



UL EduNeering

PRODUCT QUALITY | GLOBAL COMPLIANCE | PATIENT SAFETY

UL EduNeering, part of the Life & Health Division of UL (Underwriters Laboratories), provides the critical quality and compliance learning resources for Life Science companies to achieve and maintain their goals of high product quality, patient safety and compliance with escalating regulatory demands. Multiple factors differentiate UL and the expansion into the Indian market: our relationships with the US Food and Drug Administration (FDA) and respected industry organizations, our award-winning learning technology, FDA-authored and reviewed content, and experience working with more than 250 Pharmaceutical, Biologics and Medical Technology companies around the world.

Unique Partnership with the US FDA



Since 1999, UL has maintained a unique partnership with the US FDA. Under a technology Cooperative Research and Development Agreement (CRADA), UL provides the online training, documentation and CFR 21 Part 11-validated technology system, ComplianceWire®, for “ORA U,” the Agency’s Office of Regulatory Affairs virtual university. To date, more than 36,000 federal, state, local and global inspectors have used ORA-U for their onboarding and ongoing training management, including online, instructor-led, on-the-job and other credentialing requirements. In addition to the technology, UL has converted much of ORA’s classroom education into online programs for consistent and global delivery over the internet. Using this technology-based solution, the Agency has reported that the average investigator orientation time has been reduced by more than nine months. That same solution is available to UL’s Pharmaceutical, Biologics and Medical Device clients.



Award-Winning Technology

UL’s ComplianceWire technology is an enterprise-wide learning management system specifically designed for the regulated learning and training requirements of Life Science organizations. Designed to meet 21 CFR Part 11 and EU Annex 11 requirements, the technology supports the quality and validation constructs as defined by Good Automated Manufacturing Processes (GAMPs) and Good Manufacturing Practices (GMPs) as specified in CFR 820 (Quality Systems Regulations). ComplianceWire uses a cloud-based model, thereby reducing IT and validation costs, and ensuring rapid deployment by clients for the dissemination, monitoring, documentation and reporting of SOPs, corporate policies, regulatory information, in-person training and compliance-mandated education.

Available in 34 languages, including Hindi, ComplianceWire has received the coveted Brandon Hall Award for four consecutive years for technology excellence in the Compliance Training category.



Specialized Life Science Content

UL has developed more than 700 computer-based courses and hundreds of additional learning and communications tools designed to drive comprehension and promote quality across a customer's enterprise. Many courses have been written or reviewed by the US FDA. All courses are self-paced, interactive, developed for use by adult learners, and are reviewed annually to ensure they are current with all regulations. Example libraries are:

- FDA-authored Inspection and Enforcement
- Quality/GMP for Pharmaceutical and Medical Devices
- Clinical Trials Practices, Informed Consent and Compliance
- Environmental, Health and Safety
- Ethics, Code of Conduct and Proper Selling Practices
- HR Compliance and Risk Management

UL has also developed more than 5,000 client-specific online training courses, instructor-led and skills-building learning programs, corporate communications initiatives and leadership seminars.

Industry and Client Partnerships

For 33 years, UL EduNeering has worked with Life Science companies, from multinational Pharmaceutical organizations to emerging Biotechnology firms. We were a pioneer in online learning and we remain a trendsetter in the use of innovative and effective learning methods.

Currently, more than one million active users around the world rely on our technology and courses, and in 2012, ComplianceWire recorded more than 22 million training item completions. In addition to the US FDA, we maintain ongoing partnerships, including AdvaMed, DIA (the Drug Information Association), Duke Clinical Research Institute and the Personal Care Products Council.

UL's client roster includes many of the world's most respected Life Science companies, which rely on us for assistance in achieving their goals of patient safety, product quality and global compliance.

UL in India

With locations and laboratories in Gurgaon, Haryana, Bangalore and Karnataka, UL is positioned to serve the safety, science and product innovation needs of the Indian market. UL currently provides services to India's Life Science market, most recently through training India's Central Drugs Standard Control Organization (CDSCO) investigators on the ISO 13485 quality management system. UL EduNeering's ComplianceWire solution has hundreds of India-based users from more than 25 multinational companies.

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.