Advisory Solutions
List of Key Programs

Gain the Benefits of a Vast Consulting Network

When Life Sciences organizations approach UL Compliance to Performance, they are seeking not only to adhere to critical global regulations, but also to rely on proven expertise to make sustainable performance and operational improvements.

Our Advisory Solutions team is made up of full-time UL employees, as well as industry experts and consultants who can share hands-on knowledge to improve your learning, compliance and operational challenges. Our team can spend days, or even weeks, assessing our clients' current processes and delivering a custom program that can address compliance and business goals.

Here is an overview of our three most popular programs for Life Science organizations, and more details are included in this brochure:

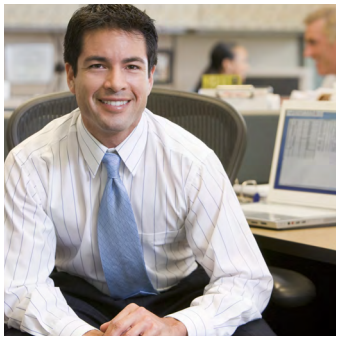
- IT Systems Governance Programs: We provide proven templates for companies that require UL validation documentation, test scripts and validation plan; or we can simply review your documents to ensure they meet FDA expectations; we can also develop an organization's training matrix to meet the training and qualification requirements;
- Risk Management Programs: We can assess an organization's current risk management processes at specific stages of the product life cycle (design, QA, CAPA, etc) and work alongside your team to integrate best practices that lead to reduced compliance risk and improved business performance.
- Inspection Readiness Programs: We can help your organization respond appropriately to 483s and FDA Warning Letters, to remediate issues and build programs that prevent future observations; we can also help internal auditing teams identify high-risk areas that often get attention by a real FDA investigator;




SYSTEMS GOVERNANCE AND VALIDATION

System Governance Development:

System governance ensures that your LMS implementation aligns with the goals set forth by your organization. It will help establish appropriate representation from all stakeholders and provides a structure for decision-making, including standardizing nomenclature, creating role-based curricula and security roles.



Our Advisory Solutions Governance Package assists companies with controlling and maintaining the system. There are several different levels of Governance support that include reviewing and forming your governance strategy, providing best practices, consulting support and the use and review of Governance templates. All templates include instructional text and/or example text to save time on system roll out and can be modified for any system.

Validation Support:

ULCompliance to Performance works with clients to validate their instance of ComplianceWire®, our own web-based, proprietary learning system, which has been designed to meet 21 CFR Part 11 requirements. Clients also turn to UL EduNeering to help fulfill the full validation of other cloud applications, and to manage specific aspects of validation support, such as validation plans, documentation, change management and governance, test scripts and user requirements specifications.

Training Assessment & Matrix Development:

FDA investigators often look at a company's training program when other observations are made. Clients rely on our Training Compliance Audit for an objective assessment of the organization's quality-focused training program. Our experts will review your training program to ensure it is structured to meet regulatory compliance expectations, and is aligned with industry best practices.

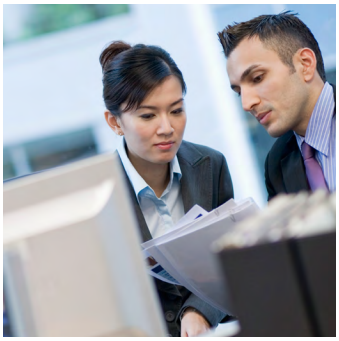
We can evaluate your organization's use of training item management, specifically the use of SOPs, classroom events and other training items. We can also develop an organization's training matrix, defining specific job roles and building curricula for each level within the organization. These curricula can include a variety of training items, including SOPs, internal documents, on the job training, classroom and computer-based modules to roles.

RISK MANAGEMENT PROGRAMS

Risk Management Mentoring:

Our risk management experts will visit your facility and work alongside your teams, reviewing your risk management approaches and sharing their best practices so approaches are aligned with both the latest ISO standards and regulatory expectations.

Our experts serve as mentors, in that they share best practices and regulatory knowledge to help your organization link your existing processes within a risk management framework, to help your company not only meet your regulation obligations, but improve quality and improve patient safety.



Risk Assessment / Mock Audit:

In this mentoring program, our experts will review your company's current risk management procedures and share recommendations on strengthening risk management principles, as defined by standards and regulations that include ISO 14971, ISO 13485, or FDA's QSR Requirements (21 CFR Part 820).

Risk-Based Decision Making in Product Design:

Our experts will review your risk management processes as they relate to engineering safety and product design, such as software development, biocompatibility, human factors engineering, as well as employee competencies.

Risk Management in Legacy Products:

Our experts will review your organization's legacy products and recommend risk management steps to take that can be retroactively incorporate into these processes, including CAPA, design controls, and other FDA's QSR Requirements (21 CFR Part 820).

AUDIT READINESS PROGRAMS

Audit Readiness Programs:

UL experts will visit your facilities and help your staff prepare 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. Our experts focus on minimizing your audit risk by focusing on the key areas of FDA focus and most common audit findings. Employees will be involved in simulated exercises to practice responding to typical interview questions. Following this program, employees are able to respond to actual audits with greater confidence and accuracy.

Our experts will also help your organization develop a sustainable 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 auditor including presentation on products, facility and organizational charts.

Mock Audits:

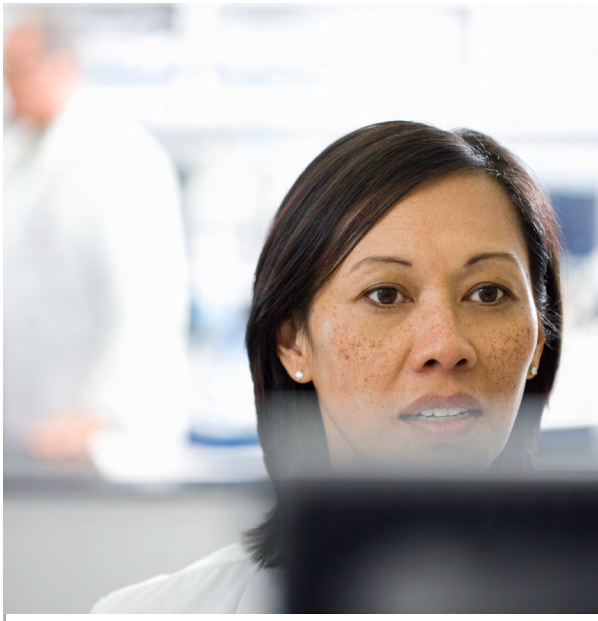
UL conducts FDA mock audit inspection to simulate routine and pre-approval FDA audits. The UL mock audit team helps prepare your staff to handle an FDA audit and it will provide a full gap analysis for QSR, cGMP, Part 11, ICH and other regulatory standards. The UL Mock audit will assist you in determining if there are systemic problems within your processes. These services ensure your organization identifies compliance gaps and assesses effectiveness of controls so that they can be remediated prior to the official audit. This gives your organization the confidence and assurance you are audit ready and helps senior management find the best course for improvement. Includes a 3-5 day audit focused on key areas audited during routine audits.

Remediation Services:

Whether your organization has audit findings/observations from official regulated body audits, internal audits or UL mock audits, UL remediation services can provide consultation and support to create and implement remediation plans for all findings allowing you to provide the required response and updates to regulatory agencies and successfully remediate all findings before subsequent re-inspections. Our experts will also assist you to write objective and logical responses to observations/audit findings and recommendations for corrective and preventative actions.

Supplier Audits:

Our experts perform Second-Party Auditing to help you improve the reliability and effectiveness of your supply chain. Our customizable auditing and inspections services allow your company greater transparency into your supply chain using your criteria and our experience audit team can be focused on critical areas such as Quality Management Systems, Medical Device Reporting and others.



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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