Life & Health

ComplianceWire® Validation Activities

Partnering with Your Validation Team

When you partner with UL EduNeering, you can expect the validation effort to represent a shared responsibility.

Because of our cloud computing model, in which our engineering and IT personnel design and maintain the computer hardware, software and security, you can expect our Quality Assurance (QA) team to conduct much of the same validation activities that your team would perform if the software was installed within your data center.

Client Audits

Client audits, which represent a core activity within the deployment of our solution, are typically hosted at UL's corporate office in Princeton, NJ. Validation teams have the opportunity to review the project file(s) developed as part of the design, development, testing and implementation of our ComplianceWire Learning Management System (LMS).

Our quality assurance documentation is located at our Princeton headquarters. Client audits have routinely demonstrated our adherence to quality software engineering and testing principles.

Based on our existing SOPs and our continuous improvement programs, our QA team has constructed a valid development methodology that has been thoroughly tested to provide confidence and assurance that ComplianceWire is fit for production use.

The UL Quality Assurance Team

Our QA team is involved in every life cycle stage and is responsible for review and approval. Quality Assurance efforts are applied in all aspects of development, through the development of functional specifications, including the business rules, graphical user interface design elements and the interoperability with existing features.

All ComplianceWire code development is performed on a dedicated development server. Then it is uploaded to a controlled QA environment server, where our QA team tests features and functionality. When approved, the code is released to the production environment.

Our process begins with a validation plan that will help you build a marketing communications strategy tailored to your specific roll-out.

QA is responsible for requirements and test traceability, and full product testing related to the ComplianceWire platform.

During our enhancement releases, our QA team tests the new features and functionality in a controlled QA environment before the code is released to the Production environment. This testing not only ensures that the new feature set is behaving as intended, but that there is no negative impact to existing functionality as a result of the new or enhanced functionality.

For each enhancement, we provide clients with a set of regression test scripts as well as a preview period so they can test the new features in our training site. These scripts are designed to aid the client with their own internal validation effort. In addition, we provide a validation summary report at the end of all UL release activities.

When a client audits ComplianceWire, they are typically requested to review these documents:

Business Requirements – Focuses on the needs of the user and spells out exactly what the system will do.

Functional Requirements – Focuses on how the system will do what the user is expecting.

System Design – Focuses on capturing the system design based on the functional requirements depicting screen layout, system functions and other aspects of the user experience to fulfill business requirements.

Requirements Traceability Matrix – Captures the relationship between the business and functional requirements and the test scripts that satisfy them.

Testing – Test scripts for new features are created for each enhancement release or custom work. Regression testing is executed using existing test scripts for impacted areas. These scripts cover basic system functionality, CFR functional and reporting features and high priority areas of the system, such as Assignments, Curricula, User Groups, etc.

In addition, custom testing is executed for client custom work such as client feeds, posts, custom login pages, etc. Our testing is extensive and takes into account new features as well as overall functions across the entire platform.

Test Plan (TP) and Validation Plan (VP) SOPs – Because ComplianceWire is a single platform, these documents have been adopted into Standard Operating Procedures.

VSR (Validation Summary Report) – Summarizes testing activities, discrepancies and other validation activities.

Activities Performed by the Client's Validation Team

While an audit of our procedures and data center often minimizes the need need for clients to "retest" core ComplianceWire functionality, the client's validation team will typically perform several activities related to the organization's validation effort.

At a minimum, here are a few of the recommended documents and activities that we have seen performed to satisfy regulatory agencies, including the FDA, who may ask for them during an audit:

Validation Plan – The Validation Plan describes the internal activities that are part of the overall validation approach to be conducted by the client.

User Requirements Specification – Clients typically develop their own User Requirements, which detail the functionality that they require of the system. These items are often categorized as "critical," "mandatory" or "nice to have" – and they are the basis of the validation/testing effort.

User Acceptance Test Scripts – Clients should have their own test scripts that either augment UL's scripts, or unique scripts that demonstrate that the company has tested specific usage of the system.

Validation of Configurations and Customizations – UL recommends that clients test their specific configurations or specific customized solutions, which may include:

- HR Integration Feeds or Posts
- Custom Login Page
- Additional Custom Fields (beyond the standard 15 Custom Fields provided)
- Self-registration Page
- Custom Report Formatting
- Custom Security Roles
- Custom Reports

Validation Report – Clients typically draft a summary document following an audit of our data center and processes, which often summarizes the validation activities undertaken, highlights deviations from the plan, lists reservations or outstanding actions and provides a statement on the validated status of the system.

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.