# ComplianceWire

Industry-leading, validated GxP and FDA 21 CFR Part 11 compliant Learning Management System (LMS) for life sciences training and qualification management.

https://www.ul.com/software/compliancewire-gxp-training-and-qualification-management

## Overview

ComplianceWire, part of the ULTRUS™ platform by UL Solutions, is a powerful, cloud-based Learning Management System (LMS) designed specifically for highly regulated industries, primarily life sciences (pharmaceutical, medical device, and biologics companies). It is widely regarded as the 'gold standard' LMS in the industry, relied upon by over 600 organizations and regulatory authorities, including the U.S. Food and Drug Administration (FDA) since 1999 under a unique Cooperative Research and Development Agreement (CRADA).

**Key Benefits & Compliance:**

**Audit Readiness:** The system is natively compliant with FDA 21 CFR Part 11 and EU Annex 11 validation requirements, providing out-of-the-box reports and a full electronic audit trail to confidently respond to internal and external regulatory inspections.
**Risk Mitigation:** It automates the creation, delivery, and reporting of role-based training, qualification, and compliance programs, ensuring employees are qualified to perform their job functions.
**Scalability:** The platform is scalable to manage complex training assignments across multiple locations, departments, and even non-employees like contractors and suppliers.
**Main Features and Capabilities:**

**Role-Based Assignment:** Automatically assigns training items (including SOPs from third-party systems) based on individual, user attributes, custom groups, or organizational hierarchy.
**Electronic Signatures & Audit Trails:** Provides real-time electronic signatures on assessments and SOPs, maintaining a complete, chronological history of end-user activity in accordance with 21 CFR Part 11.
**Content Management:** Includes a comprehensive GxP e-learning course library (400+ life sciences courses) and a built-in authoring tool (UL Create) for creating and customizing internal content, quizzes,

and exams.
**Reporting & Analytics:** Offers robust, real-time reports and “compliance status snapshots” for managers and administrators to instantly evaluate training effectiveness and compliance status.
**Mobile Learning:** Supports a responsive, mobile-friendly interface for users to complete courses on phones and tablets.

## Key Features

- FDA 21 CFR Part 11 Validation
- Role-Based Training Assignment
- Electronic Signatures
- Audit Trails and Logging
- Real-Time Compliance Reporting
- Built-in Course Authoring (UL Create)
- Version Control and Change Control
- GxP E-Learning Library (400+ courses)
- SSO (SAML) Integration

### Pricing

**Model:** subscription

Scalable, per-user subscription model. Pricing is customized based on workforce size, regulatory environment, training volume, and implementation scope. One source suggests a starting price of $15.00 per user/year.

**Starting at:** USD $15

**Target Company Size:** small, medium, enterprise

## Integrations

HRIS, EDMS (Document Management System), ERP, MES, Clinical Trials Systems, Other LMSs

## Compliance & Certifications

FDA 21 CFR Part 11, EU Annex 11, GxP, HIPAA, ISO Compliance, OSHA Compliance

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