

Validation activities for your ComplianceWire® instance

A fully validated LMS out of the box

Our process begins with a validation plan that will help you build a communications strategy tailored to your specific implementation.

Partnering with your validation team

When you partner with UL Solutions, the validation effort is a shared responsibility.

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

Validation support for ComplianceWire® implementation

UL Solutions has validation experts with global regulatory requirements and product knowledge to support customers through successful PQ validation for your project. UL Solutions will supply a validation package, which includes templates for a SaaS implementation

project. A UL Solutions validation consultant will provide complete support, during which we'll discuss/review the customer's validation strategy and provide best practice recommendations. The validation consultant will also draft documents included in the validation package, assist with review and approval of records, and offer assistance with user acceptance testing, dry runs and final runs, as appropriate.

Additionally, we highly recommend that the customer perform a vendor audit of UL Solutions as part of the validation. We can also assist with the validation of new releases.

Customer audits

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

Quality assurance documentation is located at our Princeton headquarters. Customer 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.



ComplianceWire® Quality Assurance

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 and functional specifications, including business rules, graphical user interface design elements and interoperability with existing features.

All ComplianceWire® code development is performed on a dedicated development server. Then it's 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.

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

During 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 because of the new or enhanced functionality.

For each enhancement, we provide customers 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 customer with their own internal validation effort. In addition, we provide a validation summary report at the end of all our release activities.

Business requirements

Focus on user needs and spell 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, 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 custom customer work such as feeds, posts, login pages, etc. Our testing is extensive and considers 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 customer's validation team

While an audit of our procedures and data center often minimizes the need for customers to retest core ComplianceWire® functionality, the customer's validation team will typically perform several activities related to the organization's validation effort. As always, customers can count on UL Solutions to support these activities wherever needed.

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 customer.



User requirements specification

Customers typically develop their own User Requirements, which detail the functionality they require of the system. These items are often categorized as critical, mandatory or nice to have—and they're the basis of the validation/testing effort.

User acceptance test scripts

Customers should have their own test scripts to either augment scripts by UL Solutions or unique scripts that demonstrate the company has tested specific usage of the system.

Validation of configurations and customizations

UL Solutions recommends that customers test their specific configurations and customizations, which may include:

- HR integration feeds or posts
- Self-registration page
- Custom login page
- Custom report formatting
- Additional custom fields (beyond the standard 15 custom fields provided)
- Custom security roles
- Custom reports

Validation report

Customers 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.



Learn more at [UL.com/compliancewire](https://www.ul.com/compliancewire)



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CS348622 (0622)