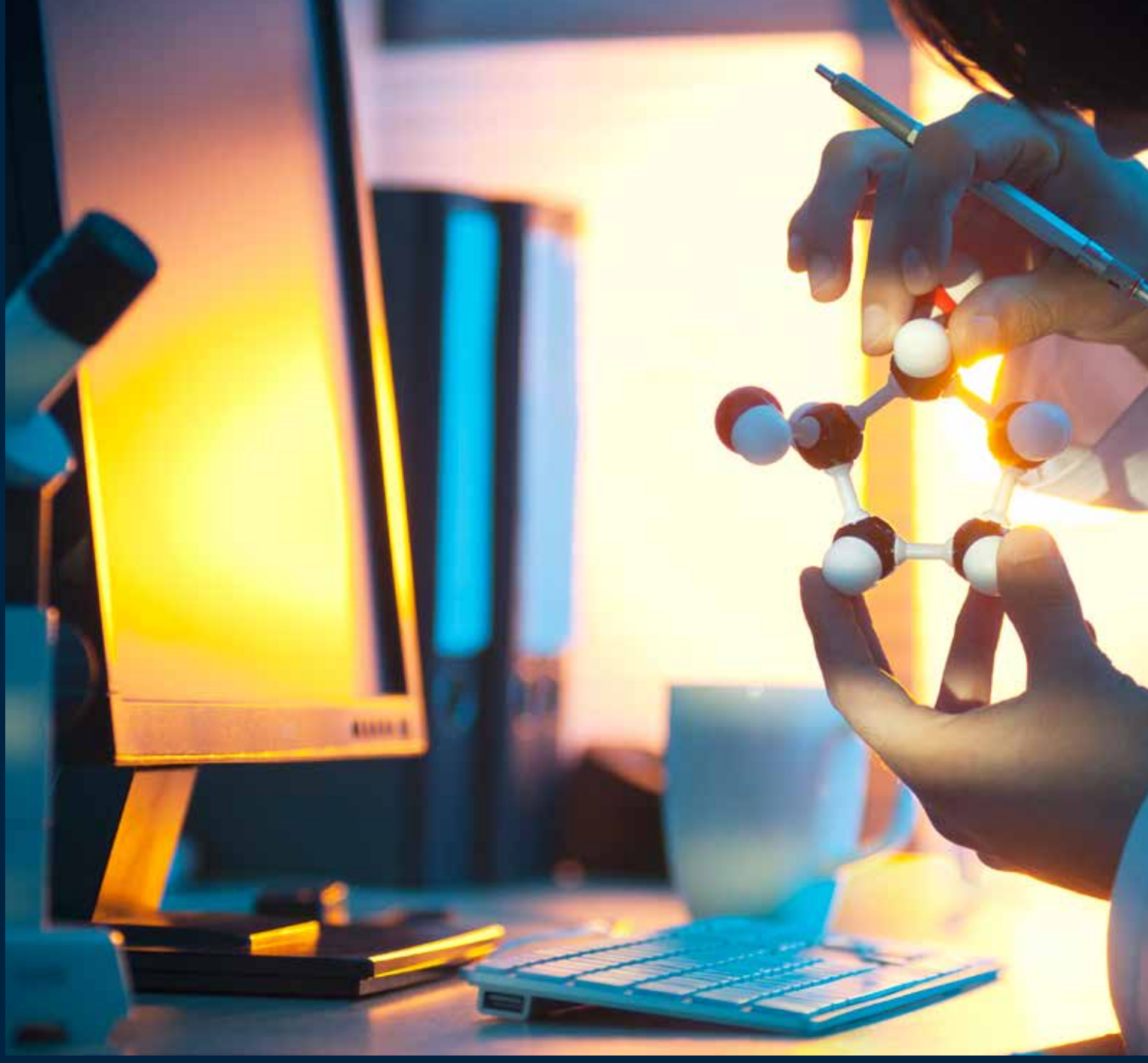

2012 Life Science Case Studies

Life & Health

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EXECUTIVE SUMMARY: Achieving Health Care Compliance

During 2011, the trends among leading Life Science companies included:

- Standardizing global job functions
- Managing risks related to third parties
- Global clinical trial management
- 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 2012 case studies represent 10 of the most relevant – and critical – projects implemented by our clients in the Pharmaceutical, Biologics and Medical Device industries.

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."

CASE STUDY

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.

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Making GCP Training for Clinical Sites More Effective and Efficient

UL has successfully provided compliance training for employees in North America since 2002.

Overview:

An international Pharmaceutical company headquartered in Europe markets its products in 179 countries, with nearly 30,000 employees in more than 70 countries. To meet both its internal policies and FDA regulations, the company wanted to ensure that its key clinical site personnel are trained in Good Clinical Practices (GCPs). Key clinical site personnel include Principal Investigators, Sub-Investigators and Site Coordinators. Traditionally, GCP training was conducted during in-person investigator meetings, but with regulatory requirements becoming more stringent and complicated, and with rapid expansion of trials and trial sites, in-person training was no longer cost-effective. The company sought a training solution that could be managed internally and also provide key stakeholders with visibility into GCP compliance.

The Solution:

The company selected UL's Learning Management System (LMS) because of our track record in providing off-the-shelf clinical content via a web-based solution. Most important, the online program reduced the overall cost per learner.

The Results:

After the company's internal Clinical Operations team received the training via ComplianceWire®, the program was deployed to clinical sites, with members of the Clinical Trial Operations team serving as system administrators. Since the launch, more than 150 clinical sites have received GCP and protocol training via the LMS, completing nearly 6,000 training items.

The solution has enabled clinical managers to add site personnel via a spreadsheet upload, thus automating the training assigned to researchers based on their role (Investigators, CRA, CRC, etc).

CASE STUDY

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.

Building an Operator Certification Program that Interfaces with ERP and MES

The new operations/ training link helps managers reduce errors related to inadequate training and run operations more efficiently.

Overview:

A global Medical Device manufacturer with 400 production employees had made a significant investment in an Operations Management System (OMS) and Plant Manufacturing Execution System (MES) with an interface to an Enterprise Resource Planning (ERP) system. This system was designed to track the flow of products through the entire production cycle. The company was seeking a way to automate the training verification process for production employees and demonstrate proficiency prior to using the equipment. The project team also identified the need to verify training against multiple curricula, making the training matrix issue a bit more complex. What was needed was a "real-time" link from the operator logging into the OMS, to the ComplianceWire® Learning Management System (LMS), where the training records were stored.

The Solution:

UL helped ComplianceWire "talk" to the MES or ERP, which integrates into a wide range of manufacturing control systems. Now, when the production employee logs on to the equipment, the system sends a query to ComplianceWire to verify that the employee attended the basic company orientation training and has read the equipment-specific curriculum SOPs. If the curricula have been completed, the employee gains access to the equipment. Conversely, if the employee's record shows a training deficiency, the equipment will not turn on. The training matrix includes 1,200 curricula to cover the company's multiple products and operations.

The Results:

The solution, which is use by the planning, quality and engineering departments, automates the operator training verification process. Prior to the implementation, production employees may have operated critical equipment without the proper qualifications. This practice can cause equipment errors, higher rates of product defects and low employee satisfaction. The new operations/training link helps managers reduce errors related to inadequate training and run operations more efficiently. What's more, management reported "zero overdue" training for the operations team. Compliance goals were achieved and product quality was improved.

CASE STUDY

Building a Standardized HCIR Certification Program

Overview:

A global Medical Device manufacturer with 2,000 Health Care representatives (sales personnel) throughout North America was struggling with the time and costs associated with credentialing its personnel. As hospitals and other medical facilities in the United States continue to restrict access of Health Care industry representatives (HCIR) without proof of requisite training and immunizations, this company required a more efficient means of complying with these increasing requirements.

The Solution:

The company used UL's certification program that responds to compliance and health care requirements as defined by such organizations as The Association of Perioperative Registered Nurses and The Joint Commission. The solution electronically notifies sales representatives of all credentialing requirements and relevant curricula in subjects that include Bloodborne Pathogen Exposure, HIPAA Privacy and Operating Room Conduct. In addition, specific information including immunization records and security background checks is documented for each representative. Required courses can be completed by sales representatives at any time and at any location with internet access. Comprehension of coursework is tested and documented, allowing the automatic generation of a Certification Letter that lists completed courses, immunization status and background information in a central transcript.

The Results:

The Safety Certification Letter has been accepted by hospitals nationwide, ensuring that sales representatives have continued access to medical facilities. Equally important, the certification documentation is integrated with third party clearing services now used by many hospitals to manage vendor compliance reporting. To assure continued certification, annual retraining schedules and immunization reminders are automated with the required coursework delivered online to sales representatives at the necessary time.

Note: In 2011, an HCIR certification program was announced as part of a joint effort of AdvaMed, AORN, Mayo Clinic, Medstar, HealthStar and UL. The goal of this program is to reduce the redundancy and inconsistent standards associated with Health Care facility training and safety requirements. The program seeks to define and agree to high training standards that will be recognized by leading Health Care facilities and include immunization records, training courses, screenings and more. Now, once a representative has completed the program, a "HCIR Safety Certification" card (like a passport) is issued and that is recognized and accepted by hospitals and other facilities around the world.

To assure continued certification, annual retraining schedules and immunization reminders are automated with the required coursework and delivered online to sales representatives at the necessary time.

Delivering FCPA and AdvaMed Code Training to External Sales Contractors

UL's implementation team created branded communication materials and user guides to facilitate training performance, motivate sales personnel and provide context to the program.

Overview:

A global Medical Device manufacturer with 100 employees and more than 500 external sales contractors around the world instituted a rigorous program designed to reinforce the importance of compliance and adherence to the company's policies.

Targeted compliance challenges were:

- **FCPA Compliance:** The company had taken a zero tolerance approach to bribery and refusing to make any type of "grease" payment to local officials, requiring all employees and non-US-based contractors to understand and abide by the law.
- **AdvaMed Code:** Following the AdvaMed Code is a mandatory requirement for all sales personnel, regardless of location. However, security issues prevented the external sales brokers from gaining access to the company's secure site to access training materials.

The Solution:

The company provided UL's off-the-shelf AdvaMed and FCPA courses to key employees and sales contractors via the web-based ComplianceWire. UL's implementation team created branded communication materials and user guides to facilitate training performance, motivate sales personnel and provide context to the program.

The Results:

The company cost-effectively achieved its goal of a 100 percent completion rate for the two courses across both the employee and contractor base.

AdvaMed
Advanced Medical Technology Association

CASE STUDY

Building an Enterprise-Wide Role-Based Qualification Program

Sponsored by the Quality Group

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.

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Enhancing the Compliance Program in Response to a CIA

The company has reported that the program has fulfilled all of the conditions of the CIA and has greatly reduced the risks associated with unfair promotional practices.

Overview:

A global Biotechnology firm agreed to a five-year Corporate Integrity Agreement (CIA) and a voluntary compliance program that applied to all employees within their operations. CIA elements included monitoring, auditing and reporting related to sales and promotional practices. The critical training program included a five-hour "Code of Business Standards" course that was to be targeted to all sales and marketing personnel and contractors. This curricula was required to be assigned on an annual basis and included company-specific Code of Conduct content as well as custom courses on promotional practices and PhRMA Code.

The Solution:

The company had been a subscriber to UL's ComplianceWire® Learning Management System (LMS) and off-the-shelf Good Manufacturing Process (GMP) courses since 2004. The company engaged UL's Learning Services team to develop customized Standards of Global Business Practices and Basics of the PhRMA Code courses. The compliance team then assembled curricula comprised of the customized courses and standard UL Health Care Compliance courses such as Promotional Practices, Conflict of Interest and OIG Compliance Program Guidance for Pharmaceutical Manufacturers. The compliance team deployed the assignments to both employees and nonemployees.

The Results:

Thus far, the assignments have been completed by more than 2,000 employees and sales contractors. The three-person compliance team has been able to manage and report on the status of the compliance program without additional staff. They have reported to UL that the program has fulfilled all of the conditions of the CIA and greatly reduced the risks associated with unfair promotional practices.

CASE STUDY

Automating an Equipment Certification Program for Health Care Professionals

Overview:

A global leader in the development of diagnostic tools had developed a training program to educate more than 500 Health Care Professions (HCPs) around the world on using the company's equipment. The director of training had managed the creation of a dozen online courses focused on equipment use, but was seeking a secure, web-based environment from which the courses could be available. In addition, the courses were authored with a third party tool that didn't provide functionality to capture assessment results. Therefore, the learners would be required to complete the assessment in the course, then fax answers to the training department. The training director required a more automated way of capturing the results of the quizzes as an auditable record of completion. Finally, the training director wanted a method for automatically providing certification to the learners immediately after completing the training program.

The Solution:

The company leveraged UL's ComplianceWire® Learning Management System (LMS) and our QuizCreator and Forms tools to integrate assessments and completion certificates with the third party courses, making the certification more robust and reportable. Because ComplianceWire supports SCORM courses, the entire training program would be conducted through the web-based LMS. In addition, ComplianceWire supports the sequencing of training items, so that immediately after completing a course, the learner would be directed to a quiz that captured their results in the LMS. Trainers can build quizzes in QuizCreator without the need for programming, making the process efficient and convenient. Finally, the Forms tool would enable learners to acknowledge their completion of all materials, generating a certificate that could be printed for their records.

The Results:

At present, the project is still being implemented, but the timely delivery thus far has exceeded the company's expectations and all 500 HCPs are expected to be trained in a six-week timeframe. HCP education is a key marketing strategy for many Life Science companies and this project demonstrates how ComplianceWire can serve as the repository and distribution tool to reach that goal.

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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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