2012 Life Science Case Studies

EMERGING COMPANIES

Life & Health

Executive Summary

Each year, UL EduNeering conducts a benchmarking study to our 250+ Life Science customers. Our customers provide valuable insight into trends and best practices used to develop effective compliance and quality training and performance programs.

This year's study highlighted a keen focus on several key trends including the increasing complexity of compliance programs from global requirements; new regulations and a climate of stricter inspections and enforcement; the application of risk-based and role-based approaches for compliance and quality training programs; and the risk presented by suppliers and third parties as regulatory agencies around the world address fraud and abuse and seek to implement common compliance strategies.

UL focuses on the unique learning and compliance management challenges faced by quality teams, manufacturing, clinical, sales compliance and corporate governance. The 2012 case studies represent some of the most relevant – and critical – projects implemented by our emerging company customers in the Pharmaceutical, Biologics and Medical Device industries.

Each of these companies shares a strong commitment to making a difference in people's lives through their products and their people by delivering important health outcomes to the community.

CASE STUDY

Automated Sales Compliance Program Fuels Additional Growth

Overview:

As a leading manufacturer of innovative spinal devices selling its products world-wide, and expanding sales to several more countries this year, this company is poised for explosive growth. With a recent 501(k) clearance from the United States Food and Drug Administration (FDA), senior leadership sought an enterprise-wide compliance training solution to more effectively manage the rapid growth of the organization while meeting specific needs of the sales organization.

The Solution:

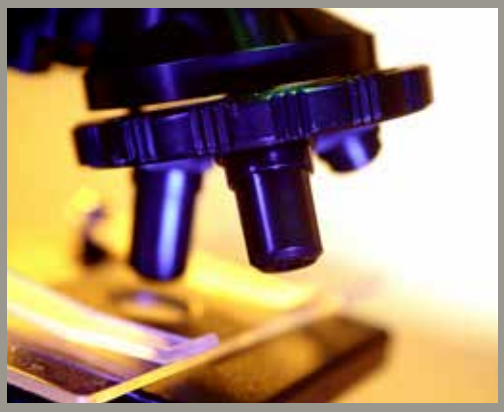
The company had initially launched a Code of Ethics course through ComplianceWire® just for their independent agents. Now, the company wanted to expand this solution to include a much broader range of sales compliance training and adherence to company policies.

During audits, the company is often asked if sales personnel are trained and if the company tracks and monitors that training. The management team was keenly aware that regulators positively respond to active sales management oversight for compliance training programs. Like the first launch, in which agents needed to complete the training to receive full sales commission, the management team wanted to put this same process in place for all sales training activities.

The company mapped out an effective training infrastructure within ComplianceWire with the goals of "ease of use" and "effective reporting." In addition, the company wanted to leverage a robust library of "off the shelf" courses, create assessments to assure role-based knowledge, and plan and execute an effective communication strategy to roll out the program, starting with top management.

The Results:

The company completed a successful pilot launch and is ready to roll out the program to the entire enterprise. The benefits have been recognized already. Senior management has been able to calculate significant cost savings by keeping employees out of the classroom.



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Training Drives a New Business Model

A web-based, Part-11 compliant Learning Management System (LMS) that could be configured to allow targeted distribution, documentation via e-signature, monitoring and management of all training activities – to both employees and third parties – was required as part of the new virtual infrastructure.

Overview:

An outsource-based, emerging development company operates virtually to bring its innovative biopharmaceuticals to patients with rare gastrointestinal and endocrine disorders. With a handful of drug candidates, the company is advancing two late-stage programs. Complementing its own proprietary products, the company often partners with larger firms to help fund the late-state development and commercialization of its drug candidates. After the United States Food and Drug Administration's (FDA) denial of its New Drug Application (NDA) and facing possible risk of failure, the Board of Directors set an aggressive corporate goal to focus every resource on the Phase III study, drastically change the structure of the organization and revamp all quality systems requiring the entire organization to be trained within four months. The organization had a short window to get into compliance.

The Solution:

The Board of Directors stood conventional wisdom on its head. The company could not afford another Phase III trial and without the study, the organization risked failure. By the time the company was audited by the FDA as part of the NDA process, they had to have an effective, compliant quality system in place for the company's next-generation operation.

After immediately hiring a new VP of Quality, an experienced industry veteran who is familiar with aggressively bringing new products to market, they started work from the ground up. The company retained an essential number of employees to build a network of home-based employees and subcontractors. Operations that had been done internally – laboratories, manufacturing and distribution – were outsourced. That starting point exposed glaring compliance gaps and an action to close these gaps:

Selecting a LMS – Training at all levels of the organization, including the executives, was mandatory. A web-based, Part-11 compliant Learning Management System (LMS) that could be configured to allow targeted distribution, documentation via e-signature, monitoring and management of all training activities – to both employees and third parties – was required as part of the new virtual infrastructure. The ability to administer the system efficiently with minimal time and resources was imperative.

Revising SOPs – In order to reflect and meet FDA's priorities and requirements, the company's 78 Standard Operating Procedures (SOPs) had to be updated and new ones created. Some employees required training and assessments to demonstrate role-based knowledge on as many as 30 SOPS.

Building a Training Curriculum – The organization needed to develop a customized training curriculum for the company, incorporating 78 new SOPs. Targeted curriculum and related training assignments needed to be designated for employees and subcontractors based on those roles.

The Results:

The entire program and system were customized and brought online in five weeks. The program met the aggressive goals of the Board and is poised for the exponential growth of the future.

- The company achieved 100% compliance by all employees and contractors in 30 days;
- The Executive team was the first to complete training;
- Training records were presented to the auditors with zero findings;
- The virtual system maintains itself with as little as 10 hours of system administration per month;
- Employees and contractors are thrilled with the training and the ability to manage their own training plansc.

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Regulatory and Compliance Training for Sales Force Accreditation and Credentialing

The company's critical compliance challenge was to ensure that sales representatives and third parties were trained on United States and European Union (EU) anti-bribery and false claims compliance, meeting accreditation and hospital vendor credentialing requirements.

Overview:

As a manufacturer of non-invasive medical devices for electrotherapy and cardiac monitoring, this company sells its FDA-approved product lines around the world. In the last year, the company made several product expansions, including a considerable investment in a European subsidiary, which will initially focus on sales and marketing within the European marketplace. The company's critical compliance challenge was to ensure that sales representatives and third parties were trained on United States and European Union (EU) anti-bribery and false claims compliance, meeting accreditation and hospital vendor credentialing requirements.

The Solution:

The company had limited administrative resources, and as such, required tools that would automate the administration, tracking and reporting of all compliance and regulatory training for the global sales organization and third party distributors. Training records were especially important for audits, accreditation surveys, hospital credentialing and reimbursement. What's more, the company required "off the shelf" compliance content that covered FDA, HIPAA, OSHA, AdvaMed and CDC.

The Results:

Within 30 days, the company rolled out an effective and measurable compliance and regulatory training program for their sales organization and third parties:

- Training compliance adoption has reached 93 percent;
- Convenient, web-based access to the courses was cited as the main reason for engaging the sales organization;
- The effort of audit preparedness through the generation of training record reports was significantly reduced;
- The solution has positioned the company as a technologically-savvy organization that respects the time of the sales individuals;
- A recent accreditation survey has yielded very positive results for the program.

The company has noted that the 30-day deployment time would not have been possible without UL's solutions. They are now planning Phase 2, which includes the extension of this training solution to all remaining employees, covering other compliance topics.

CASE STUDY

Transitioning from Paper to Electronic Recordkeeping for Manufacturing

Overview:

An innovative Health Care manufacturing company and worldwide leader in disposable health care products has a single-site US-based manufacturing facility. As the company continues to grow at a rapid pace and drive global sales, they recognized a strategic need to automate their compliance and quality training process. Their goal was to move to an electronic system so they could effectively manage compliance requirements and improve the quality of their training program.

The Solution:

Despite a paper-based training process, the company took a very systematic approach that included well-defined curriculum and roles. They were confident that by moving from a paper-based system to an online system, they would increase operational efficiencies and improve training effectiveness.

The company leveraged a "best practices" approach that went beyond the "read and understand" SOP and policy requirements of the past. They added "assessments" on critical SOPs and defined rules for ongoing refresher training. They also tapped into UL's "off-the-shelf" Good Manufacturing Process (GMP) and Quality System Regulation (QSR) courses. However, they needed to factor in that learners within their manufacturing facility would take training through "kiosks" right on the plant floor, so accessing and starting training had to be easy.

The Results:

Three months after the rollout, the company reports an increase in training engagement and compliance among employees and management:

- The Learning Management System (LMS) administrator understands how to translate compliance and business needs into the LMS, and has been 'key' to helping employees manage their own training;
- An effective rollout plan and communication strategy resulted in a workforce excited at the prospect of managing their own training plans;
- Managers can create assessments instantly on critical SOPs and capture assessments for "hands on" training, so they can gain feedback on a learner's retention level;
- All workers report improved training "time management;"
- Managers report increased visibility through regularly scheduled training status reports.

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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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