Speed to market represents an important competitive advantage for Life Sciences manufacturers, and can be a key factor in the total lifetime profitability of new Life Sciences organizations. Successful organizations have robust internal programs and processes that streamline new product development activities.

Succeed In Navigating The Complexities Of The

FDA REGULATORY PROCESS FOR US MARKET ENTRY

UL's US Market Entry Program

The U.S. market for Life Sciences companies is the world's largest and potentially the most lucrative. Life Sciences companies from around the world are all looking to expand their reach into the US for which FDA approval is required. To achieve FDA approval, organizations have to navigate and understand the complexities of the ever changing regulatory process. Any delays or setback during the process can result in costly delays in bringing new product to market. However, Life Sciences Companies can reduce the likelihood of these delays by becoming more knowledgeable about the FDA's requirements, staying current with the constantly changing regulatory landscape, and working with an experienced advisor or consultant to ensure that their quality management systems, technology platforms, competencies and product submission will meet the rigor of FDA.

Typical questions that are on the
minds of global companies
as they prepare to enter the US market are:

How do we gain clarity on US FDA requirements?

How can we best understand the customs and import requirements?

Do we have the proper GxP infrastructure that will meet the rigor of an FDA audit?

Are employees and contractors properly qualified and competent to perform their functions?

Do we have the right technology in place to meet US FDA requirements?

Which industry standard and regulatory certification options are we required to prepare for?

Are we prepared to respond to any audit observations?

UL: A Global Network of Market Entry and FDA Experts

Life Sciences companies have come to rely on UL's expertise to build a sustainable US market entry strategy. UL's extensive experience with both the meaning and the intent of FDA regulations, from approval through post-market audits, has made UL a reliable partner for global organizations seeking entry into the US market.

Using our expertise, global companies can minimize product approval delays, and also reduce the ongoing quality and regulatory risks that result in product detention, product seizures, regulatory fines and other disruptions that threaten the long-term success of a company's presence in the US market.

UL's Market Entry Solutions rely on proven processes, formulated by global experts who have successfully launched many Life Sciences products into the US marketplace. The UL team will provide a combination of onsite consulting and hands-on mentoring to support your organization's journey through the process. We will help you:

- Develop strategies and roadmaps for regulatory compliance – identifying risks and gaps in product design, quality system, technology infrastructure, IT validation, and competencies relative to requirements with timelines and critical milestones

- Understand regulatory/application specific requirements - from process redesign to quality systems management, competency mapping, audit preparation and registration readiness
- Understand how new and existing regulations will impact their product development activities, processes and systems
- Stay ahead of issues and violations, drive operational efficiencies and operational excellence to create a competitive advantage

Program Elements

WHAT UL WILL DELIVER

requirements and road-mapping

tactical planning and design

readiness assessment

remediation

registration, testing and certification

Requirements and Road-mapping

We will act as an extension of your licensing and regulatory team, providing a clear understanding of regulatory requirements, best practices and functional risks critical to the regulatory process. We'll also share best practices from dozens of real-world submissions and conduct a gap analysis of your product, processes, systems and competency relative to requirements. We'll summarize all the key steps in navigating the proper registrations and approvals for the US market , with timelines and critical milestones you have to meet.

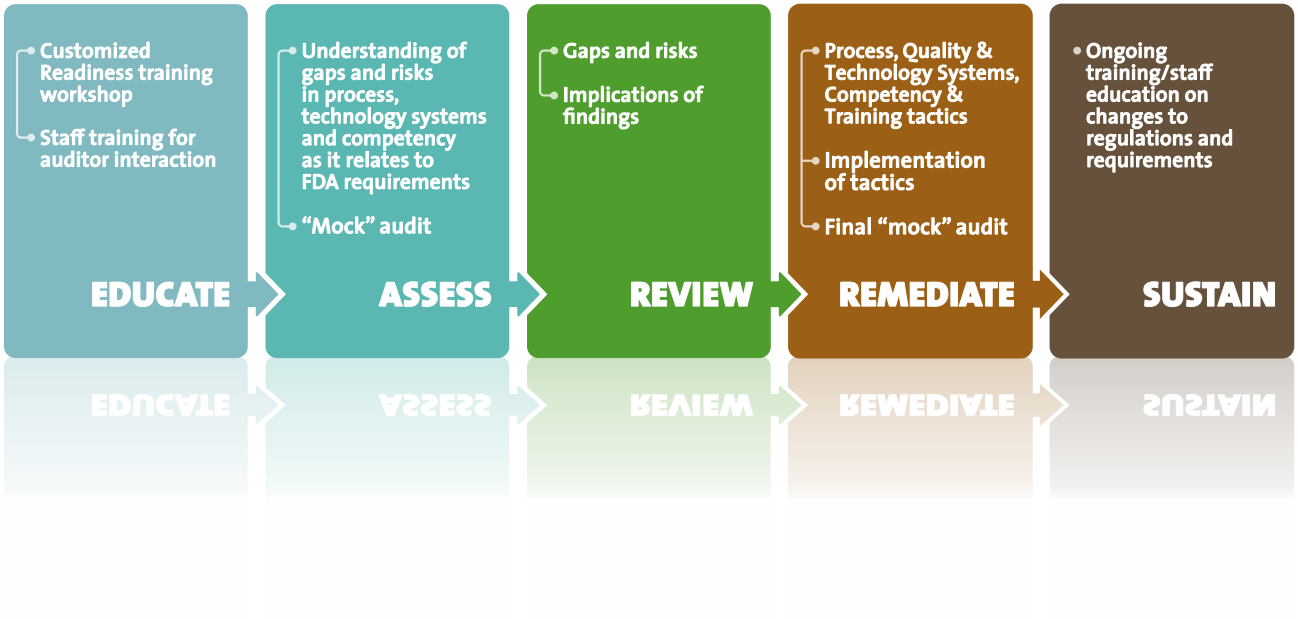
EXTEND YOUR PRESENCE IN THE WORLD'S LARGEST MEDICAL DEVICE MARKET

The US medical device market is expected to reach $133 billion by 2016, making it the largest market in the world[1].

Tactical Planning and Design

We work alongside your team to generate an operating plan to address and meet FDA requirements. These include the creation of risk mitigation strategy (based on ISO 14971 or ICH Q9), a Quality System Governance plan, a training and competency plan for your staff and a GxP system design. Recommended tactics on resources, tools and process changes needed for FDA compliance will be outlined and the UL team will provide hands-on support to implement the proposed actions.

READINESS ASSESSMENT PROGRAM



Readiness Assessment

UL's Readiness Assessment Program is designed to uncover weaknesses in your processes, competencies and documentation before you start to market your product. It is critical that you understand the status of your quality system and how to anticipate the types of questions and requests you will receive from FDA inspectors. UL can help you and your suppliers prepare for these critical audits by beginning with an awareness/readiness workshop followed by a mock audit of your quality systems, competency and records. UL will also support you with a post-audit action plan that details and prioritizes corrective actions necessary to reduce non-compliance vulnerabilities along with a follow-up inspection awareness plan to sustain the changes.

THE US REGULATORY APPROVAL PATH HAS BRIGHTENED

FDA has accelerated drug approvals in the past two years. In 2015, FDA approved 45 drugs with never-before-sold ingredients in 2015, which is the highest approval number since 1996.[2]

Remediation

Receiving a 483 or warning letter from the FDA can be disruptive to your product development and commercialization process. Most companies are not prepared for remediation and UL is here to support your company's resources prepare for submission. We'll review your organization's existing procedures and create a roadmap for improvements to operational, quality, competency programs, based on findings. We will then implement corrective and preventive action (CAPA) programs to ensure your organization's incident management and change control procedures address FDA requirements.

Registration, Testing & Certification

We will help you identify the most efficient path for your drug or device, review your pre-clinical and clinical phases, prepare your FDA submission, and help you appoint a designated FDA US agent to function as your organization's point of contact with FDA.

UNDERSTAND IMPORT PROCEDURES AND REGISTRATION ACTIVITIES

UL can help you understand the FDA registration process. US FDA requires that any importer responsible for import of a drug or device must ensure their facility is listed under the foreign manufacturer's site establishment registration. Key data such as Importer Name, DUNS, telephone number and e-mail address must be submitted electronically to the FDA by the foreign establishment.[3]

Take the Next Step in Your Journey to Enter the US Market

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References:
1 Source: Selecta USA. The Medical device Industry in the United States, November, 2015
2 Source: FDA, "Novel New Drugs Summary 2015", Jan. 5, 2016
3 Source: AAEI, FDA Import Requirements & Best Practices For Drugs & Medical Devices, September 2015

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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