ComplianceWire®

COMPLIANCE MANAGEMENT FOR LIFE SCIENCE ORGANIZATIONS

COMPLIANCE. PROFICIENCY. PERFORMANCE.

ComplianceWire, the best-in-class solution for regulated industries, is a powerful, Part 11 compliant and fully validated LMS relied on by Pharmaceutical, Medical Device and Biologics companies to help improve productivity and reduce risk. ComplianceWire is the same platform chosen by the FDA to train more than 36,000 global, federal, state and local investigators.

Astute business leaders recognize regulatory compliance as a practical roadmap for improving business value. They know that 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 increases the organization's competitive edge through proactive compliance, risk-adverse performance and enhanced bottom-line productivity.

Learning Technology Chosen by the FDA... and Trusted by Industry Leaders

When the FDA was challenged to ensure the proficiency of more than 35,000 federal, state and local investigators, the Agency chose UL EduNeering's compliance training solution under a unique Cooperative Research and Development Agreement (CRADA). This solution integrates the ComplianceWire web-based Platform with curriculum we co-develop with the FDA. The same technology Platform and coursework used by the FDA in its virtual university are available exclusively to UL's customers.

Talent Management

Solutions for Regulated Industries

- Performance Management
- Succession Management
- Goal Management
- Skills Development
- Compliance Features
- Leadership Development

ComplianceWire™

Improve Performance from the Executive Floor to the Shop Floor

Build Your Leaders
Develop Your Skilled Workforce
...with one solution.

Powerful, Part 11 Compliant and Fully Validated

More than 90 Pharmaceutical, Medical Device and Biologic companies rely on UL's technologies, curriculum and services every day. Our comprehensive compliance training solution integrates three critical components:

- ComplianceWire, a robust and scalable Learning Management System (LMS) on the UL Platform that facilitates the management of training activities, learner proficiency and compliance status.
- Knowledge assets that include a standard library of more than 450 Life Science courses, including 110 developed by the FDA and UL, as well as custom coursework created for individual companies.
- Professional service teams that assist customers by assessing organizational and infrastructure needs, ensuring the seamless integration of your compliance management solution.

Focused on Validation, 21 CFR Part 11 Quality

ComplianceWire is a fully-validated knowledge and LMS that ensures compliance with 21 CFR Part 11 requirements. Equally valuable to Life Science companies, it supports the quality and validation constructs defined by Good Automated Manufacturing Processes (GAMPs) and GxPs, including:

- Electronic signatures and records
- Audit logs
- Record versioning
- Data security
- Fully documented Software Development Life Cycle (SDLC)
- Quality systems

FDA-Authored Curriculum

UL's learning resources are developed 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. Our courses target the diverse needs of learners regardless of language, culture or education, and include:

- FDA-authored and/or reviewed courses identical to those used by the FDA to train its inspectors and investigators.
- Standardized courses on issues regulated by federal agencies including the OIG, SEC, EPA, OSHA 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.

"Regulatory compliance is the centerpiece of risk management and governance in the Life Science industry. Firms that fail to comply with regulations – and a growing number of financial assurance and legal precedent requirements – set by these agencies, will suffer shutdowns in manufacturing operations, product withdrawals, fines, lawsuits, revenue loss and tarnished reputations. Operational risk, as well as regulatory compliance, places a greater burden on pharma risk managers ..."

Pharma Risk Managers:
ERM Is in Your Future, Forrester Research

"Life Science companies appear to not be taking full advantage of better communication and guidance from the FDA. One-half of Life Science firms overall, and nearly two-thirds of Medical Device companies surveyed (62 percent), admitted that they are not incorporating the Agency's feedback into their product development progress. In addition, a significant number said they do not participate in stage review meetings, especially later in the product approval process."

Pharma 2020: The Vision – which path will you take?, PriceWaterhouseCoopers

BENEFIT FROM THE LATEST TECHNOLOGY AND ADULT LEARNING PRINCIPLES

Courses are developed through UL's proprietary instructional design and technology process, which employs learning principles and a user-interface design that maximizes the understanding and retention of information.

Courses are developed using a "Mastery Learning" approach that requires learners to interact with the content and demonstrate proficiency in order to advance through the course and become qualified on the content.

All materials conform to the US Federal Government section 508 guidelines, providing visual or hearing-impaired users' access to the same instructional material as their nonimpaired peers. And courses are narrated, as research suggests that learners often listen at a higher level than they are able to read.

Manage Creation and Distribution of SOPs

- Our widely used Critical Information Control System© (CICS) enables companies to manage the distribution of SOPs, corporate policies, forms, surveys and routine communications with documented electronic receipt and tracking to employees, suppliers and contractors. Quizzes can be created and linked to SOPs and critical documents, so that you can test understanding of the material.
- ComplianceWire also enables you to receive "e-acknowledgement" from employees to signify receipt of these critical documents, or an "e-signature" for employees to sign off on their understanding of the information in a validated, Part 11-compliant environment. Leveraging this technology, you gain an auditable record of all activity associated with your critical information.

Manage the Most Complex Training Assignments

ComplianceWire provides the versatility and flexibility to enable you to manage multiple training items within multiple locations and departments. Leveraging the ComplianceWire Platform, you can address these challenges:

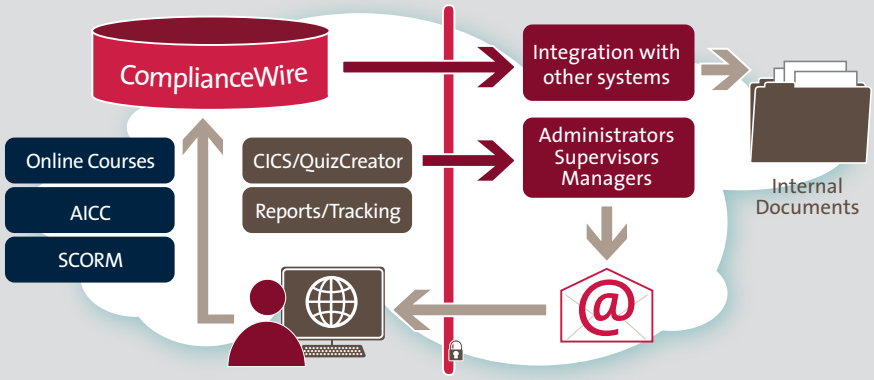
- Maintain an unlimited set of training items and curricula with full support for versioning, change control and 21 CFR part 11 requirements.
- Link related training items to meet any knowledge or compliance requirement, and assign these curricula to specific job roles, so when employees transfer to new job roles, they will automatically receive new training.
- Leverage a single device to manage 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 to company-specific procedures.

- Build your own electronic quizzes and exams, and assign these items so they display in the end users' "To-Do" pages alongside courses, SOPs and other third party materials.
- At a moment's notice, you are a mouse click away from a complete, chronological history of end user activity, as ComplianceWire maintains full audit trail capability in accordance with 21 CFR Part 11.
- Robust reporting for users, administrators and managers against a wide range of metrics.

Benefit from the SaaS Model

Our engineered knowledge solutions are offered via a Software as a Service (SaaS) model. This widely-used outsourcing model allows UL to design and maintain the computer hardware, software, security and personnel we need to deliver our solutions. And our customers significantly reduce capital investments and operational commitments. UL's 24/7 data center delivers 99.99 percent up time with redundant storage, backup power and best-of-breed security.

INTEGRATION THAT STRENGTHENS YOUR EXISTING APPLICATIONS



ComplianceWire is interoperable with industry-standard systems, including HRIS, document management, clinical trials, ERP, MES and other LMSs.

For example, by integrating a document management system with ComplianceWire, an update to a document automatically triggers actions for employees. This solves the compliance challenge of how to properly distribute and track SOPs and other critical documents – and changes to those documents – in a timely way. Once alerted, employees must not only read, but also demonstrate understanding – thus increasing operational efficiency and document-based compliance.

With ComplianceWire, you gain the ability to assign 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.

ComplianceWire Learner's App for iPad

Empower your workforce on the go like never before using the world's most popular mobile tablet. With UL EduNeering's ComplianceWire Learner's App, your employees have access to their ComplianceWire To-Do List, but with the natural touch-and-feel and convenience of a mobile device. UL EduNeering's Learner's App supports ComplianceWire's functionality including CICS, quizzes, exams, forms, electronic signatures, EduFlex courses and AICC courses.

Learn more at uleduneering.com/ComplianceWire_for_iPad

Extend Compliance Learning Securely to Nonemployees

If you are responsible not only for the compliance of your own employees, but also physicians, clinicians, suppliers and subcontractors, you can leverage the SaaS model inherent with ComplianceWire. The solution can be ideal, as it maintains your network security (user activity occurs outside your company's firewall) while also integrating vital nonemployee compliance information for audit-related purposes.

Provide High-Level Executive Dashboards

ComplianceWire provides "compliance status snapshots" so that senior managers can instantly evaluate compliance training effectiveness – and take remedial action if necessary.

Integrate Operator Certification Programs

ComplianceWire enables you to integrate training curricula with established operator certification programs using biometrics and card reader systems, so that machinery will not operate unless the employee has fulfilled training assignments as defined by your organization.

Improve Your Manpower Planning

With ComplianceWire, you gain innovative tools to help you identify and address performance.

For example, our User Qualification reports enable you to quickly determine the qualification status of a department or employee against any job role requirements.

You can also generate "What if" scenarios to determine who in the organization is qualified to perform a specific job or role.

THE UL EDUNEERING DIFFERENCE

A Company Founded on the Principle of Compliance and a Solution Chosen by Global Industry Leaders

For over 30 years, UL EduNeering has provided solutions to many of the world's leading Life Science companies.

- Partnership and solution **chosen** by the **FDA**, used to train over 36,000 investigators globally.
- Enterprise-wide compliance management solution used by **large companies** such as Johnson & Johnson, Stryker and Teva as well as **small/emerging** Biomedical and Medical Device companies.
- Established network of industry leading partners including **AdvaMed**, **DIA** and **CrossKnowledge**.
- Brandon Hall Research Award for **Best Compliance-Based Learning Management System** for the past 6 years.
- **Global** support with UL offices located in the US, EMEA and Asia Pacific.
- Over **400 customers/1 million learners** in 50+ countries.

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 solution.
- **Built-in Talent Management Tools**
- **SaaS/Cloud Delivery and mobile-ready** – includes software updates and supports third party training.
- Readily integrates with **critical compliance** and business systems including **EDMS**, **HRIS** & **MES**.
- LMS features **SOP tracking**, performance assessment, learning assessment and **OJT management**.
- **Over 500 off-the-shelf** computer-based training modules, including over 125 authored or reviewed by the FDA.
- **200+ Instructor-led** classes available globally.
- In-house expertise for content development: **3,000+ custom courses**.
- **Over 1 million users** annually with content available in 30+ languages.

About UL EduNeering

UL EduNeering is a division within the UL Ventures business unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

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®. In addition, UL offers a talent management suite that provides companies the ability to improve workforce skills & competencies within established role-based talent training programs to drive business performance.

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, 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.

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