Life & Health

Quality, Compliance and Learning Solutions

FOR BIOTECHNOLOGY COMPANIES

Enterprise-Wide Learning Management Solution Focused on:

- *Quality, Regulatory and Health Care Compliance*
- *Training Distribution and Reporting*
- *Unique FDA-Authored Courses*

Addressing Regulatory Priorities

The Biotechnology industry continually redefines medicine. Innovative technologies and therapies prevent, detect, diagnose and treat diseases that often defy established drugs and devices. Biotech companies at every stage of research, development, approval and commercialization face compliance and business risks that can be mitigated by education and documentation:

- Regulatory compliance (FDA, global)
- Good Manufacturing Practices (GMPs) and Quality Systems
- Good Clinical Practices (GCPs), Good Laboratory Practices (GLPs) and data integrity
- Staff proficiency, communication, training and development
- Subcontractor/third party monitoring and compliance

UL EduNeering's unique combination of online course libraries, award-winning Learning Management System (LMS) and technology services enables Biotech companies to seamlessly achieve global regulatory and compliance requirements across their organizations and supply chains.

Validated, Audit-Ready System Used by the FDA

For more than 15 years, under a unique partnership with the United States 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 FDA's virtual university.

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

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:

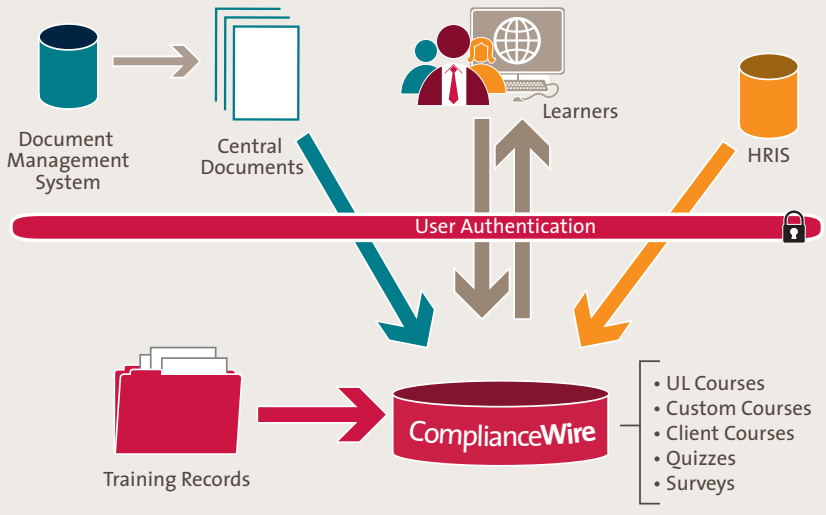
- **Capture multiple training types** and organize them into well-defined curricula, including control documents, computer-based training, on-the-job training, assessments, stand-alone exams, podcasts and more;
- **Manage the training of employees** and nonemployees on a single platform, segmented by 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;
- **Ensure targeted training** assignments by defining employees into learner groups based on job role or function;
- **Customize system administrative privileges** that align with your security goals, so that department trainers, managers and other personnel can receive security clearance within the system;

Your quality, manufacturing, compliance 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?"



Our Technology Services team integrates ComplianceWire into a customer's IT infrastructure, dramatically reducing costs and implementation time. Customers gain operational efficiencies that lead to accurate training records and embed learning into mission-critical systems.

- **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);
- **Give learners visibility** into their learning 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;
- **Meet 21 CFR Part 11** and Annex 11 requirements for electronic signatures.

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

FDA Enforcement and GMP Course Libraries

Gain Deeper Insight into FDA Expectations

UL's FDA-authored, online training courses facilitate new hire, ongoing and refresher training. These courses reflect the FDA's most current requirements, priorities and policies in the areas of quality systems, import operations, drug safety and more. Your organization takes the same FDA courses that are delivered to the FDA and global investigators, so that your teams will know what to expect – and how to react – during an inspection.

Our Good Manufacturing Process (GMP) and Regulatory Libraries cover topics such as process validation, process controls, corrective and preventive actions, documentation, pharmacovigilance and adverse event reporting, care and handling of drug product components, maintenance and cleaning of manufacturing equipment, principles of aseptic processing and batch record reviews, and much more.

Deliver ICH Guidance Knowledge

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.

A COMPLIANCE SOLUTION TAILORED FOR SMALL AND EMERGING COMPANIES

There is no "one-size-fits-all" compliance solution, even though all Biotech companies face the same regulatory requirements. Small and emerging companies, often with limited financial and staff resources, benefit from streamlined compliance and learning programs that target their needs without adding unnecessary functionality and expense. Our EduXpress compliance solution is tailored for small and emerging companies, enabling companies to:

- Educate on a wide range of regulatory and industry required topics
- Distribute, validate and document compliance training online
- Deliver audit readiness programs
- Manage and report on training records
- Create the framework for expanded functionality when needed

Additional Compliance Course Content

Clinical Libraries

Our Clinical Course Library can be used by both employees and study personnel for both core Good Clinical Practice (GCP) topics as well as role-based topics for investigators, site coordinators and more.

Sales and Marketing Library (Health Care Compliance)

This Library is focused on issues ranging from global anti-bribery, proper interactions with Heath Care Professionals and promotional practices, to compliance with the PhRMA Code and off-label promotion. Additionally, we have a robust Ethics Library and broad expertise in Code of Conduct development and training.

Environmental Health and Safety

Our Library covers subjects including bloodborne pathogens, hazard communications, workplace safety, fall protection and more.

AUTOMATE SOP TRAINING MANAGEMENT

SOPs are the backbone of consistent GMP compliance. UL enables you to 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 Biotech 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.