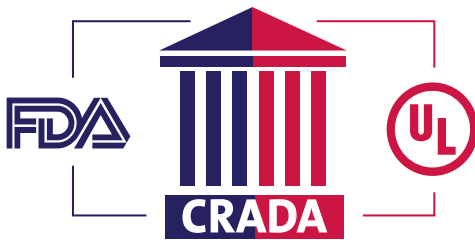




# UL EduNeering's Partnership with the FDA



The FDA's Cooperative Research and Development Agreement (CRADA) with UL EduNeering has created a collaborative partnership between the two organizations and was recently renewed and expanded until 2019. The CRADA was launched in 1999 to respond to the Agency's need for consistent training of its growing number of Investigators and transparency surrounding industry's inspection expectations. The CRADA is the only learning technology agreement of its kind between FDA and a private-sector company.

Underpinning the relationship between FDA and UL EduNeering is the transition of FDA's training into a global, online learning program. The cornerstone of the program is ORA-U, the virtual university for FDA's Office of Regulatory Affairs (ORA). UL EduNeering and FDA collaborated on and co-developed the ORA-U infrastructure in 1999 to train the Agency's Food, Drug and Medical Device Investigators. UL EduNeering continues to provide the online training, documentation and 21 CFR Part 11-validated technology for ORA-U.

ORA-U has continued to evolve using UL EduNeering's ComplianceWire® platform, a fully validated learning management system designed to meet the regulated community's high-security needs including compliance with 21 CFR Part 11. ComplianceWire, a cloud-based technology, has been awarded the Brandon Hall award for best compliance learning technology for each of the past six years. ComplianceWire provides access to more than 500 courses, exams and documents used by Investigators, including 145 courses authored or reviewed by FDA and co-developed with UL EduNeering. These specialized courses provide instruction on subjects including Good Manufacturing Practices, Good Clinical Practices, Quality Systems Requirements, Bioresearch Monitoring and Food Safety. More than 36,000 global FDA investigators have used ORA-U and the ComplianceWire Solution for onboarding and ongoing training.

The FDA/UL EduNeering CRADA has been renewed and expanded five times since its inception, enabling FDA to use the new learning technologies and approaches developed by UL EduNeering. The most recent CRADA expansion, signed in December 2013, focuses on addressing the challenges of globalization through services that include:

- Content development for new curricula on topics related to international inspections and the import/export of FDA-regulated products;
- Access to the ORA-U curriculum and ComplianceWire for designated international counterpart agencies;
- Access to the ORA-U curriculum and ComplianceWire for other US government regulatory agencies;
- Development of mobile learning tools and content.

The CRADA solution developed for FDA is available to UL EduNeering's Pharmaceutical, Biologics and Medical Device clients, providing the industry with the same level of preparedness and learning relied on by FDA. ComplianceWire has been deployed to more than 250 Life Science organizations worldwide and in 34 languages. The CRADA includes to ongoing expansion of the ComplianceWire resource to learners in countries including China, India, Japan and members of the European Union.



## 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.

