Life & Health

UL EduNeering's Online Course Libraries

Highlights:

- *More than 700 off-the-shelf courses*
- *Regularly updated content*
- *Custom course development available*

Our Approach to Learning

Our online learning philosophy is based on Mastery Learning. Through this approach, learners must interact with dynamic course content and demonstrate proficiency in order to advance from one topic to another. Our courses support adult learning styles and enhance behavior change in a variety of proven ways.

Currently, we maintain a library of more than 700 courses that are written and reviewed by recognized subject matter experts, including the US FDA and AdvaMed. Courses are regularly updated to reflect the most current expectations and requirements of regulators and industry groups.

For a full listing of our libraries and curricula, we invite you to view our library of off-the-shelf courses; which can be customized to meet your organization's specific needs. Additionally, our in-house learning services team has developed 2,500 custom courses on topics ranging from software usage to Code of Conduct and new product introduction.

FDA Inspections and Enforcement Library

Under a unique partnership with the FDA, UL works with the Agency to develop these courses as part of the training program delivered to 36,000 federal, state and local investigators. By taking one or more of these FDA-authored courses, employees within the regulatory affairs, auditing, quality assurance and manufacturing areas can gain a better understanding of FDA's activities related to inspection and enforcement. Our clients have noted that being able to anticipate FDA enforcement actions has lead to a more proactive compliance program and a more prepared audit response. This valuable education has led to improved inspection outcomes and stronger relationships with FDA inspectors and enforcement officers.

UL's Libraries include more than 700 courses that feature expert regulatory interpretation by company specialists and respected consultants. Courses may also be customized based on our clients' particular needs.

Global Pharmaceutical GMP Library

This Library contains courses that help global Pharmaceutical companies keep pace with European Union (EU) and International Conference on Harmonisation (ICH) guidelines. Specific quality and manufacturing courses contain both FDA and EU guidelines. In addition, ICH courses focus on the latest ICH Q7 through Q10 guidelines.

GMP Dietary Supplement Library

Since the United States FDA issued the Dietary Supplement Current Good Manufacturing Practice (cGMP) Final Rule in 2007, the Agency has been more actively enforcing these regulations through inspections of manufacturing sites. Manufacturing companies can use this Library to cost-effectively train senior managers, quality managers, manufacturer staff and other key personnel on 21 CFR Part 111 and how to maintain proper controls during the manufacturing, packaging, labeling and holding operations. By combining these courses with specific policies and procedures, companies that manufacture, package and label supplements for sale in the US can demonstrate to internal and external auditors that qualified personnel have been trained in the 21 CFR Part 111.

Pharmaceutical and Medical Device GMP Libraries

Our Pharmaceutical GMP and Medical Device GMP curriculum focus on the specialized knowledge needs of individual business functions in Pharmaceutical, Biotechnology and Medical Device companies. Beginning with the core quality and regulatory knowledge typically needed by new hires and reassigned workers, to the more advanced needs of managers and supervisors, courses target the function-specific needs of the entire organization. These robust Libraries are used by the US FDA and hundreds of Life Science companies for onboarding employees and annual GMP refresher training. Many of these courses have been written and/or reviewed by the US FDA and AdvaMed, the leading advocacy group for Medical Device organizations.

Global Clinical Libraries: Pharmaceutical and Medical Device Industries

Our Global Clinical and Regulatory Libraries cover underlying Good Clinical Practice (GCP) concepts as well as specific, advanced information for clinical professionals based on their role in the study. The courses are designed for those in clinical development, clinical operations, quality management and regulatory affairs. The global curriculum includes courses describing FDA regulations, EU directives and ICH guidance; many feature course content provided by the FDA.

Sales and Marketing: Pharmaceutical and Medical Device Industries Libraries

UL's Sales & Marketing Library meet the needs of regulatory, legal, communications, compliance and other Pharmaceutical or Medical Device professionals who engage in sales, marketing, advertising, promotional and communications activities. Clients make these courses part of their vendor credentialing programs, or Health Care Industry Representative (HCIR) programs, to ensure that sales representatives have the proper training to enter health care facilities.

Food Safety and Food Code Library

With the enactment of the FDA Food Safety Modernization Act (FSMA) in January 2011, food manufacturers and food service retailers based in the United States, as well as importers, must be aware of the FDA's food inspection process. The FDA Food Safety and Food Code Library includes nearly 50 courses that focus on FDA inspection and enforcement guidelines, as well as Food Code guidelines, so that learners gain insight into FDA expectations related to food safety and compliance.

HR Compliance and Risk Management Library

HR Compliance and Risk Management courses use a multi-tiered concept focused on the respective concerns of managers/supervisors, employees and HR professionals. All of our courses are designed in accordance with federal regulations and guidelines, as well as HR best practices, and are continually updated to reflect regulatory changes.

Ethics and Corporate Responsibility Library

Your ethics, compliance and corporate responsibility program is only as effective as its ability to impact the way that your employees think and behave. Programs that do this successfully reflect the organization's commitment to employees, customers and stakeholders. These programs also serve to differentiate companies in the marketplace by strengthening their reputation, bolstering customer loyalty and reducing financial risks. The Library provides a highly unique approach to Code of Conduct training and focuses on general industry risk areas such as Conflicts of Interest, Accurate Books and Records, Harassment and Discrimination, Intellectual Property, the Foreign Corrupt Practices Act (FCPA), Global Anti-Bribery and much more.

Our fundamental design objective is to create knowledge solutions that enable you and your organization to learn... and succeed. Our courses are instructionally engineered for effective, interactive and self-paced learning.

Health Care – Medicare Advantage, Part D and HIPAA Libraries

Authored by nationally recognized experts, our Health Care curricula includes several Libraries:

- **Health Care General Compliance Library** enables Health Care organizations to meet federal requirements while supporting the need for a consistent corporate message, dependable employee performance and adherence to company policies and procedures.
- **Medicare Advantage Compliance Library** enables Medicare Advantage Organizations (MAOs) to meet regulatory and corporate policy requirements and goals.
- **Medicare Part D Library** enables compliance with requirements of The Centers for Medicare & Medicaid Services and the United States Department of Health and Human Services Office of Inspector General.
- **PPACA Libraries** these courses focus on the changing U.S. Health Care system wrought by the Affordable Care Act and the options that individuals will have to purchase health insurance.

Energy Operations Library

UL partners with companies in the Energy, Petroleum and Natural Gas industries to address the challenges of on-site safety, cross-functional staff utilization, subcontractor performance and the escalating scrutiny of regulatory agencies. Our combined technologies, services and training curricula support corporate goals for compliance with applicable federal and state requirements, skills training, risk management and efficient operations.

Environmental, Health and Safety Library

Our Environmental, Health and Safety Library helps companies meet OSHA, DOT and EPA requirements. We work closely with subject matter experts from industry, as well as federal and state regulatory agencies, to cover topics ranging from field safety and hazardous materials handling to office safety concerns and ergonomics.

UL Partnership Libraries:

UL has formed strategic partnerships with industry leaders and key government agencies. These partnerships enable UL to incorporate best practices, the latest regulatory and compliance information and state-of-the-art technology into our knowledge solutions.

The AdvaMed and UL Relationship

Since 2008, AdvaMed and UL have worked together to develop online compliance management and training programs for Medical Technology companies. Specialized programs address issues including Quality System Regulations, regulatory inspections and enforcement, good manufacturing and clinical practices, fraud and abuse, and corporate ethics.

The Personal Care Products Library

UL and the Personal Care Products Council have created a custom compliance and knowledge solution for the industry that addresses the key tenets of promoting safety, advancing science, informing the public and harmonizing global standards. Topics to be addressed include industry guidelines for Quality Assurance and GMPs, Safety Evaluation and Microbiology.

Professional Development Libraries

Provided under a partnership with CrossKnowledge, these Libraries provide over 15,000 learning assets covering 100 themes of management and leadership. CrossKnowledge's content is developed by experts in management and leadership from the most successful Business Schools (Cambridge, Harvard, HEC Paris, IMD, etc.), and provides the widest and the most complete product range to train employees in topics such as leadership, diversity, value creation, client orientation, change management and strategy, while enhancing their professional skills development.

Duke Clinical Research Institute

Duke Clinical Research Institute (DCRI) and UL have partnered to develop the Clinical Research Education and Training (CREATe) program. CREATe leverages DCRI's vast clinical research experience as the world's largest academic clinical research organization and performance metrics with UL's adult learning methodologies and award-winning software technology. The result is a comprehensive clinical research certification program that meets the needs of clinical personnel at varied knowledge levels, and helps them apply these lessons into their clinical trial performance... which is at the heart of clinical trial success.

The ComplianceWire® Learning Management System (LMS)

For over 30 years, UL has provided compliance learning management solutions to many of the world's leading companies. The backbone of that solution is ComplianceWire, our award-winning 21 CFR Part 11-validated LMS, used for training, tracking and audit-ready real-time reporting. Highly noted features include :

Automated Training Management:

- Make initial, one-time assignments
- Set up refresher training
- Define training groups
- E-mail reminders
- Individual training transcript for each user
- Add historical assignments
- Supports multiple versions
- SCORM/Aviation Industry Computer [Based Training] Committee (AICC)-Compliant

Reporting:

- 20+ standard reports
- E-mail to managers
- CSV/PDF/Online formats
- Audit-ready
- Ad hoc reports via query tool
- Schedule regular reports
- View training completions
- View qualification status

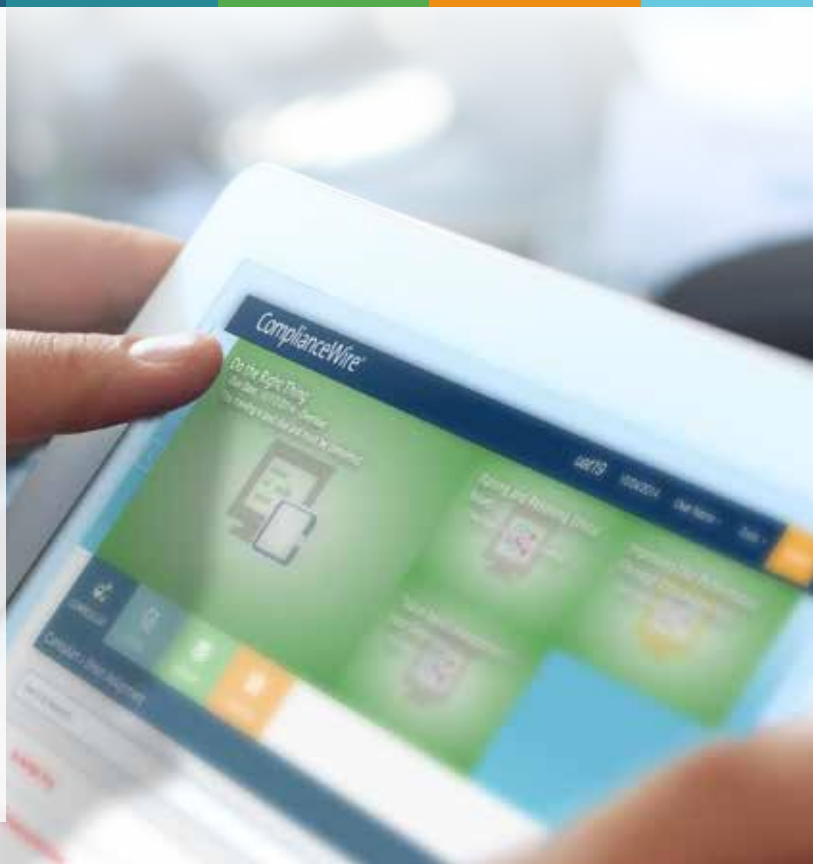
Welcome to the NEW ComplianceWire

ComplianceWire has earned its place as the industry's leading learning management system and for five years running, has won an Excellence in Technology Award from Brandon Hall.

With our latest release, ComplianceWire now provides a dynamic, engaging and user-friendly interface. Mobile ready and easy to use, the new ComplianceWire can make your training better than ever before.

The new ComplianceWire UI is centered on making the learning experience more intuitive and logical for learners, while also enabling them to tailor their experience. A new key feature is the "Action Center," in which learners can identify and focus on tasks and training items that are most important to complete. In addition, you can custom brand their instance of ComplianceWire, helping to instill consistency across your entire enterprise.

View our brief video at **uleduneering.com/compliancewire** to learn more, or contact us at 609.627.5300 or email **EduNeeringInquiry@UL.com**.



UL EduNeering Content

Title	Type
Master Course List	Master Course Titles

Pharmaceutical Course Libraries

Title	Type
FDA Inspections and Enforcement	Life Science
Pharmaceutical Sales and Marketing	Pharmaceutical, Sales and Marketing
GMPs: Dietary Supplements	Pharmaceutical
GMPs: Pharmaceutical	Pharmaceutical
Clinical Pharmaceutical	Clinical
CREATe (Courses authored by Duke Clinical Research Institute)	Clinical

Health Care Course Libraries

Title	Type
Medicare Advantage	Health Care
General Health Care	Health Care
HIPAA	Health Care
Medicare Part D	Health Care
Health Care Industry Reps	Health Care

General Course Libraries

Title	Type
HR Compliance and Risk Management	General Compliance
Ethics and Corporate Responsibility	Ethics
Workforce Health and Safety	EHS
Energy Operations	Energy
Food Safety	Food Safety
Environmental, Health and Safety	General Safety
Personal Care	Personal Care Products

Medical Device Course Libraries

Title	Type
Global GMP	Life Science
GMPs: Medical Device	Medical Device
AdvaMed & UL Partnership	Medical Device
Clinical Medical Device	Medical Device, Clinical
Medical Device Sales and Marketing	Medical Device

UL EduNeering Partnership Libraries

Title	Type
Cross Knowledge	Leadership Development, Cross-cultural Training

UL EduNeering: Additional Offerings for Learning and Compliance

Title	Type
UL's Custom Code of Conduct	General Compliance
Custom Course Development Services	Learning Management
Custom Courses that Satisfy Both Your Business and Budget Needs	Learning Management
Advisory Services: Quality and Compliance Training Programs	Life Science Best Practices
FDA Inspections and Enforcement Curriculum	Life Science, Learning Management
Compliance and Quality Learning Solutions for the Pharmaceutical Industry	Life Science Best Practices

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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