U.S. Food and Drug Administration Inspections and Enforcement

UL Solutions

Safety. Science. Transformation.™

Highlights

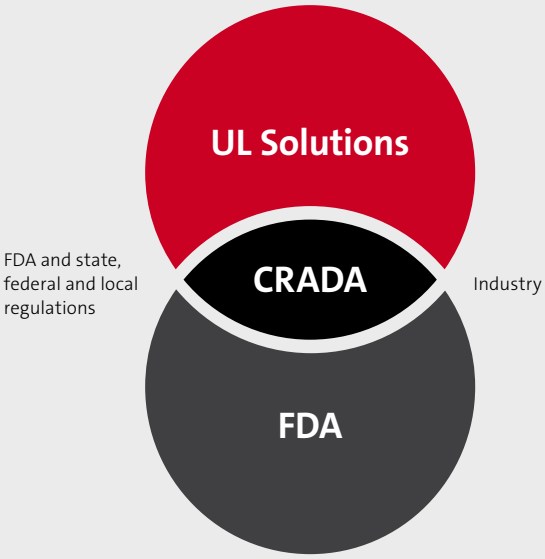
- Curriculum of over 50 courses
- Content co-developed and/or reviewed by the FDA and used to train FDA investigators
- Available via ComplianceWire®, 21 CFR Part 11 and EU Annex 11 Validation and Compliance Learning Management System (LMS)
- Tools to help drive employee comprehension of critical operating procedures, regulatory requirements and performance expectations

A proactive approach to U.S. Food and Drug Administration's (FDA) inspections

Concerns are growing regarding the safety of medical products used by the American public. The United States Congress has solicited testimony about the U.S. Food and Drug Administration's (FDA) inspection and enforcement actions, spurring the demand for greater vigilance by the FDA in both the breadth and frequency of inspections. At the center of these intersecting issues is a life sciences industry attempting to understand – and adhere to – the FDA's requirements.

FDA inspections are time-consuming and personnel-intensive, even for high performance facilities. Since noncompliance can result in significant revenue losses and denial of product approvals as well as recalls and consent decrees, companies should work with the FDA before, during and after their inspections. A proactive stance on FDA inspections and enforcement not only weighs in a company's favor, but it also helps create a culture of compliance that can improve business performance and operational efficiency.

UL Solutions quality, compliance and learning help companies develop and implement compliance programs that translate into practical benefits such as cost savings and the protection of a company's reputation and credibility with its regulators, stakeholders, the medical community and the public.



Our relationship with the FDA

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

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

FDA Inspections and Enforcement Course Listing

Basics of Inspections

- Basics of Inspections: Beginning an Inspection
- Basics of Inspections: Issues and Observations
- Courtroom Testimony
- Destruction and Reconditioning
- Enforcement of the Postmarketing Adverse Drug Experience Reporting Regulations
- Evidence and Proof
- FDA 483s: Inspectional Observations
- FDA Establishment Inspection (EI)
- FDA Establishment Inspection Report Writing
- FDA Good Guidance Practices (GGPs)
- Failure Investigations for Medical Device Manufacturers
- Field Examinations
- Food and Drug Law: Criminal Acts Violations
- Food and Drug Law: FDA Jurisdictions and Prohibited Acts
- Food and Drug Law: Imports and Exports
- Food and Drug Law: Judicial Actions
- Food and Drug Law: Prohibited Actions
- Handling an FDA Inspection
- Interviewing Techniques
- MDR Regulation 1: Overview and General Provisions
- MDR Regulation 2: Device User Facility, Importer and Manufacturer Reporting Requirements
- MDR Regulation 3: Requirements for Individual Adverse Event Reports
- Recalls of FDA-Regulated Products
- Sample Collections
- Special Investigations
- Systems-Based Drug Inspections

Quality System Regulations and Inspections

- Introduction to Quality System Regulations (QSR)
- QS Regulation 1: Overview and General Provisions
- QS Regulation 2: Quality System Requirements
- QS Regulation 3: Design Controls
- QS Regulation 4: Document and Purchasing Controls
- QS Regulation 5: Identification and Traceability: Production and Process Controls
- QS Regulation 6: Acceptance Activities; Nonconforming Product
- QS Regulation 7: Corrective and Preventive Action
- QS Regulation 8: Labeling and Package Control; Handling, Storage, Distribution and Installation
- QS Regulation 9: Records
- QS Regulation 10: Servicing; Statistical Technique)
- QS Regulation 11: Application and Inspection of QS Regulations
- QSIT 1: Beginning the Inspection
- QSIT 2: The Management Controls Subsystem
- QSIT 3: The Design Controls Subsystem
- QSIT 4: The Corrective and Preventive Actions Subsystem
- QSIT 5: The Production and Process Controls Subsystem
- A Guide to ISO 9001:2015 _ Quality Management Systems Requirements

Import Operations

- Import Operations 1: Background
- Import Operations 2: The Process
- Import Operations 3: Other Activities

Risk Management

- Risk Management 1: Key Concepts and Definitions
- Risk Management 2: Pharmaceutical cGMPs for the 21st Century

Validation and Part 11 Compliance

- Computerized Systems Inspections in the Pharmaceutical Industry
- Computerized Systems Inspections in the Medical Device Industry
- Part 11: Electronic Records and Signatures – Applications
- Part 11: Electronic Records; Electronic Signatures

Continual Content Updates

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

About ComplianceWire®

ComplianceWire® is the best-in-class learning management system (LMS) designed specifically for highly regulated industries. Our team designed the platform to effectively and efficiently automate the creation, delivery, and reporting of role-based training, qualification and compliance programs for the life sciences industry.

This time-tested technology is used extensively by U.S. and global pharmaceutical, medical device and biologics companies as well as global regulatory authorities in the United States, China and India.

UL Solutions is a premier global independent safety science company that has championed progress more than 125 years. More than 14,000 professionals are guided by the our mission to promote safe working and living environments for all people.

To learn more about how to achieve enterprise-wide compliance, quality and performance goals with ComplianceWire® LMS, visit UL.com/compliancewire, or call +1.609.627.5300 to speak with one of our LMS product specialists.

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