System Acceptance is documented by the approval of the Validation Report. The Validation Report summarizes the completion of all validation activities and resulting deliverables and supporting documentation that provide documented evidence that the system is validated. The Validation Report will identify any validation activities or supporting documents that have not been successfully completed as specified in the Validation Plan. Additionally, the Validation Report will include any outstanding issues generated by source code reviews and/or test problem reports. A justification	• BSME • IT SME • QA • BQA	• SC • SO • CSQA	Regulus

Validation Product	Description/Discussion	Reviewer(s)	Approver(s)	Deliverable Location (Regulus, QC etc)
	for implementing the system with the known issues, and an accompanying issue resolution action plan will be included in the Validation Report. The action plan will include the individual or role responsible for each action and a due date for each action.			
Requirements	The Requirements Definition validation deliverable will define what the system capabilities should be. This will include functional, security, and ER/ES requirements for the system.	• IT SME • BSME	• SC • SO • CSQA • BQA	Quality Center
System Overview	A System Overview document will be created that provides high-level information about the system.	• IT SME • QA	• SC • SO • CSQA	Regulus
Design Specifications	A Design Specifications document will be created to address the requirements defined in the Lilly Quality Practice: *Requirements and Design (LQP302-16).*	• IT SME	• IT SME • SC* • SO * **if system utilizes OSS*	Quality Center
System Configuration Specifications	A System Configuration Specification document will be created to address the requirements defined in the Lilly Quality Practice: *Requirements and Design* (LQP302-16).	• IT SME • QA	• SC • CSQA	Regulus
Source Code Review	Source Code Reviews will be conducted in accordance with the LQP *Application Source Code*	• N/A	• IT SME	Quality Center

Validation Product	Description/Discussion	Reviewer(s)	Approver(s)	Deliverable Location (Regulus, QC etc)
	Review (LQP302-3).			
Testing				
Test Plan	A Test Plan will be created to define the strategy for testing requirements and design specifications, as well as address the process for test documentation and problem resolution.	• IT SME • QA • BSME	• SC • SO • CSQA	Regulus
Test Cases/Scripts	Test cases and scripts will be developed and approved to test requirements and specifications.	• BSME or IT SME	• BSME or IT SME	Quality Center
Installation and Verification Instructions (IVI)	An IVI will be developed to verify that the system has been installed and configured properly.	• N/A	• IT SME	Quality Center
Test Summary Report	Following completion of testing, a Test Summary Report will be created to summarize the execution of testing as well as document problem reports encountered during testing.	• IT SME • BSME • QA • BQA	• SC • SO • CSQA	Regulus
Supporting Documentation				
Security Plan	The Security Plan will be created to describe the physical and logical security controls for the system.	• IT SME • QA • BQA	• SC • SO • CSQA	Regulus
Security Administration SOP	The Security Administration SOP will be created to describe how physical and logical security will be administered.	• IT SME • QA	• SC • SO • CSQA	Regulus
Disaster Recovery Plan	A Disaster Recovery Plan (DRP) will be created to describe the process	• IT SME • QA	• SC • CSQA	Regulus

Validation Product	Description/Discussion	Reviewer(s)	Approver(s)	Deliverable Location (Regulus, QC etc)
	that will be followed to recover the system in the event of a disaster.			
Business Continuity Plan	A Business Continuity Plan (BCP) will be created to describe the process that will be followed to continue operations in the event the system becomes unavailable.	• BSME • QA	• SC • SO • BQA	Regulus
System Administration and Support SOP	A System Administration and Support SOP will be created detailing policies, procedures, and practices applicable to system administration and support activities. This should include: • Change Control • Periodic Reviews • Code Migration and Software Installation • System Inventory • Audit Trail Generation • Access Roster Generation • Routine Administration Tasks • System-specific Processes	• IT SME • QA	• ITSME • SC • SO • CSQA	Regulus
Other Deliverables				
Traceability Matrix	A Traceability Matrix will be created to document the traceability of requirements to design to testing.	• N/A	• IT SME	Quality Center
Asset Inventory (Configuration Management	A record of [System Name - Update in Document Properties] will be added to CMDB	• IT SME • QA	• N/A	Service Now

Validation Product	Description/Discussion	Reviewer(s)	Approver(s)	Deliverable Location (Regulus, QC etc)
Database) CMDB	in ServiceNow.			

4.3 Validation Deliverables Not Produced

The following is a list of deliverables that will not be produced, along with the rationale:

- Backup and Restoration Plan (backup and recovery services are provided by Global Infrastructure Center of Excellence [GICOE])
- Platform Qualification - The system is supported by Global Infrastructure Center of Excellence (GICOE). GICOE supports the hardware and software platforms where the system resides and provides resources to perform those platform support services.
- IQ/OQ document – This will not be covered as IVIs will be created to ensure installation process.
- Data Migration Plan – Data Migration Plan will not be created as this is a new system.
- Data Migration Report – Data Migration Report will not be created as this is a new system.

5. REFERENCES

A current list of system-specific documents stored in Regulus can be generated using Regulus. The documents are stored in the IT Library Regulus repository at IT_Library > LRL IT > Systems C to D > CLUWE Web Tool.