



Compliance and Quality Learning Solutions

FOR PHARMACEUTICAL COMPANIES



Enterprise-Wide Quality Learning Management Solution focused on:

- *Quality, Regulatory and Health Care Compliance*
- *Audit-ready, Real-time Training Distribution and Reporting*
- *Unique US FDA-Authored Courses*
- *21 CFR Part 11-compliant LMS used by the US FDA and more than 250 Life Science Organizations*

Addressing Your Regulatory Priorities

Today's Pharmaceutical industry operates within a global supply chain, in which manufacturing, packaging, handling, storage and distribution operate independently. The pressure to remain competitive, yet meet quality standards, has become quite challenging. That's why leading Pharmaceutical companies of all sizes trust UL EduNeering's unique combination of online course libraries, award-winning cloud-based Learning Management System (LMS) and professional services. This enables Pharmaceutical companies to seamlessly achieve global regulatory and company-specific requirements across their organizations and supply chains.

Customers leverage these solutions to assure qualification and certification of employees and third parties.

Validated, Audit-Ready System Used by the US FDA

For more than 15 years, under a unique partnership with the US FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation, tracking and 21 CFR Part 11-compliant technology system for ORA-U, the US FDA's virtual university.

Since that time, over 36,000 federal, state, local and global investigators have been trained in quality and compliance. UL provides the only LMS designed specifically to address the unique regulatory needs of US FDA-regulated organizations.

Your quality, manufacturing and regulatory personnel will be able to generate reports that answer questions asked by investigators, such as:

"How have work processes been documented to identify skill-based job tasks and operations?"

"How are employees retrained on a SOP if critical changes have been made or if you have responded to a corrective action?"

"How is ongoing compliance training accomplished for existing, new and subcontractor staff?"

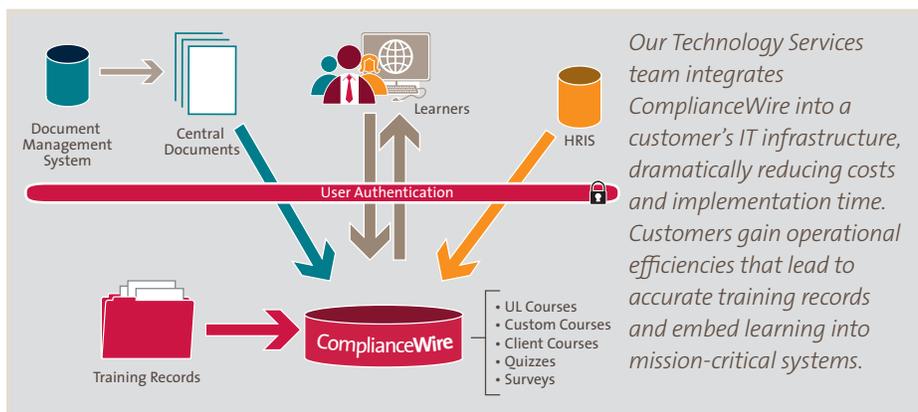


Benefits of Partnering with UL

Exceeding the Minimum Requirements for Training and Qualifications

UL's ComplianceWire® LMS supports the rigorous quality and validation constructs defined by Good Automated Manufacturing Processes (GAMPs) and GxPs. ComplianceWire helps organizations manage the distribution and recordkeeping of critical learning information, providing the ability to:

- **Capture multiple training types** and organize them into well-defined curricula, including control documents, computer-based training, on-the-job training, assessments, stand-alone exams, podcasts and more.
- **Automate training by linking assignments** directly to your own internal documents, such as SOPs and other critical policies and track versions automatically (by integrating with document management systems).
- **Ensure targeted, role-based training assignments** by defining employees into learner groups based on job role or function.
- **Manage the training of employees** and nonemployees on a single platform, segmented by security permissions.
- **Improve employees' experience** as the cloud model enables learners to take courses and to review and sign-off on documents, anytime and from any location via the internet.
- **Reduce strain on the IT department** as the cloud computing model reduces the time and resources needed to perform system validation.
- **Give learners visibility** into their progress by enabling employees to review their training history and view other learning plans via an online catalog.
- **Document all learning and compliance activities** in audit-ready format, with easy access to designated personnel for program supervision and examination by inspectors.
- **Generate reports** during audits and customize audit reports that retrieve critical content stored in ComplianceWire.





US FDA Enforcement and GMP Course Libraries

Gain Deeper Insight into US FDA Expectations

UL's US FDA-authored computer-based training courses facilitate new hire, ongoing and refresher training. These courses reflect the US FDA's most current requirements, priorities and policies in the areas of quality systems, import operations, drug safety and more. Nearly a dozen courses also include European Union (EU) regulations. Your organization can also take the same US FDA courses delivered to US FDA and European Medicines Agency (EMA) inspectors, so that your teams will know what to expect – and how to react – during an inspection.

In addition, our 90-course Pharmaceutical GMP Library includes courses reviewed by the US FDA. They cover topics such as process validation, process controls, corrective and preventive actions, documentation, care and handling of drug product components, maintenance and cleaning of drug manufacturing equipment, principles of aseptic processing and batch record reviews.

Deliver Insights into ICH Guidance

Our library includes courses on specific areas of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), which brings together the regulatory and industry authorities of Europe, Japan and the United States.



For 15 years, UL has had a unique partnership (CRADA) with the US FDA, under which it developed and maintains the Office of Regulatory Affairs's online university (ORA-U). Comprised of ComplianceWire, our award-winning 21 CFR Part 11 LMS and 120 online courses, that same solution is used by more than 250 Life Science companies globally.



Provide your quality, manufacturing and regulatory teams with access to GMP courses to help them grasp the importance of US FDA regulations and to understand expectations of the US FDA's and global regulatory inspection processes.



Automate SOP Training Management

SOPs are the backbone of consistent GMP compliance. UL helps you build an effective SOP management program, assuring that all responsible employees and external parties receive, comprehend and apply the information needed to comply with GMPs and other critical information and documents.

Our Critical Information Control System® (CICS) tool enables Pharmaceutical companies to manage the distribution of any electronic material with documented electronic receipt to employees, vendors and suppliers. With CICS, you can perform

the following training related to control documents:

- **Assign** critical information to employees and suppliers;
- **Deliver** the electronic file directly to learners, with new versions of SOPs automatically reassigned;
- **Acknowledge** receipt and understanding by having learners electronically sign off that they understand the material;
- **Document** the assignment completion for easy retrieval;
- **Manage** reports/audits as standard and custom real-time reports are always available for distribution.

Create SOP Assessments

QuizCreator is the fast, convenient way to measure your learners' understanding of the control documents they've just read. Without any programming skills required, your trainers can create quick assessments that measure proficiency of the material and attach them to each SOP. The combination of CICS and QuizCreator provides assurance that SOP training was effective, understood and completed with a level of competence for a learner to be qualified.

Additional Compliance Course Content Libraries

Global Clinical

Our Global Clinical and Regulatory Libraries cover underlying Good Clinical Practice (GCP) concepts as well as specific, advanced information for clinical professionals based on their role in the study. The global curriculum includes courses describing US FDA regulations, EU directives and ICH guidance; many feature course content provided by the US FDA.

US FDA Inspections and Enforcement

By taking one or more of these US FDA-authored courses, employees can gain a better understanding of US FDA's activities related to inspection and enforcement, which has led to a more proactive compliance program and a more prepared audit response.

HR Compliance and Risk Management

HR Compliance and Risk Management courses use a multi-tiered concept focused on the respective concerns of managers/supervisors, employees and HR professionals.

Sales and Marketing (Health Care Compliance)

Our Sales and Marketing Library can be delivered to regulatory, legal, sales and marketing professionals who must understand the latest government regulations and guidelines such as PhRMA Code promotional guidelines and interactions with Health Care Professionals (HCPs).

Ethics and Corporate Responsibility

The Library provides a highly unique approach to Code of Conduct training and focuses on general industry risk areas such as Conflicts of Interest, Accurate Books and Records, Harassment and Discrimination, Intellectual Property, the Foreign Corrupt Practices Act (FCPA), Global Anti-bribery and much more.

About UL EduNeering

UL EduNeering is a business line within UL Ventures. 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-enabled knowledge solutions for helping to assure regulatory compliance and improve business performance. For more than 30 years, the company has served corporate and government clients in the Life Science, Health Care, Energy and Industrial sectors using our award-winning learning management platforms, unique regulatory and business content and professional services.