Life & Health

US FDA Inspections and Enforcement Curriculum

Highlights:

- *Curriculum of over 50 courses.*
- *Content co-developed and/or reviewed by the US FDA and used to train US FDA inspectors and investigators.*
- *Available via ComplianceWire®, the validated 21 CFR part 11-compliant system to manage and document knowledge.*
- *Tools to help drive employee comprehension of critical operating procedures, regulatory requirements and performance expectations.*

Background

Concerns are growing about the safety of medical products used by the American public. The United States Congress solicits testimony about the US FDA's inspection and enforcement actions, spurring demands for greater vigilance by the FDA in breadth and frequency of inspections. At the center of these intersecting issues is a Life Science industry trying to understand and adhere to the US FDA's requirements.

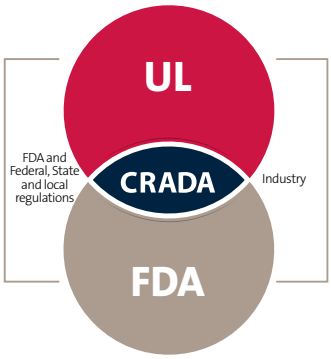
US FDA inspections are time-consuming and personnel-intensive, even for the best-run facilities. Since noncompliance can result in significant revenue losses, product non-approvals, recalls or Consent Decrees, companies should work with the US FDA before, during and after their inspections. A proactive stance on US FDA inspections and enforcement not only weighs in a company's favor, but helps create a culture of compliance that can improve business performance and operational efficiency.

UL EduNeering helps companies develop and implement compliance programs that can translate into practical benefits, both in cost savings and in protection of a company's reputation and credibility with regulators, the medical community and public, and stakeholders.

UL's Relationship with the US FDA

In 1999, UL and the US FDA established a Cooperative Research and Development Agreement (CRADA). The agreement enables the US FDA to standardize training courses and deliver them online to thousands of regulators and investigators. Plus, US FDA-regulated companies now have access to the online content provided, reviewed and used by the US FDA.

Following the inception of CRADA, basic training time for new US FDA investigators has decreased from six to 12 months to only three months. Since 2002, US FDA students have completed more than 100,000 web-based activities. As a result of our relationship, the US FDA now has a system that enhances knowledge and reduces training time and cost by providing consistent learning anytime, anywhere via the internet or through blended learning enhanced by UL's Critical Information Control System© (CICS).



Courses Descriptions by Functional Area:

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QS Regulation 6: Acceptance Activities; Nonconforming Product QSR06
QS Regulation 7: Corrective and Preventive Action QSR07
QS Regulation 8: Labeling and Package Control; Handling, Storage, Distribution and Installation QSR08
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Computerized Systems Inspections in the Medical Device Industry ISPE04
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Part 11: Electronic Records and Signatures – Application FDA61

Continual Content Updates

Regulatory agencies and related information sources are continually monitored, analyzed and incorporated into course updates or new courses.

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