ComplianceWire® learning management system

Empowering Trust®

ComplianceWire® is the best-in-class web-based platform designed specifically for highly regulated industries. Built from the ground up, our team designed the platform to effectively and efficiently automate the creation, delivery and reporting of your role-based training, qualification and compliance programs.

Known as the gold standard learning management system (LMS) for the life science industry, this time-tested technology is used extensively by U.S. and global pharmaceutical, medical device and biologics companies as well as global regulatory authorities in the United States, China and India.

The learning management technology chosen by the FDA

For over 20 years, ComplianceWire®, as well as UL's life science e-learning courses, have been the trusted learning solution used by the U.S. Food and Drug Administration (FDA) to train more than 36,000 global, federal, state and local investigators. The agency chose the ComplianceWire® platform as their training solution to ensure the proficiency of their investigators under a unique cooperative research and development agreement (CRADA). This solution integrates the ComplianceWire® web-based platform with curricula UL co-developed with the FDA. The same technology platform and coursework used by the FDA in its virtual university are available exclusively to UL's customers.

Compliant with 21 CFR Part 11 and EU Annex 11 validation requirements

As part of the implementation, customers receive validation summary reports, Part 11 white papers, audit with our quality team, and validation test scripts.

Employees can be automatically sorted into training groups based on criteria such as job function. The functionality governs the role-based training process. Automated version control lowers the risk of human error from manually performing multiple version reconciliations and updating a library of constantly changing standard operating procedures.

Backed by life sciences online training content

ComplianceWire® is built to support AICC and SCORM learning content. Our professional development education training courses carefully target the diverse needs of learners, regardless of industry, language, culture or education:

- FDA-authored and/or reviewed courses identical to those used by the FDA to train its inspectors and investigators
- More than 600 life science industry courses off-the-shelf, including 100+ co-developed with the FDA
- Standardized courses on issues regulated by federal agencies including the OIG, SEC, EPA, OSHA and HHS
- Curricula focused on critical workplace subjects ranging from employee confidentiality to sexual harassment, site security, health and safety, and data integrity
- Customized, customer-specific courses including:
    - Code of Conduct
    - Corporate culture
    - Industry-specific regulations

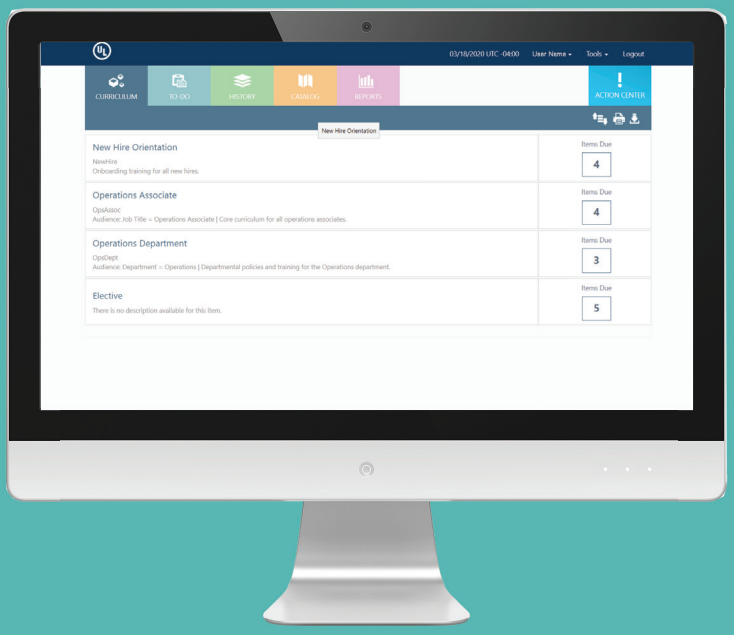
Assignment-based training functionality

- Audit trails on critical assignment activities
- Flexible security roles
- Real-time electronic signatures on assessments and SOPs
- Real-time reports for managers and administrators
- Record protection
- Role-based assignment functionality
- Secure integrations with essential enterprise systems
- Version control of training items
- Visibility into training status

Reporting

Access hundreds of off-the-shelf reports in ComplianceWire® to easily view assigned training, status, administrative views of compliance and qualification statuses, and more.

- Provide details on the orientation training that describes GMP regulations and instructions
- Demonstrate that work processes have been documented to identify critical skill-based job tasks and operations
- Demonstrate how employees receive retraining on an SOP (procedure) if critical changes have been made in the procedure, or if in response to a corrective action
- Indicate how ongoing, periodic GMP training is accomplished
- Show all training assigned and the status of each training item for employees
- Demonstrate that on-the-job training was performed for each function to be performed (before the employee is allowed to perform such tasks)
- Present training documentation that indicates training dates, training content and the signature of the employee and the trainer
- Demonstrate training records are readily retrievable, easily determine what training an employee has received, which employees have been trained on a specific procedure, or have attended a training program

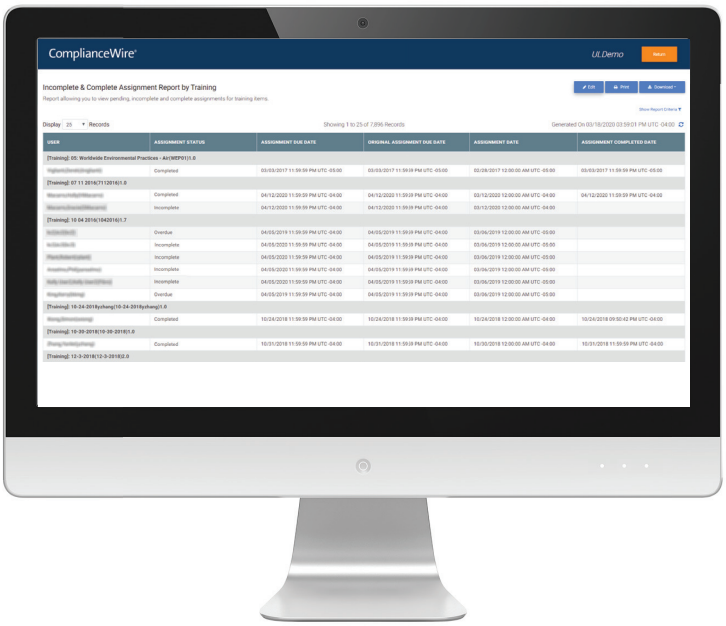


Platform integration to strengthen existing applications

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 the creation and/or update of the training item associated with the document, as well as the real-time training actions for your learners.

This solves the compliance challenge of how to properly distribute and track training to SOPs and other critical documents — and the changes to those documents — in a compliant, effective and efficient way.

ComplianceWire® Application Programming Interface (API) provides the building blocks needed to create integrations across systems. Developers have access to API information on-demand.



CONTACT US TODAY

To learn more about how to achieve enterprise-wide compliance, quality and performance goals with ComplianceWire® LMS, visit ULpurelearning.com or call +1.609.627.5300 to speak with one of our LMS product specialists. **Visit ulehss.com**

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