MEDICAL DEVICES
Comprehensive Lifecycle Services to Support Regulatory Approvals

Full Support During the Product Development and LifeCycle
There are many risks involved with placing medical devices on the market. As an independent and trusted third party, UL helps manage, reduce, or mitigate risks so companies can focus on their core competencies of designing, manufacturing, marketing, and selling their products. With global expertise and expanding capabilities, we provide this support throughout the product lifecycle.

WORKING WITH UL TO HELP MITIGATE YOUR GLOBAL RISKS

RISK

Product:
Product risk is a very tangible reality for the medical industry. The risks extend to product usability, safety and even to safe interoperability with other devices. UL provides risk mitigation through testing, validation, supplier management through vendor and component inspections, responsible sourcing and RoHS compliance.

Regulatory Approvals:
The risks in gaining and maintaining regulatory approvals has its own unique risks. The first risk is getting the approval. UL provides the advantage of years of experience working with regulators to help manufacturers with regulatory technical documentation and regulatory submissions support. We also help demonstrate regulatory compliance post-market through mock audits, quality management approvals, and post-market support.

Business:
Potential risks to the business extend to the company brand, reputation and ability for all suppliers and affiliated representatives to comply with global standards of business conduct.

SERVICES

Safety testing
EMC
Unique Device Identifier (UDI) compliance
Usability/HFE
Interoperability testing

Technical Documentation preparation
Mock audits to regulatory requirements
Submission services
Remediation support

Third Party Regulatory Approvals:
Japan PAL
Brazil INMETRO
EU CE Mark
Canada CMDCAS

Robust, FDA regulatory learning management systems that can be adapted to meet Notified Body, and other country regulatory requirements
Training modules, systems and seminars to give your global staff a consistent understanding of the requirements and fulfill regulatory training needs
Compliance management systems to support key application and consistency to minimize your business risk with a global sales and supply chain
From idea to post-market
Supply chain services to verify your component and materials suppliers and vendors to your criteria
INTEGRATED ASSESSMENTS TO ACCESS GLOBAL MARKETS

FULL SUPPORT DURING PRODUCT DEVELOPMENT AND LIFECYCLE

- Training & Compliance
- Quality System Registration & Support
- Risk Management
- Non-Clinical & Analytical Testing
- Human Factors Engineering, including User Interface Design Support and Usability Testing
- Clinical Investigation
- Global Regulatory Advisory
- Product & Process Validation
- Interoperability & e-Health
- Supply Chain Services

UL provides comprehensive services to support medical and IVD companies with global regulatory submissions. Our local services include integrated systems registrations for ISO 13485, Canada CMDCAS, European Notified Body, Japan – PAL, Brazil – INMETRO, and Risk Management ISO 14971. Our experienced engineers provide safety assessments to IEC 60601, IEC 61010, Home-Healthcare and CB Scheme. Our Human Factors Engineering experts provide design support and validation testing. Our team can also support your Regulatory and Learning Management Systems through ComplianceWire®, online and in-person training.

UL also conducts non-clinical tests including sterility, shelf-life, transport and packaging validation and biocompatibility.

UL experts are on the leading edge of supporting customers with global regulatory submissions documentation, clinical evaluation, advisory and support including evolving regulatory advisory and testing services for eHealth mobile medical applications and interoperability.

Find out more: www.ul.com/medical

REGULATORY SUBMISSIONS WITH UL

- Integrated Safety Certification Assessment
  - CSA C22.2 No. 601.1 Canada requirements
  - EMC – IEC 60601-1-2
  - ANS/UL 60601 US requirements
  - CB Scheme "MED"
  - NBR IEC 60601 Brazil requirements
  - EN 60601 EU requirements
  - JS 60601 Japan requirements
  - Base Standard: IEC 60601-1-K

- Integrated Quality & Management Systems Assessment
  - ISO 13485
  - FDA QSR
  - JapanMO No. 169
  - ISO 13485 under CMDCAS
  - EU Annexes under MDD and IVDD
  - ISO 14971
  - Base Standard: ISO 13485

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

With integrated assessments, UL gives you the data to support multiple regulatory submissions and can help you with learning management, technical file preparation, advisory services and submission.
COMPREHENSIVE SERVICES

HUMAN FACTORS ENGINEERING (HFE)

- Support during Product Development
- UL can assess your product’s interactive quality and conformance with FDA’s HFE Guidance and IEC 62366
- Summative and Formative HFE assessments
- Help you establish an HFE program – an essential step for all medical companies.

UL’s HFE 30+ expert team members, based in multiple countries, have written HFE textbooks and standards, teach at prestigious universities, and hold multiple design patents.

www.wilkundrd.com

SAFETY TRAINING & CERTIFICATION

A Blended Approach: Integrated test plans to meet requirements in multiple countries.

- Combined safety: UL, cUL, CB, IIS, INMETRO, EN, Canada
- ISO 10993, USP, MHLW
- Materials Characterization
- Microbiological testing
- Virological testing
- Cleaning, Reprocessing, Sterilization
- Physico-Chemical analysis
- Shelf Life of devices and packages
- Transport safety
- Testing of ophthalmic devices
- #1 issuer of CB’s for MED
- CB combined with UL Mark for streamlined global access

www.ul-mdt.com

EARLY ENGAGEMENT

Programs to help you make certification decisions early in the design process

Many flexible programs available:
- Technical Assistance Program
- “Office Hours”
- Preliminary Investigations
- Gap Assessments
- Proactive Review with assigned engineer

Optimized timing for value-added engineering during the concept, design, and development phases to avoid costly re-work later in pre-production.

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PRE-CLINICAL TESTING FOR MEDICAL DEVICES

- Biocompatibility testing
- ISO 10993, USP, MHLW
- Materials Characterization
- Microbiological testing
- Virological testing
- Cleaning, Reprocessing, Sterilization
- Physico-Chemical analysis
- Shelf Life of devices and packages
- Transport safety
- Testing of ophthalmic devices

www.ul-mdt.com
GLOBAL SUPPORT

CLINICAL CRO SERVICES
Clinical Investigations and multinational studies – Full Compliance with GLP and ISO/IEC 17025

Clinical trial support includes:
- Project Management – Requirements, timelines, coordination of study sites/investigators, study activities and info flow across parties.
- Monitoring & Quality Assurance – Site visits, source data verification, support of investigators.
- Medical Writing – Documentation across all clinical activities, patient info/consent forms, investigation plan/protocol, final integrated clinical report.

QUALITY MANAGEMENT SYSTEMS
- ISO Registrar – ISO13485, CMDCA5, ISO14971, audit consolidation
- CE Notified Body – MDD, IVDD, new regulations, local/regional auditors
- Global Footprint – One calibrated medical team
- Combined Audits – IEC, 13485/CMDCA5, CE, 14971, FUS, DAP
- Risk Management – Options to support 3rd ed 60601-1
- Transfer to UL – Streamlined transfer (including label transfer options)
- Supply Chain Verification Services

RoHS 2 SERVICES FOR MEDICAL AND LAB EQUIPMENT
Support to meet EU and global environmental regulations
- Training
- Gap Analysis
- Bill of Materials Scrub
- Analytical Testing
- Ongoing Assessments for due diligence
- Documentation preparation
- IDES material information database

eHEALTH AND MOBILE HEALTH
- Advisory – Global regulatory strategy and planning
- FDA submission support
- Education and Private Workshops:
  - EMC, Wireless Co-Existence Testing, and Interoperability
  - Security, Data Integrity, and Quality of Service (QoS)
- Assistance with Mobile Medical Applications
- Continua Alliance (CA) Testing
- Wireless Services
- Software-only medical devices
- Medical Device/Systems Software and System Safety
- Continua certified test lab

GLOBAL SUPPORT
MEDICAL REGULATORY ADVISORY SERVICES FOR GLOBAL MARKET ACCESS

- FDA 510(k) Preparation and Registration Services
- Global Regulatory Quality System Support & Prevention
- FDA Inspection Support & Remediation
- Global Regulatory Technical File Gap Analysis, Preparation & Submission
- Global Regulatory Registration Support
- Test Plan Development
- Human Factors Engineering / Usability Design Support
- Clinical Evaluation
- Environmental Support Services
- Unique Device Identification Support

www.uleduneering.com

UL EDUNEERING – QUALITY, COMPLIANCE, LEARNING

ComplianceWire® – A regulatory based learning management system (LMS): an all in one role based training solution & SOP/document control system

- Cloud-based 21 CFR & Annex 11-validated LMS System
- FDA and AdvaMed content – Unique CRADA with FDA - 36,000 FDA investigators trained on ComplianceWire
- Standardized training & qualification across your organization – Role-based programs, minimize risk and improve quality and business performance.
- Online Tools – Ensure SOPs and other policies are being followed and identify “high risk” employees
- Online records to streamline audit preparation

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SERVICES BY COUNTRY

United States

- UL classification under IEC/UL 60601
- EMR testing for FCC and 60601-1-2
- Non-Clinical Testing Biocompatibility, packaging validation, shelf life studies, materials characterization
- Home healthcare
- Infusion pump performance testing to support FDA submissions
- Human Factors Engineering and Usability to support FDA submissions
- Clinical Investigations, CRD
- FDA QSR – 21 CFR 820 Mock audits, audit preparation and gap assessments
- MDR Filing
- USD labeling advisory and support
- Form 483 and warning letter response
- CDRH Radiation submission support – FDA CFR 1040-1020 and IEC 60625
- Validation of 21 CFR Part 11
- 510(k) Premarket Notification gap analysis, preparation and submission and biocompatibility test plan development
- Risk management (ISO 14971)
- Software validation and documentation review
- Assess compliance with Usability IEC 62366 and FDA’s HFE Guidance
- Clinical trial support for FDA GAMP (CRO) Test
- Additional Services to Support Global Regulatory Submissions

- CB informative test report
- Global market access
- Instructor led training
- On demand learning and webinars
- ISO 13485:2016 quality system registration
- EMC testing and SAR testing
- ISO 14971 risk management registration
- Testing to meet country specific requirements
- Infusion pump performance testing to IEC 60601-2-24 particular standard requirements
- Assessments to IEC 60601-1-6 (Usability) and ISO 62366 for global regulatory submissions
- Award winning ComplianceWire regulatory learning management system
- Human Factors user interface and user documentation design support
- Supply Chain Verification Assessment Services

European Union

- Clinical Evaluation
- ISO 13485:2016 quality system registration
- CB Scheme test certificates and informative reports
- Non-Clinical Testing Biocompatibility, packaging validation, shelf life studies, materials characterization
- EMC testing
- UL - EU mark
- CE mark
- D mark
- Home healthcare
- Infusion pump performance testing to support NB submissions
- Own brand labeling for Notified Body Human Factors Engineering and Usability to support Notified Body submissions for CE Mark
- Clinical Investigations, CRO, ISO 14155
- Regulatory Quality System Support and Prevention
- FDA 510(k) PreMarket Notification gap analysis, preparation and submission and biocompatibility test plan development
- Risk management ISO 14971
- Software validation and documentation review
- Assess compliance with Usability IEC 62366 and FDA’s HFE Guidance
- Clinical trial support for FDA GAMP (CRO) Test
- Additional Services to Support Global Regulatory Submissions

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- Supply Chain Verification Assessment Services

Canada

- ISO 13485 under CMDCAS
- Testing and classification to Canadian safety standards - CSA C22.2 No 61010 and CSA C22.2 No 60601
- Quality system support and prevention for ISO 13485 under CMDCAS CMDR

Brazil

- Testing to Brazil safety standards NBR/IEC 60601 and IEC 60100
- INMETRO certification

China, Taiwan, Korea

- Application services approvals for regulatory advisory services
- Taiwan technical cooperation program

Japan

- Testing and certification to JIS standards: 60601
- PDL, 3rd party approvals for Class 2 designated controlled devices
- ISO 13485 under JGMP Ministerial Ordinance 169
- Non-Clinical Testing:
  - Biocompatibility, packaging validation, 3 shelf life studies, materials characterization, transportation testing
- EMC testing

North America

- HealthSciencesNA@ul.com

South America

- HealthSciencesAP@ul.com

Asia and others

- HealthSciencesAP@ul.com

Europe

- HealthSciencesEU@ul.com