Quality, Compliance and Learning Solutions

FOR MEDICAL TECHNOLOGY COMPANIES

Enterprise-Wide Compliance Learning Solution Focused on:

- *Quality and Regulatory Compliance*
- *Training Distribution and Reporting*
- *FDA-Authored Courses*
- *AdvaMed-Supported Health Care Compliance Programs*

Addressing Your Regulatory Priorities

Today's Medical Technology industry operates within a global supply chain, in which manufacturing, packaging, handling, storage and distribution operate independently. The pressure to remain competitive, yet meet quality standards, has become quite challenging. That's why leading Medical Technology companies of all sizes trust UL EduNeering's unique combination of online course libraries, award-winning cloud-based Learning Management System (LMS) and professional services. Our solution enables Medical Technology companies to seamlessly achieve global regulatory and compliance requirements across their organizations and supply chains.

Customers leverage these solutions to assure qualification and certification among employees and third parties.

Validated, Audit-Ready System Used by the US FDA

For more than 15 years, under a unique partnership with the US FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated technology system for ORA-U, the FDA's virtual university.

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

Your quality, manufacturing 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 third party staff?"

Why Companies Partner with UL

Exceeding the Minimum Requirements for Training and Qualifications

UL EduNeering'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.
- **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).
- **Ensure targeted, role-based training assignments** by defining employees into learner groups based on job role or function.
- **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.
- **Give learners visibility** into their 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.

Since 2008, UL EduNeering has served as the exclusive online compliance partner to AdvaMed and MTLI. Under the partnership, the two organizations work collaboratively to develop content and programs to educate Medical Technology companies on regulatory and compliance issues. From the development of e-learning courses on the AdvaMed Code, Introduction to Medical Device Compliance, and Global Anti-bribery – to Regulatory Filings, Quality Systems Review and Medical Device Packaging and Recalls, our programs address the specific needs of the industry.

AdvaMed
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– 6X Winner –
Best Advance in Learning Management Technology for Compliance Training

US FDA and QSR Course Libraries

Gain Deeper Insight into US FDA Expectations

UL's US FDA-authored, computer-based training courses facilitate new hire, ongoing and refresher training. These courses reflect the US FDA's most current requirements, priorities and policies in the areas of quality systems, import operations, medical device regulations and more.

For example, the introduction to Quality System Regulation (QSR) curriculum includes 11 courses that specify general objectives, such as use of trained employees, design reviews, design validation, calibrated equipment, process controls, etc., rather than methods, because a specific method is not appropriate to all operations.

Members of your organizationare provided the same content used to train FDA inspectors, such as the US FDA Quality System Inspection Technique (QSIT) and Medical Device Reporting, so that your teams will know what to expect – and how to react – during a US FDA inspection.

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

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, QSRs and other critical information and documents.

Our Critical Information Control System® (CICS) tool enables Medical Device 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.

Managing Clinical and Device Safety Requirements

UL designs and manages both pre- and post-marketing clinical and regulatory programs for various stakeholders throughout the life cycle of a medical device including clinical personnel, investigator site staff, CROs, contractors, vendors and distributors. Our programs assure knowledge of key obligations such as adherence to Good Clinical Practices (GCPs) and device safety reporting responsibilities. The inherent scalability and secure global access of our technology provides a cost-effective solution to deliver and document protocol and non-protocol-specific knowledge in an automated, audit-ready format.

Partnering with the Duke Clinical Research Institute (DCRI), we have developed the Clinical Research and Training (CREATe) program. CREATe is a comprehensive clinical resource certification program that meets the needs of clinical personnel at varied knowledge levels, and helps them apply these lessons into their clinical trial performance.

Embedding Ethical Behaviors

Implementing proactive strategies that achieve goals for corporate governance, ethics and integrity is the key to company stewardship. UL's solutions integrate components of a company's compliance program – from the regulation-mandated Sarbanes-Oxley Act and HIPAA requirement, to Corporate Codes of Conduct – into a cohesive system based on industry best practices. Corporate culture is reinforced through our proven multi-year skill-building program of training, communications and case study guidance. This practice also allows new hires to be quickly introduced to the corporate culture.

Achieve Health Care Compliance

UL's solutions enable Medical Device companies to not only comply with AdvaMed Code policies, but also the regulatory requirements associated with interactions with HCPs, Anti-Kickback statutes, off-label promotion, False Claims Act (FCA), Global Anti-Bribery, Sunshine Act and Foreign Corrupt Practices Act (FCPA). These programs not only address compliance, but help change the underlying behaviors.

Using our technology and specialized content, Medical Device companies manage training, distribute and certify understanding of compliance policies and procedures both internally and for third parties, monitor field force activities, and assure that interactions with HCPs are appropriate and vetted. Additional programs provide a streamlined method for sales teams to manage Vendor Credentialing requirements.

About UL EduNeering

UL EduNeering is a division within the UL Ventures business unit. UL is a premier global independent safety science company that has championed progress for 120 years. Its more than 10,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

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®. In addition, UL offers a talent management suite that provides companies the ability to improve workforce skills & competencies within established role-based talent training programs to drive business performance.

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, 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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