Life & Health

AdvaMed and UL EduNeering:

THE PARTNERSHIP FOR COMPLIANCE EDUCATION

Building a Compliant Culture Across Your Organization

Leading Medical Device companies have recognized that an unwavering commitment to compliance and quality are key to perennial success. That commitment is demonstrated through senior management commitment, stellar customer service and robust training.

As AdvaMed's compliance education partner, UL EduNeering brings its years of proven enterprise-wide compliance management experience in the Medical Technology industry to association members. Our web-based technologies, risk-based advisory approach, subject matter expertise and experience in adult learning enable organizations to improve employee and supply chain performance, reduce risk, increase operational efficiency, optimize quality and demonstrate consistent compliance with regulatory requirements and corporate standards. Our solutions, delivered in more than 30 languages, are designed to support the needs of global enterprises as well as emerging companies.

AdvaMed
Advanced Medical Technology Association

A Unique Partnership with the FDA

For more than ten years, 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 technology system for ORA-U, the FDA's virtual university. Since the formation of ORA-U, more than 36,000 federal, state, local and now global investigators have been trained and certified in the areas of quality and compliance.

Each year, the FDA and UL collaborate on new technologies and curricula that integrate the FDA's most current strategic thinking to enhance the ORA-U solution. The same solution developed and used by the FDA is available exclusively to UL's clients.

Recently, the FDA expanded and extended its CRADA with UL until 2019. The expansion is focused on the FDA's global responsibilities, enabling international regulatory agencies to access the ORA-U solution.

FDA CRADA UL

Automated, Integrated Enterprise-Wide Learning

ComplianceWire®, our 21 CFR Part 11-validated Learning Management System (LMS) enables organizations to manage employee and third party training, SOP and critical information distribution and document compliance activities.

Using this enterprise-wide solution, our 200 life science clients have gained operational efficiencies and reduced noncompliant activities by integrating our system with key business functions across the product life cycle from clinical studies through manufacturing, sales and marketing, post-marketing device safety and HCP training.

Manage Health Care Compliance

Compliance teams, especially those with global sales teams, need to effectively communicate and train on myriad regulations and requirements. 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. Topics include Global Anti-bribery, Sunshine Act and Transparency, Interactions with HCPs, Anti-Kickback Statute, Off-label Promotion, HIPAA and Privacy, False Claims Act (FCA) and Foreign Corrupt Practices Act (FCPA). These programs not only address compliance, but help change the underlying behaviors that cause noncompliance.

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. The inherent scalability and secure global access of our technology provides a cost-effective solution to deliver and document required knowledge in an automated, audit-ready format. Off-the-shelf courses, including Medical Device reporting, GCP and Complaint Management, can be readily customized for individual companies or products.

Third Party SMI Compliance Management

Perhaps the greatest risk for compliance teams to manage today is the identification and activities of third party sales agents, and other intermediaries. To assist in the risk management, training and communication of those third parties, UL provides a web portal-based solution that uses automated tools to collect risk profiles, deliver training and policy content aligned specifically to that individual's risk profile, and document and report on completions and activity from third parties around the world. Our Third Party Solution not only ensures that your policy training is fully disclosed and documented, but that you have established risk mitigation steps based on third party attributes.

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.

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AdvaMed Regulatory & Compliance Certificate Program

AdvaMed and UL EduNeering have teamed up to develop the online AdvaMed Regulatory & Compliance Certificate Program, offering three separate program options (tracks) for Medical Technology professionals. The program leverages UL's extensive online libraries, including both FDA and AdvaMed-approved content to help today's Medical Technology organizations' demand for mastery of specific regulatory compliance and quality issues and commitment to continuous improvement to remain competitive.

CORPORATE COMPLIANCE

The **Corporate Compliance Certificate** is ideal for compliance, legal and/or sales management professionals.

This track covers four core topics, including:

- Basics of the AdvaMed Code
- Introduction to Medical Device Compliance and HIPAA
- Privacy Guidelines for Medical Device Sales Representatives
- Your choice from these options:
  - Doing the Right Thing: Anti-Bribery (FCPA)
  - Global Anti-Bribery

This track also offers the choice of six electives from an extensive list of courses, which include:

- Introduction to Quality System Regulation
- Risk Management: Key Concepts and Definitions
- Compliance Improves Business Performance

MEDICAL TECHNOLOGY

The **Medical Technology Overview Certificate** is ideal for industry generalists who may be new to the Medical Device industry or whose job role requires broad knowledge of several key areas.

This track offers three core topics, including:

- Basics of the AdvaMed Code
- Global Regulatory Strategy and Planning Process
- Introduction to Quality System Regulation (QSR)

This track also offers the choice of seven electives from an extensive list of courses, which include:

- FDA Inspections
- Complaint Management
- Introduction to Medical Device Compliance

RA / QA

The **RA/QA Certificate** is ideal for Regulatory Affairs and Quality professionals.

This track offers four core topics, including:

- Global Regulatory Strategy and Planning Process
- Medical Device Filings: 510(k), PMA and IDE
- Introduction to Quality System Regulation (QSR)
- ISO 14155: Obligations of Sponsors & Monitors for Medical Device Trials

This track also offers the choice of six electives from an extensive list of courses, which include:

- Failure Investigations for Medical Device Manufacturers
- Handling a Product Recall
- QS Regulation: Overview and General Provisions

For complete details and to enroll, go to advamedcertificate.org