Life & Health

Our Commitment to Quality, Validation and Part 11

ComplianceWire® Release Statement

A message from our Quality Assurance, Engineering and Data Center Teams

UL EduNeering strives to improve the software security, reliability and quality of ComplianceWire through the effective application of world-class systems and software development methods, practices and techniques. UL EduNeering provides tailored technical program management by applying software engineering and quality assurance "best practices" to evaluate the correctness and quality of critical and complex software systems throughout the system development life cycle.

During each ComplianceWire SDLC stage, specific documentation is generated that is reviewed by UL EduNeering personnel with specific review and signature responsibilities, including Quality Assurance for Compliance and Quality Control for Testing. If a reviewer, for any reason, rejects a document, the development process cannot continue until the problem is satisfactorily resolved and approved.

Any and all of the original documents generated during system development are approved with dated signatures by qualified UL EduNeering personnel, and filed manually and electronically in a secure and controlled environment (physical and logical). Documents are tracked through the use of a Traceability Matrix that maps the business requirements with the system requirements, system design, and test scripts that satisfy them. UL EduNeering's QA Compliance and QC Testing teams are involved in the development of the Traceability Matrix and the tracking of all associated documentation. Certification of validation to UL EduNeering processes and procedures can be obtained for all ComplianceWire Releases.

In addition, UL EduNeering routinely hosts client audits at our corporate headquarters to review the project files developed as part of the design, development, testing and implementation of releases. These audits routinely demonstrate our adherence to quality software engineering and testing principles. Based on all current and historical project file documentation and on client audit findings, subject to measures to maintain confidentiality, UL EduNeering believes that upon each new release of ComplianceWire, the system will meet the specified requirements of UL EduNeering and our Clients' contracts. ComplianceWire has been developed according to a documented development methodology and has been thoroughly tested. Further, we test that each release does not negatively impact the 21 CFR Part 11 status of ComplianceWire. Although the system functionality is enhanced as described in our release announcements, both the technical constructs within ComplianceWire and our procedural controls remain intact.

UL EduNeering has an open-book approach to sharing information with our Clients. As such, and subject to the terms of a Client's contract with UL EduNeering, all applicable documentation is readily available for Client inspection and review at the corporate headquarters in Princeton, NJ. Upon written request, UL EduNeering will make this information available for agency inspection.

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.