



Health Care Compliance Learning Solution



Web-Based Compliance Solution that Helps You Manage:

- *Code of Conduct*
- *Employee Training*
- *Third Party Oversight*
- *Policy Tracking*
- *Audit Inquiries*
- *Risk Assessment*

Today's Multi-Layered Compliance Challenge

Compliance Officers need to demonstrate that their organization's compliance programs are robust, effective and foster a culture of ethical best practices.

Compliance teams are challenged in many ways to develop, distribute and track dozens of policies, establish a Code of Conduct, oversee internal reporting and "feedback" mechanisms, and interact with multiple constituencies from the Board of Directors and regulatory authorities to the sales team, employees, third party intermediaries and distributors.

Plus, the regulatory layers expand each year: FDA, DOJ and other federal requirements, industry guidelines, state regulations, privacy requirements and global statutes.

A Proactive Approach to Compliance Programs

Through our Health Care Compliance Learning Solution, our Life Science clients have stripped the complexity from their compliance learning programs, while establishing an environment for continuous compliance improvement. That solution includes our ComplianceWire® learning system, plus compliance-specific content and services, enabling you to better manage these activities:

- ✓ **Embed your Code of Conduct** into everyday work practices;
- ✓ **Deliver off-the-shelf courses** spanning critical compliance topics;
- ✓ **Manage the delivery of policies** to both employees and third parties;
- ✓ **Build targeted risk profiles** based on self assessments;
- ✓ **Generate real-time audit reports** that answer detailed compliance questions;
- ✓ **Make third party education** as easy to manage as internal training.





CODE OF CONDUCT TRAINING

Bring Your Code, and Your Corporate Values, to Life

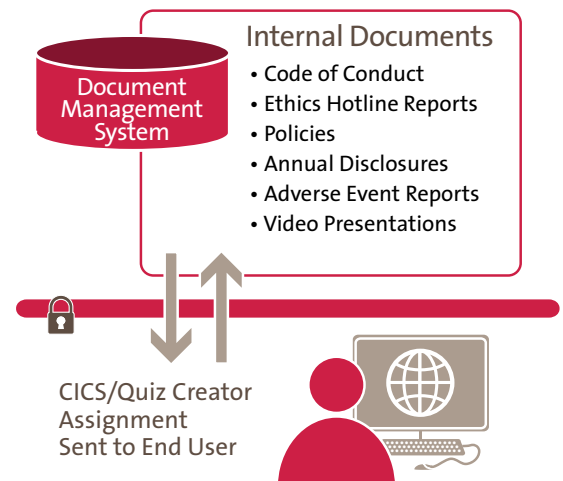
The foundation of an effective compliance program is rooted in a strong values-based Code of Conduct. Incorporated into that Code are the seven Office of Inspector General (OIG) elements, recommendations of the US Sentencing Guidelines and major health care compliance tenets. UL EduNeering develops custom Code of Conduct training content that not only incorporates these tenets, but delivers relevant scenarios and interactions for effective adult learning.

To implement more sophisticated compliance programs, our solution focuses on an integrated compliance learning model. Through this model, compliance officers can identify high-risk employees and nonemployees, then deliver the Code of Conduct and ensure an auditable receipt.

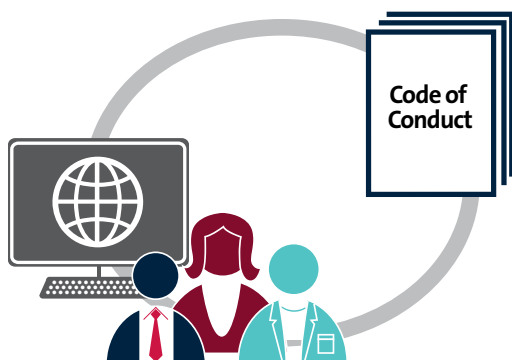
Assign Code of Conduct Training with Full Audit Trail

To streamline the delivery of Code of Conduct training and other compliance policies with a complete audit trail, UL provides an electronic assignment distribution system called Critical Information Control System® (CICS).

A differentiating tool within ComplianceWire, our 21 CFR Part 11-validated Learning Management System (LMS), CICS enables you to deliver training assignments that “link” the user to your policies and procedures. You can also build quizzes to assess whether the learner read and understood the policy.



SERVICES TO MAKE YOUR CODE OF CONDUCT MORE MEANINGFUL



Your company has a unique culture and voice. Our team can incorporate these into your Code of Conduct to build an ethical culture and drive behavior change.

We develop customized Codes for our clients, or can modify existing Codes to meet current regulatory and company requirements. In addition to Code writing, we develop custom courses on your Code, or on a series of “continuous ethical improvement” topics to more effectively impact company culture.

Employees learn from real-life situations uniquely applicable to their company and industry, so they can recognize potential problems before they occur.

We can also assess existing materials and offer recommendations to make sure the code reflects your company’s values, satisfies all regulatory requirements, and helps employees exemplify these values in their work environment.



OFF-THE-SHELF COURSES STREAMLINE TRAINING

Engaging Web-based Courses Designed to Change Behavior

As regulatory requirements grow more complex, your training content must be crafted to ensure proper retention and improve employee and contractor performance.

Our highly-engaging compliance course libraries, when aligned with organization-specific policies and procedures, can serve to motivate individuals by focusing on the consequences of their actions from a regulatory and business perspective.

Our courses employ proven instructional design methodology and mastery to foster deep processing and understanding of the material and actually result in behavior change – the goal of effective training.

UL works with leading subject-matter experts to update our courses as regulations and guidelines change. Several courses can be taken on a mobile device, such as an iPad, to make learning more convenient for on-the-go sales and marketing teams.



ADVISORY SERVICES

Helping You Map Content to the Right Audience

For many compliance teams, it can be a challenge to understand which areas of the company need to be trained on the latest government regulations, codes and guidelines. In addition, when you subscribe to our Sales and Marketing library, our HR library and our Ethics and Corporate Responsibility library, you are gaining access to more than 100 courses. Taking the time to target the right training to employees and third parties results in a much more effective learning experience, as it ensures that individuals only gain actionable knowledge that they can apply in their work environment.

That's where our Advisory Services team can help. We can work with your compliance team to develop "Compliance Curricula" that maps the right content to all employees, as well as particular roles: regulatory, sales, service, marketing, medical education, etc. These curricula can include our off-the-shelf courses as well as internal policies and procedures.

Our Advisory Services team can also support your overall compliance program by conducting "best-in-class" audits, development of policies, and review and education of global laws and regulatory requirements.

Following are recommended matrices based on current usage of our Medical Device and Pharmaceutical clients. Our Advisory Services team can refine these recommendations based on your organization's unique requirements.



SUGGESTED COMPLIANCE LEARNING MATRIX for Medical Device Professionals

Compliance Curriculum: All Employees

COURSE TITLE	CODE	REFRESHER
Confidentiality, Intellectual Property Protection and Information Security	LAV19	Year 1
Global Anti-Bribery	RH0041	
HIPAA: General Awareness	HIPAA01	
E-mail and Corporate Communications	RH0042	Year 2
Handling Confidential Information	RH0006	
Privacy and Data Protection	RH0027	

Compliance Curriculum: All Sales and Marketing

COURSE TITLE	CODE	REFRESHER
Basics of the AdvaMed Code	MDSM01	Annually
Reporting Adverse Events for Medical Devices	MDSM02	
Introduction to Medical Device Health Care Compliance	MDSM05	
Physician Payment Sunshine Act	PHSM11	
Eucomed Guidelines on Interactions with Health Care Professionals	MDSM04	
Note: EU employees only		

Compliance Curriculum: Field Sales and Service

COURSE TITLE	CODE	REFRESHER
Bloodborne Pathogens – Health Care Workers	EHS09	Annually
Operating Room Conduct	PHA68	
HIPAA and Privacy Guidelines for Medical Device Sales Representatives	PRIVACY01	
Basic Radiation Awareness	EHS05	

Compliance Curriculum: Medical Education

COURSE TITLE	CODE	REFRESHER
Medical Education for Health Care Professionals	PHSM03	Annually
Financial Disclosure by Clinical Investigators	GCP24	

HR Compliance Topics: Employees and Managers

COURSE TITLE	CODE	REFRESHER
Substance Abuse	LAV10	Bi-Annually
Diversity in the Workplace	LAV05	
Violence in the Workplace	LAV11	
Family and Medical Leave Act (FMLA)	LAV06	
Sexual Harassment Awareness for Employees	LAV08	
Sexual Harassment Awareness for Managers (Meets CA and CT Requirements)	LAV22	



SUGGESTED COMPLIANCE LEARNING MATRICES for Pharmaceutical Professionals

Compliance Curriculum: All Employees

COURSE TITLE	CODE	REFRESHER
HIPAA: General Awareness	HIPAA01	Year 1
Global Anti-Bribery	RH0041	
Postmarket Reporting of Adverse Drug Experiences	PHSM08	
E-mail and Corporate Communications	RH0042	Year 2
Handling Confidential Information	RH0006	
Privacy and Data Protection	RH0027	

Compliance Curriculum: All Sales and Marketing

COURSE TITLE	CODE	REFRESHER
Basics of the PhRMA Code	PHSM01	Annually
HIPAA and Privacy Guidelines for Pharmaceutical Sales Representatives	PRIVACY02	
Introduction to Pharmaceutical Compliance	PHSM09	
Postmarket Reporting of Adverse Drug Experiences	PHSM08	
Physician Payment Sunshine Act	PHSM11	
Introduction to the Regulation of Prescription Drug and Biologic Promotions	PHSM10	

Compliance Curriculum: Field Sales and Service

COURSE TITLE	CODE	REFRESHER
Bloodborne Pathogens – Health Care Workers	EHS09	Annually
Contracting with Health Care Professionals	PHSM02	
Interactions with Health Care Professionals – Field	PHSM07	
Promotion of Pharmaceutical Products – Field Facing	PHSM05	

Compliance Curriculum: Inside Sales and Marketing

COURSE TITLE	CODE	REFRESHER
Interactions with Health Care Professionals – In-House	PHSM06	Annually
Promotion of Pharmaceutical Products – In-House	PHSM04	

Compliance Curriculum: Medical Education

COURSE TITLE	CODE	REFRESHER
Contracting with Health Care Professionals	PHSM02	Annually
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HR Compliance Topics: Employees and Managers

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MANAGE THIRD PARTY EDUCATIONAL ACTIVITIES

Improve Knowledge Flow to Contractors, Agents and Vendors

Several CIAs have focused on “third party educational activities” that must be conducted by organizations. Further, AdvaMed and Eucomed recently approved joint guidance for compliance management of third party sales and marketing intermediaries. And yet, compliance teams struggle to deliver training and communication to these individuals, as their contact information is often not available through traditional HR and training system databases.

ComplianceWire eliminates the need to invest in an alternative compliance learning program to accommodate training of third parties. Because the web-based system provides “security nodes” that can segment internal training administration from external training administration, you can deliver and track training and communication items to nonemployees from a single system, without compromising your organization’s IT policies.

Generate Audit Reports in a Matter of Minutes

With each activity, ComplianceWire captures the individual’s electronic signature, which is unimpeachable and secure, simplifying recordkeeping and administrative tasks. There is a complete audit trail of all changes made to training items and user accounts, namely the field that was changed, the old value, the new value, the user who made the change and the date/time of the change.

ComplianceWire provides dozens of standard reports and data query tools that let you configure standard reports to meet your workflow and monitoring activities. Using these tools, you gain complete information and analysis of all compliance learning activity.

Routinely integrated with other workflow systems, such as HRIS, ERP or CRM, our solution allows compliance officers to quickly monitor compliance activity across the enterprise.



Gain access to real-time audit reports that provide management with visibility and answers to detailed compliance questions.

POLICY TRACKING MADE EASY



ComplianceWire features policy tools that enable you to quickly assign and track assignments that link individuals to your electronic policies, which reside on your servers or your document management system.

You can easily and quickly build quizzes to ensure that learners read the documents before signing off.

The electronic signatures are unimpeachable and secure, leveraging the web-based ComplianceWire platform, which streamlines recordkeeping and administrative tasks, and integrates with document management systems to automatically trigger new training as documents are updated.

RISK ASSESSMENT AND RISK MITIGATION

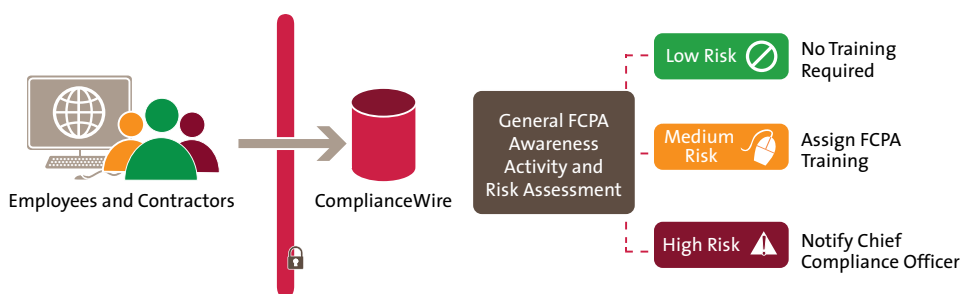
Combine Policy Distribution, Risk Assessment and Mitigation Planning

ComplianceWire ensures that your policy training is fully disclosed and documented, and that risk mitigation steps have been signed off on by the employee and manager.

You can have all of your policies delivered via ComplianceWire: anti-bribery, conflicts of interest, off-label use, guidelines on hiring HCPs, etc. Prior to assigning policy training, you can determine the risk profiles of each learner by sending an online self-assessment.

Our SmartForms tool enables you to add a “resulting action” rule to an online risk assessment, so that as an individual answers each question, the system assigns targeted training or sends an alert via e-mail to the compliance team. For example:

- **Conflict of Interest:** One compliance team helped individuals recognize potential conflicts in their daily business interactions – before these incidents occurred. The compliance team sent an electronic COI form that automated the assessment process by directing any “high-risk” individual to COI training. This process also gave the compliance officer visibility into compliance and risk through robust management reports.
- **Anti-Bribery (FCPA):** A compliance team was aware that several sales agents and distributors in a specific global region were interacting with physicians who were considered government officials. The assigned them a “Physician Interaction” form that identified the individuals and automated the delivery of detailed training on the topic.



Benefit from Our Relationships with US FDA and AdvaMed

Our Health Care Compliance Learning Solution leverages our 13 year partnership with the US FDA, under which we provide the online technology infrastructure and regulatory content to more than 36,000 investigators.



In addition, UL serves as AdvaMed’s exclusive online training partner for compliance solutions, addressing issues including quality system regulations, interactions with Health Care Providers, fraud and abuse, and corporate ethics.



AdvaMed

Advanced Medical Technology Association

About UL EduNeering

UL EduNeering is a business line within UL Life & Health's 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®.

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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