



## 2013 Life Science Case Studies



Life & Health





# EXECUTIVE SUMMARY: Achieving Health Care Compliance

Since 2011, the trends among leading Life Science companies have included:

- Standardizing global job functions
- Managing risks related to third parties
- Providing leadership and development opportunities
- Building employee qualification programs

UL EduNeering focuses on the unique management challenges faced by quality teams, manufacturing, clinical, sales compliance and corporate governance, serving more than 250 Life Science clients worldwide.

These three 2013 case studies represent the most relevant – and critical – projects implemented by our clients in the Pharmaceutical, Biologics and Medical Device industries.



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# Implementing an Enterprise-Wide LMS

Sponsored by the IT Team



“The ComplianceWire rollout was the single most successful project for our team and it is the only system to touch all 7,000 employees.”

## Overview:

The North American headquarters of a global Pharmaceutical company acquired several business units during the prior few years. In an effort to standardize roles and consolidate training and qualifications, company leaders were seeking a single Learning Management System (LMS) to unify its eight operating companies and 7,000 employees.

Leading the LMS evaluation were members of the Information Technology (IT) team. The IT team had shortened the LMS vendor list to two: UL EduNeering and a leading, multinational enterprise software company. After an in-depth review, the IT team recognized that the enterprise software vendor lacked pharmaceutical expertise. Additionally, the IT team estimated that much more programming customization was necessary to achieve the company’s critical business and Good Manufacturing Practices (GMP) functional requirements. Finally, the IT team foresaw a long timeframe for implementing the LMS.

The IT team selected ComplianceWire® as it provided the necessary LMS functionality, ease of implementation, an extensive courseware library and “curricula” wrapper necessary for the customer’s SOPs. ComplianceWire gained an advantage in the IT team’s view, because it was designed from its inception to be 21 CFR Part 11-compliant and has undergone numerous audits by UL’s clients. Because the LMS operates in a cloud computing environment, the validation effort was streamlined, expediting system rollout.

## The Solution:

The LMS implementation spanned all disciplines, from quality and manufacturing to sales, marketing and administration. ComplianceWire was integrated with the company’s HRIS and EDMS systems from project inception. The project enabled the company’s entire learning and qualifications program to be moved from a paper-based approach to an online system – including the data migration of historical records.

## The Results:

After the first year, more than 9,000 learners completed more than 230,000 assignments, including over 5,000 UL courses. According to the head of IT, “the ComplianceWire rollout was the single most successful project for our team and it is the only system to touch all 7,000 employees.”



# Achieving Health Care Compliance

## Overview:

A global consumer products manufacturer with 1,000 employees whose products include medical devices was looking to automate a manual, paper-based process of tracking ethics learning and implement a new Code of Conduct training program.

## The Solution:

UL worked with the company to rewrite their Code of Conduct, incorporating recent Health Care compliance requirements and implement a five-year “skill-building” training program. During the second year of the program, UL is developing two Raising and Resolving Ethical Issues courses, one for managers and the other for nonmanagers. The Code course is being translated and localized for five regional sites.

## The Results:

The company is on track to achieve close to 100 percent adoption for this Code of Conduct training, with positive feedback from employees at all levels. Going forward, the company plans to expand training to include anti-bribery, fair competition and conflicts of interest.

## CASE STUDY



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# Building an Enterprise-Wide Role-Based Qualification Program

Sponsored by Quality Assurance



UL was given an “Excellent” rating for technical support and adherence to the project schedule. As a vendor, UL was rated “Outstanding” for exceeding expectations and adapting to the company’s culture.

## Overview:

A global Medical Device manufacturer with nearly 10,000 employees at approximately 20 facilities in North America, Europe and Asia, had been relying on several “departmental” Learning Management Systems (LMS). Global qualification standards were not defined and not easy to consolidate or manage across multiple sites. In addition, the disparate systems were not integrated into the corporate HR system, nor were they integrated with the other content management systems, where SOPs were saved. Managers could not easily identify compliance or knowledge gaps.

## The Solution:

The company chose UL’s ComplianceWire® LMS along with the FDA Inspection and Enforcement, Good Manufacturing Processes (GMPs) and Environmental, Health & Safety (EH&S) course Libraries and also leveraged UL’s technology services to integrate the LMS with the corporate Human Resource Information System (HRIS) and Data Management System (DMS). Leveraging the training matrix defined for a specific facility, the global quality team was able to standardize qualifications based on individual roles.

## The Results:

The system was rolled out to more than 3,000 employees in two of the company’s largest facilities. These assignments revolve around the creation of 1,000 curricula that includes 300 UL off-the-shelf courses, company policies and internal training materials. The company has been able to enforce global qualification standards while identifying knowledge gaps among manufacturing employees. In a report to senior management, UL was given an “Excellent” rating for technical support and adherence to the project schedule. As a vendor, UL was rated “Outstanding” for exceeding expectations and adapting to the company’s culture.





# Transitioning from Paper to Electronic Recordkeeping (Emerging Company)

## Overview:

An American subsidiary of a large Pharmaceutical company based in Asia, which focuses on Central Nervous System (CNS) research, is considered an “emerging company” with roughly 125 employees. In order to manage its regulatory compliance, the project leader explained that the company was suffering from the burdens of “paper chase” training.

All of the training and compliance records were stored as paper files, making it difficult to find the appropriate information during audits and manager inquiries. In addition, many of the records were incomplete and difficult to sort. The company sought an electronic system to replace its outdated record management.

## The Solution:

The company selected ComplianceWire® and UL's Good Clinical Practices (GCP) and Good Manufacturing Processes (GMP) online courses. The project team described the platform as “best-in-class,” given the system functionality's alignment with company requirements.

The three-phase solution was rolled out in just two months:

- Phase 1: Employees received computer-based GxP training via a company-branded site on the ComplianceWire. All training records were captured in the Learning Management System (LMS);
- Phase 2: Employees received company SOP training via the LMS, based on their roles. The project team also saved employee Curricula Vitae (via the CV Builder tool) and historical training records;
- Phase 3: The system was fully integrated with the company's document management system and ComplianceWire.

## The Results:

Before implementation, the customer had no way of assessing its compliance status. With ComplianceWire, they can now measure compliance status in real time, both at a high level and department level, through a single dashboard. Since the launch, 130 learners completed more than 7,000 training assignments. As a result of the Data Management System (DMS) integration, the solution now supports one of the company's critical paths regarding compliance and regulatory obligations. Today, the company manages all of its GxP training records electronically, including tracking its many instructor-led events. The customer has expressed benefits related to ease of set-up, reduced administration time, scalability of the solution and the reduced cost per learner.



The project team described the platform as “best-in-class,” given the system functionality's alignment with company requirements.



## About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

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®.

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, UL 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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