Life & Health

Comprehensive Services to Support Global Regulatory Submissions and Ongoing Compliance

When UL acquired EduNeering in 2012, our clients gained easier access to a vast array of services delivered through UL. For more than half a century, UL has served as a leader in the Medical Device industry, providing expertise and value throughout the product development life cycle, from product concept to regulatory approvals to commercialization.

Consider these facts about UL:

- While UL was in the third party program, we reviewed more than any other third party
- The First Service Provider to Launch ISO 14971 Registration Service
- The #1 Issuer of CB Certificates for MED
- The Global Leader in Regulatory Services (Market Access)
- ISO 13485, ISO 9000, Notified Body

While UL was in the Third Party Program, We Reviewed More Than Any Other Third Party

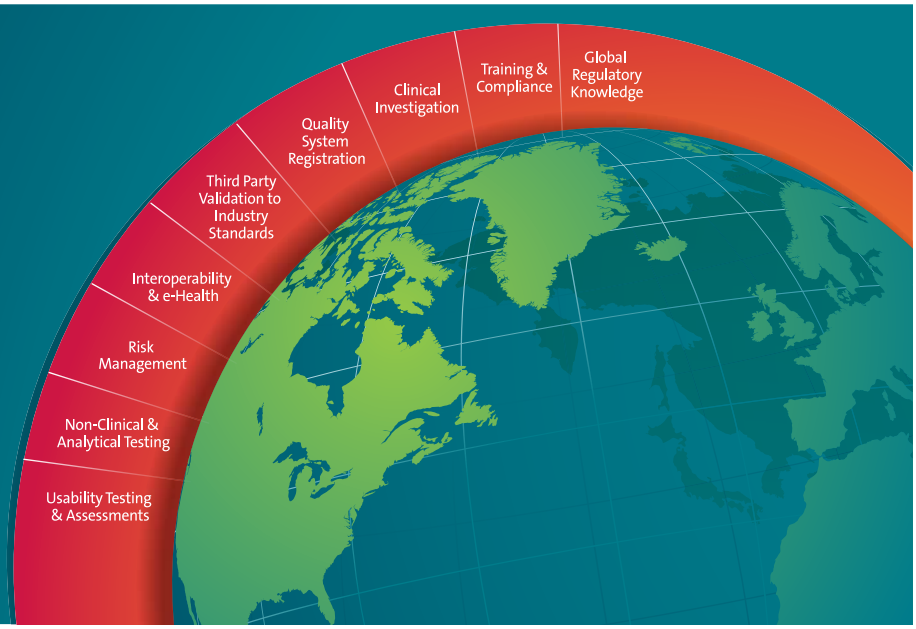
UL became an Accredited Person at program inception and UL experts have reviewed hundreds of 510(k)s for conformity to the FDA's regulations. UL's experience in providing the FDA 510(k) service is one reason why so many global Medical Device manufacturers chose UL as their preferred 510(k) reviewer. Now UL provides more value in taking our experience as a third party from 1996-2013 (or 17 years) and helping manufacturers with their 510(k) submissions and technical documentation. Our years of experience in a variety of device categories mean UL is uniquely qualified to provide support for 510(k) submissions.

UL Was the First Service Provider to Launch ISO 14971 Registration Service

UL was the first compliance and regulatory service provider to launch an ISO 14971 registration service and continues to support the health sciences industries with knowledge of ISO 14971, risk management file preparation and services to support global regulatory submissions. As the only international standard for risk management for medical devices, ISO 14971 has become an integral element for satisfying regulatory requirements in most major markets and should be incorporated into the medical device development life cycle.

ISO 14971 has been formally recognized by the U.S. Food and Drug Administration (FDA) and by Health Canada; the European Union has adopted it as a harmonized standard; Japan has designated it as a Japanese Industrial Standard; and Australia has made it their "de facto" standard for risk management.

UL provides expertise for the Medical Device industry, and offers value throughout the product development life cycle, from product concept through commercialization.



The # 1 Issuer of CB Certificates for MED

UL is a leader in issuing CB (Certification Body) test certificates for the MED (Medical Devices), MEAS (Laboratory and Test & Measurement Equipment), BATT (Battery) categories, and issued more CB Certificates in the OFF (IT Equipment) category in 2011 and 2012 than any other NCB. This demonstrates that UL is the NCB of choice in the industry when it comes to certifying the safety standards of electrical and electronic components, equipment and products.

The Global Leader in Regulatory Services (Market Access)

Regulations and compliance requirements tend to evolve over time presenting another challenge to manufacturers and requiring constant vigilance to identify and address changes that can impact the continued marketability of their products.

Fortunately, the global network and compliance expertise of UL can help manufacturers navigate through these complexities with a simplified and customized market access solution.

UL provides third party regulatory services such as ISO quality audits and regulatory approvals where permitted by the country regulator such as the US, European Union, Canada and Japan.

UL can obtain the required certifications/marks via its own certification organizations, partnerships with other certification organizations or participation in mutual recognition schemes such as the CB Scheme. UL identifies and bridges the specific compliance gaps by leveraging the most efficient options.

For example, UL is an INMETRO accredited test agency for medical equipment for the Brazilian market and can provide the mandatory product certification and factory inspections required by the regulations. The UL-BR mark can help simplify your access to the Brazilian market. Once your product is certified, it will bear the INMETRO mark as well as the UL-BR mark. UL helps clients gain access to the markets they need to sell their medical and IVD (In vitro diagnostic) devices to the people that need them. Our teams provide these services:

- Integrated audits
- Early engagement
- Global accreditations
- Independent third party
- Local service
- Global locations
- Developing emerging markets
- Continuously integrating new value-add services

How UL Can Integrate Your
Global Regulatory Assessments

REGULATORY SUBMISSIONS WITH UL

Integrated Safety Certification Assessment

- CSA C22.2 No. 601.1 Canada requirements
- EMC – IEC 60601-1-2
- ANSI/UL 60601 US requirements
- CB Scheme "MED"
- NBR IEC 6061-1 Brazil requirements
- EN 60601 EU requirements
- JIS 60601 Japan requirements

►**Base Standard: IEC 60601-X-X**

Integrated Quality & Management Systems Assessment

- ISO 13485
- FDA QSR
- Japan MO No. 169
- ISO 13485 under CMDCAS
- EU Annexes under MDD and IVDD
- ISO 14971

►**Base Standard: ISO 13485**

Pre-Clinical Analytical Testing & Verification Services

- Biocompatibility – ISO 10993, USP
- Sterility – ISO 11137
- Packaging – ISO 11607
- Physico-chemical
- Clinical investigations using ISO 14155

►**And other applicable standards**

YOUR TECHNICAL FILE

With integrated assessments, UL gives you the data to support multiple regulatory submissions.

Regulatory Approvals for global emerging markets

Canadian Regulatory Approvals

FDA Approvals

Chinese Approvals

Japanese Regulatory Approvals

Brazilian Approvals

European Union Regulatory Approvals

A comprehensive, start-to-finish program that moves your product through global approvals.

At **UL**, we've expanded our services to give you the advantage when it comes to

GLOBAL REGULATORY APPROVALS

- Auditing
- Integrated testing
- Quality management registration
- Third party regulatory approvals
- Product certifications support
- Global application assistance

As a UL client, you can also rely on these valuable services:

Integrated Safety Certification Assessments	Our experts can conduct safety test reports, CB scheme and human factors engineering. We can test and certify products to globally harmonized standards for safety, biocompatibility, usability, EMC, wireless, etc.
Integrated Quality & Management System Assessments	We are a Notified Body under MDD and IVDD, UL is an accredited registrar for ISO 13485, and we provide ISO 14971 Registration.
Pre-Clinical Analytical Testing & Verification Services	We conduct biocompatibility testing (ISO 10993), sterility validation and packaging validation.
Clinical Research (CRO)	We conduct clinical evaluations, protocol development, site selection and statistical analysis.
Registration Support Services	FDA 510(k), China SFDA, Taiwan TFDA, Korea KFDA
Services for IEC 60601 & UL 60601	• Options to use a question-based approach or an on-site audit-based approach to demonstrate conformity to IEC 60601-1:2005 • Public and private training to IEC 60601 2nd and 3rd editions, differences, ISO 14971 and more • Gap assessment to IEC 60601 and ISO 14971 • Evaluations for devices intended for home use • EMC, wireless safety and security
Software Evalution, Usability and Human Factors Engineering	• Evaluation to the recognized standards for usability and software to meet global regulatory requirements • Design support throughout the product development cycle
Interoperability, eHealth, mHealth, Continua Alliance Certification Testing	• UL experts are on the cutting edge of technology and provide testing and advisory services for eHealth applications and interoperability • UL is a certified Continua Alliance Certification test lab