

ComplianceWire®

Learning, compliance and qualification
management for life science organizations



Safety. Science. Transformation.™



Compliance.
Proficiency.
Performance.



Assessing compliance, enhancing performance

Business leaders recognize regulatory compliance as a necessity for conducting business. An effective compliance program reflects both regulatory and business needs, increases knowledge and performance at every level of the organization, reduces liability, and streamlines interrelated training information and document management. The resulting culture sharpens the organization's competitive edge through proactive compliance, improved performance and enhanced bottom-line productivity.

Learning technology chosen by the Food and Drug Administration (FDA) and trusted by industry leaders

When the FDA faced the challenge of ensuring the proficiency of more than 40,000 federal, state and local investigators, they partnered with UL Solutions under a unique Cooperative Research and Development Agreement (CRADA). The resulting compliance training coursework integrates our ComplianceWire® web-based platform with a curriculum that we co-developed with the FDA. This coursework is also available to our ComplianceWire® customers.



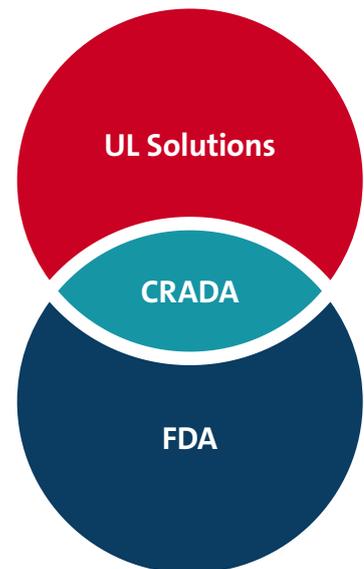
Introducing ComplianceWire®

ComplianceWire® is one of the world's leading qualification-focused tools helping global companies deliver and track role-based qualifications and certification requirements.

Award-winning functionality addresses necessary compliance-related learning needs and allows individuals with training and skill requirements to access ComplianceWire® directly from the main learning management system (LMS) navigation page.

Features include:

- An intuitive interface for both learners and administrators
- Excellent response times and a 99.98% uptime reliability
- Supports all e-learning standard formats such as AICC and SCORM
- Full retention capabilities for training records
- Integrates with enterprise systems, including HRIS, EDMS, QMS, SSO, MES and other applicable systems
- Available in 34 languages
- In-house, 24/7 global customer support



ComplianceWire® is a powerful, Part 11- and EU Annex 11-compliant, fully validated LMS that pharmaceutical, medical device and biologics companies have relied on for more than 20 years.



21 CFR Part 11- and EU Annex 11-compliant

More than 600 pharmaceutical, medical device and biologics companies have relied on ComplianceWire® technology, curriculum and services for more than 20 years. Our comprehensive compliance training software integrates four critical components:

Software

ComplianceWire® is a robust and scalable LMS that facilitates the management of training activities, learner proficiency and compliance status.

Education

Custom coursework and knowledge assets include a standard library of more than 450 life science courses, including 110 that we developed with the FDA.

Experts

Our professional service team assists in assessing organizational and infrastructure needs, ensuring seamless integration with other quality systems, e.g., document management, human resource information systems, single sign-on, etc.

Easy content authoring

UL Create™ is an easy-to-use SCORM-compliant content authoring and editing tool.

Focused on validation

ComplianceWire® is a fully validated LMS that assesses compliance with 21 CFR Part 11 and EU Annex 11 LMS requirements.

Equally valuable to life science organizations, ComplianceWire® supports the quality and validation constructs defined by Good Automated Manufacturing Practices (GAMP®) and GxPs, including:

- Electronic signatures and records
- Audit logs
- Record versioning
- Data security
- Fully documented software development life cycle (SDLC)
- Robust quality system for software development and testing

FDA-authored curriculum

ComplianceWire® targets learners' diverse needs, regardless of their language, culture or education level. We develop these resources through our relationships with the FDA and nationally recognized subject matter experts with experience in life science research and development, manufacturing, clinical operations, compliance, training and business operations.

Courses include:

- FDA-authored and/or reviewed courses identical to those the FDA uses to train its inspectors and investigators
- Standardized courses on issues regulated by federal agencies, including the FDA, ICH, OSHA, CMS and HHS
- Curricula focused on workplace subjects ranging from employee confidentiality to sexual harassment, site security, health and safety
- Customized, company-specific courses, including codes of conduct, reinforcement of corporate culture and issues related to specific drugs or devices



Manage creation and distribution of standard operating procedures (SOPs)

Critical Information Control System® (CICS)

Distribute SOPs, corporate policies, forms, surveys and routine communications with a documented electronic receipt and tracking to employees, suppliers and contractors. Create quizzes and link them to SOPs and critical documents to test material comprehension.

ComplianceWire®

Receive e-acknowledgment from employees to signify receipt of these critical documents or enable an e-signature for employees to sign off on their understanding of the information in a validated Part 11-compliant environment. This technology creates an auditable record of all activity associated with your critical information.

Gain versatility and flexibility

Manage multiple training items within numerous locations and departments.

ComplianceWire® can also address these top challenges:

- Maintain an unlimited set of training items and curricula with full support for versioning, change control, 21 CFR Part 11 and EU Annex 11.
- Link related training items to meet knowledge or compliance requirements and assign these curricula to specific job roles. Employees who transfer to new job roles will automatically receive further training.
- Implement existing learning methods for a blended system that includes instructor-led, classroom, on-the-job and mentoring components.
- Supplement best-practice, compliance-driven courses with internal content to assure conformance with company-specific procedures.
- Create custom quizzes and exams and easily assign them to end users to display on their to-do pages, along with courses, SOPs and other third-party materials.
- Maintain full audit trail capability per 21 CFR Part 11 and EU Annex 11 with complete, chronological histories of user activities.
- Leverage robust reporting for users, administrators and managers against a wide range of metrics.

Leverage the latest technology and adult learning principles

UL Solutions develops courses through our proprietary instructional design and technology process, which employs learning principles and a user interface design that maximizes the understanding and retention of information.

Our mastery learning approach requires users to interact with the content and demonstrate proficiency to advance through the course and become qualified.

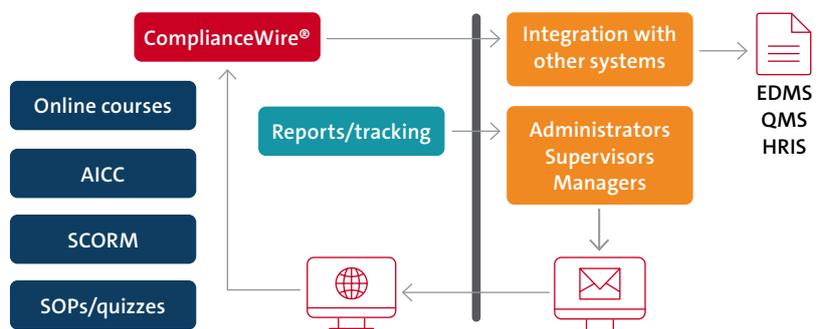


SaaS model benefits

Software as a service (SaaS) offers engineered knowledge services. This hosted model allows ComplianceWire® to maintain validation constructs with the hardware, software, security and personnel required to deliver fully validated services.

- Significantly reduce capital investments and operational commitments.
- Our 24/7/365 data center delivers high availability with redundant systems and best-in-class security.

Integration that leverages your existing technology



ComplianceWire® is interoperable with standard enterprise systems, including HRIS, document management, QMS, ERP, MES and SSO systems. It automatically solves the compliance challenge of properly distributing and tracking SOPs and other critical documents — and changes to those documents — in a timely manner.

After integrating ComplianceWire® with your current document management system, updates automatically trigger actions for employees. Once alerted, they must not only read but also demonstrate understanding, thus increasing operational efficiency and document-based compliance.

ComplianceWire® assigns training items, including SOPs stored in a third-party document management system, to users by individual user attributes, custom-defined groups and/or organizational hierarchy.

Extend compliance learning securely to nonemployees

Anyone with a web browser can access ComplianceWire®'s SaaS application, which can help you manage your employees' compliance, as well as that of outside physicians, clinicians, suppliers and subcontractors, all from a single web-based location.

This maintains your network security since user activity occurs outside your company's firewall) while also integrating vital nonemployee compliance information for audit-related purposes.

Provide high-level executive dashboards

Instantly evaluate compliance training effectiveness and take remedial action if necessary with compliance status reports.

Integrate operator certification programs

Implement biometric and card reader systems to ensure that machinery will not operate unless the employee has fulfilled the organization's training curricula and certification programs.

Improve resource planning

ComplianceWire® gives you innovative tools to help identify and address performance:

- Quickly determine the qualification status of a department or employee against any job role requirements.
- Generate what-if scenarios to determine who in the organization is qualified to perform a specific job or role.





UL Solutions

Founded on the principles of safety, science and transformation

For more than 20 years, UL Solutions ComplianceWire® has supported many of the world's leading life science organizations.

- Partnership and service chosen by the FDA, used to train more than 40,000 investigators globally
- Enterprise-wide compliance management service used by both large and emerging pharmaceutical, medical device and biologics companies
- Established network of industry-leading content partners
- Global support with UL Solutions in the U.S., EMEA and Asia Pacific offices
- More than 600 customers in 50 countries
- More than 500 million successful training completions

A powerful combination of technology, content and services

Our comprehensive compliance management approach integrates technology, content and professional services, designed specifically for the life science industry.

- 21 CFR- and Annex 11-validated LMS technology platform – Fully scalable service
- SaaS/cloud delivery – No IT involvement, software updates at no additional cost, support for third-party training
- Readily integrates with critical compliance and business systems including EDMS, HRIS, SSO and MES
- LMS features SOP tracking, performance assessment, learning assessment and on-the-job training (OJT) management
- More than 1,100 off-the-shelf computer-based training modules, including more than 110 authored or reviewed by the FDA
- In-house content development expertise – More than 5,000 custom courses
- More than 3 million users annually with content available in 34 languages
- Developed with responsive design for optimal mobile device experience

ComplianceWire® by UL Solutions

ComplianceWire® is a best-in-class LMS designed specifically for highly regulated industries.

Our LMS effectively and efficiently automates the creation, delivery and reporting of role-based training, qualification and compliance programs for the life sciences industry.

U.S. and global pharmaceutical, medical device and biologics companies have used this time-tested technology for more than 20 years, as have global regulatory authorities in the United States, China and India.

We are a world leader in applied safety science, transforming safety, security and sustainability challenges into opportunities for users in 153 countries. ComplianceWire® provides a variety of training resources to help you achieve regulatory compliance in the manufacture of pharmaceuticals and medical devices. Our safety, data and technology expertise allow businesses to innovate with confidence. With UL Solutions, our science is your advantage.



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