AUDIT & INSPECTION READINESS

UL Advisory Solutions

AUDIT / INSPECTION READINESS

Life Sciences companies that serve multiple national markets or rely on dispersed supply chains commonly face compliance challenges from these agencies include the US Food and Drug Administration, the European Commission, the International Committee on Harmonization, the International Standards Organization and national governments.

Preparation is essential for any audit because of the escalating complexity and overlap of global quality regulations. Failure to meet audit requirements can severely impact the organization causing delays in product launch.

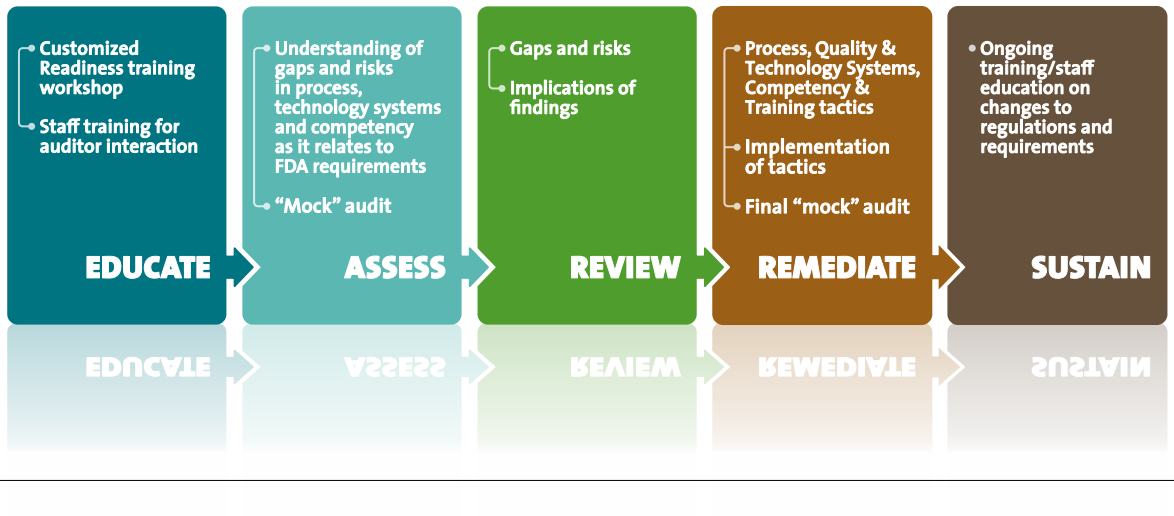
While all facilities within a regulated company should be audit-ready at any time, there are certain triggers that might warrant additional levels of preparedness:

- Opening or expanding a facility
- Launching a new product
- Serious adverse events or recalls
- Higher product class
- Prior issues at other company facilities
- Merger, acquisition, product purchases
- Change in manufacturing registration
- Major change in production equipment, approach or key ingredients

READINESS ASSESSMENT PROGRAM

For companies that are seeking to enter North America markets, UL's Audit and Inspection Readiness solutions span a wide range of programs, which are explained on the next few pages. You can select one or all of these programs to identify potential observation risks in your processes, competencies and documentation - before you start to market your product.

Our programs are designed to be proactive in nature, and not simply focus on addressing regulatory scrutiny. We also consider your company's long-term business objectives, such as eliminating process redundancies, ensuring control at each work stream, reducing operating costs, and more.



INSPECTION READINESS WORKSHOP

UL's Advisory Solutions team includes industry experts who help you prepare your quality systems, competencies and processes for a successful regulatory audit. Our hands-on approach begins with an Inspection Readiness Workshop where UL instructors will train your staff on how to prepare your organization for an FDA audit, understand the FDA inspection process, with emphasis on how to interface with FDA investigators, and recommended audit Do's & Don'ts. The workshop is based on minimizing your audit risk by examining the key areas of FDA focus and most common audit findings. You will learn how to develop an inspection infrastructure, processes for hosting and responding to inspections and training for individuals in their roles during an inspection. Best Practice tips on how to prepare your opening presentation to an auditor including presentation on products, facility and organizational charts as well as closing the meeting will be taught.

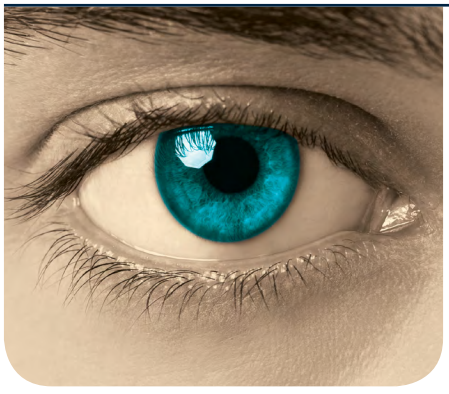
The workshop will also allow your employees to practice responding to typical interview questions which will ensure a smoother audit process and help employees answer with confidence and accuracy. Additionally, the workshop will assist you in planning for future internal and mock audits This one-day workshop can be conducted as a blended learning program comprised of foundational online training followed by an onsite workshop and post online support .

FDA is increasing both the number and intensity of its inspections, using a risk-based approach. Activities such as mock audits, gap analysis, critical process reviews and inspection-readiness training are key to maximizing your preparedness.

MOCK AUDIT

Following the Readiness Workshop, the UL team conducts a Mock Audit to simulate routine and pre-approval FDA audits and to assess your process and business readiness. The 4-5 day engagement with an auditor experienced with the key focus areas examined during a routine audit will:

- Help prepare your staff to handle an FDA audit
- Provide a full gap analysis for QSR, cGMP, Part 11, ICH and other regulatory standards
- Assist you in determining if there are systemic problems within your processes
- Help assure your organization identifies compliance gaps and assesses effectiveness of controls so that they can be remediated prior to the official audit
- Give your organization the confidence and assurance that you are audit-ready and help senior management find the best course for improvement



DURING A MOCK AUDIT, WE WILL CONDUCT HIGH LEVEL INSPECTION REVIEWS OF YOUR CRITICAL/HIGH RISK AREAS:

MEDICAL DEVICE (QSIT) FOCUS:

- Management Control
- Corrective and Preventativection (CAPA)
- Design Controls
- Production and Process Controls
- Material Control
- Document/Record/Change Control
- Facility and Equipment Control

PHARMA/BIOTECH FOCUS:

- Quality Systems
- Facilities and Equipment
- Materials System
- Production System
- Packaging and Labeling System
- Laboratory Control System

AUDIT REMEDIATION SERVICES

Whether your organization has audit findings/observations from official regulated body audits, internal audits or UL mock audits, UL remediation services can partner with you to provide consultation and support to create and implement remediation plans for all findings:

- **Allows you to provide the required response and updates to regulatory agencies and successfully remediate all findings before subsequent re-inspections**
- **Assists you to write objective and logical responses to observations/audit findings and recommendations for corrective and preventative actions**
- **Reduces the risk of further regulatory scruitiny**

SUPPLIER AUDIT PROGRAM

A successful Supplier Management Program requires companies to establish detailed procedures related to the qualification of suppliers and, in some cases, supplier quality agreements. These procedures and agreements must be sufficiently detailed to ensure adequate control of the materials and supply chain. Before a supplier can be used, companies qualify the supplier through an onsite audit/assessment as well as inspection and approval of the material. Once qualified, the on-going supplier management program requires periodic audits of the supplier. In addition, any change in outsourcing decisions or changes initiated by the supplier may require review, re-audit/assessment and re-approval.

Using a risk-based approach, companies set up an auditing cycle for their qualified suppliers. The frequency or depth of audit can be commensurate with the risk posed by that supplier or the materials it provides.

UL provides robust outsourced supplier audit capability ranging from a single 1-2 day supplier audit to annual contracts for managing your complete supplier auditing program. Let our experienced and highly qualified auditors provide your company the assurance that your suppliers are complying with your standards, reducing the risk to your organization.

About UL Compliance to Performance

UL Compliance to Performance provides knowledge and expertise that empowers Life Sciences organizations globally to accelerate growth and move from compliance to performance. Our solutions help companies enter new markets, manage compliance, optimize quality and elevate performance by supporting processes at every stage of a company's evolution. UL provides a powerful combination of advisory solutions with a strong modular SaaS backbone that features ComplianceWire®, our award-winning learning and performance platform.

UL is a premier global independent safety science company that has championed progress for 120 years. It's more than 12,000 professionals are guided by the UL mission to promote safe working and living environments for all people.

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