VALIDATION & GOVERNANCE

Validation Support

Computer system validation is a critical regulatory requirement for any computer system that is used to store electronic records, according to FDA 21 CFR Part 11.10(a) and Annex 11 Paragraph 4. The process of validating a system can sometimes be complex, time-consuming and expensive, but it doesn't have to be. Validation standards, such as GAMP 5, encourage companies to maximize supplier involvement in order to leverage their knowledge, experience and documentation, subject to satisfactory supplier assessment, reducing their validation requirements through a risk-based approach.

- UL EduNeering works with clients to validate their instance of ComplianceWire®, our own web-based, proprietary learning system, which has been designed to meet 21 CFR Part 11 requirements.
- Clients also turn to UL EduNeering to help fulfill the full validation of other cloud applications, and to manage specific aspects of validation support, such as validation plans, documentation, change management and governance, test scripts and user requirements specifications.
- UL EduNeering can assist your team with the validation effort related to both installed and cloud applications (ERP, DMS, LMS, SCMS, QMS, etc).
- We have helped dozens of clients manage their validation activities more efficiently.
- Our team can provide detailed templates, scripts and support to help your team meet your validation and corporate governance requirements, thus streamlining your validation effort, and at the same time ensuring that you've incorporated current industry best practices.
- Having a solid validation and governance structure, based on a risk-based approach, can help reduce overall costs of the system's life at your company.

Validation Audit

UL EduNeering can also partner with clients to provide 21 CFR Part 11 computer system validation audits to assist with review of your current validation documentation, provide gap assessments and assist you with preparing and executing remediation plans.

Our team's experience includes dozens of real-world validation projects, and leverages auditing efforts related to our own cloud-based Learning Management System (LMS), ComplianceWire, which was built from the ground up to be a validated FDA 21 CFR Part 11 and Annex 11 compliant system.

VALIDATION TEMPLATE OVERVIEW

Template Name:	Description:
Request for Proposal	Template for requesting a proposal from vendors, including User Requirements answers.
Vendor Audit (VA)	Template for completing vendor assessment/audit, including planning of audit and audit final report.
LMS User Requirements (USR)	Basic User and system Functional Requirements for an LMS use and operation.
Validation Traceability Matrix	Traceability mapping from User Requirements to Validation Scripts, SOPs, ACS.
LMS Validation Plan (VP)	Main Validation document describing project and deliverables, including business need/objectives, resource planning, project team members, roles and responsibilities, implementation approach, risk assessment, document deliverables, team training requirements, maintenance and support.
LMS User Acceptance Testing (UAT)	User Requirements test scripts and validation execution details.
LMS Validation Summary Report (VSR)	Describes all validation activities, deviations, testing processes, system release summary.

Level 1: This service provides clients with the Validation Package, which includes prewritten templates for an LMS SaaS platform. The templates include validation planning, vendor assessment, UAT scripts, traceability mapping and a validation summary report as well as eight hours of support. During the support, UL will discuss/review the client's validation strategy, provide best practice recommendations and educate the client on the templates and how to use them.

Level 2: This service provides all of the elements of the Level 1 engagement, plus it allows for the additional service of 20 hours of support to assist with reviewing the final documents and providing feedback and direction based on that review.

Level 3: This service provides 40 hours of consulting support to interview teams and gather user requirements/validation approach, draft main documents for the Validation Package (remote) – URS (User Requirement Specification), Validation Plan, UAT Test Scripts and Validation Summary Report.

Level 4: This service provides all of the elements of the Level 3 engagement, plus it allows for the additional service of two weeks of onsite support to manage/direct the validation project up to 100 hours of consulting support.

Level 5: This service is for any system that needs validation. It provides consulting support that can range from reviewing and providing feedback on the client's validation approach and final documents to full outsourced validation support of the system. Our services can be customized to meet your needs.

System Governance

A well-defined and executed system governance strategy is essential to the successful operation and maintenance of your LMS. System governance ensures that your LMS implementation aligns with the goals set forth by your organization. It will help establish appropriate representation from all stakeholders and provides a structure for decision-making, including standardizing nomenclature, creating role-based curricula, data security and administrative security roles.

GOVERNANCE TEMPLATE OVERVIEW	
Template Name:	**Description:**
LMS General Use and Operation	User Standard Operating Procedure for use of system, User e-signature certification.
LMS System Administration	System administration Standard Operating Procedures, including security roles, system admin roles and responsibilities, maintenance (including system releases), changes requiring change control.
LMS Computer System Change Control	Change control Standard Operation Procedures for system configuration changes, addition of new functionality, handling system releases.
Training Policy	Policy for corporate training, including scope, training responsibilities, procedures for GXP training and non-GXP Area Personnel, Training Curricula, Training Documentation, Annual GXP Training and External Training.

Level 1: This service provides clients with the Governance Template Package, which includes four document templates as well as four hours of remote support. UL will discuss/review the client's governance strategy, provide best practice recommendations and educate the client on the templates and how to use them.

Level 2: This service provides all of the elements of the Level 1 engagement, plus it allows for the additional consulting support of 12 hours for reviewing the final documents and providing feedback and direction based on that review.

Level 3: This service provides all of the elements of Level 1 plus additional consulting support of 40 hours for document requirements, drafting the governance documentation (based on the UL templates) and assisting with the review and approval of all final documents.

FDA has clearly defined system validation regulations described in 21 CFR Part 11. During inspections, your electronic systems will be scrutinized for compliance to these regulations. Activities such as validation of new systems or remediation of existing systems to identify gaps can greatly reduce your compliance risk during an audit.

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