MEDICAL DEVICE EVALUATION SERVICES

FOR MEDICAL DEVICE EVALUATION SERVICES THAT EXCEED YOUR EXPECTATIONS, VERANEX IS YOUR DIFFERENCE

Veranex
Transforming Your MedTech Innovation

OPTIMIZE OUTCOMES WITH WELL-DESIGNED MEDICAL DEVICE EVALUATION STRATEGIES AND PROTOCOLS FROM VERANEX

We deliver extensive evaluation capabilities, including validation and bench testing, in state-of-the-art, FDA-inspected, and AAALAC-accredited facilities. Our expertise is unparalleled in the successful completion of sophisticated studies of novel medical and surgical technologies.

Veranex's highly unique, full-service approach saves money and reduces time-to-market by delivering carefully planned studies that are professionally documented and expertly conducted to the highest ethical standards. We excel in procedures ranging from early feasibility studies through Good Laboratory Practice (GLP)-compliant studies to support worldwide regulatory clearance/approvals.

Our Services:

- Biocompatibility
- Safety
- Toxicology
- Histopathology
- Interventional and surgical research
- Physician training

Our Therapeutic Areas of Expertise:

- Cardiovascular
- Neurology
- Ophthalmology
- Thoracic surgery
- Orthopedics
- Gastroenterology
- Urology
- Surgical robotics

FOR MEDICAL DEVICE EVALUATION EXPERTISE TO ADVANCE YOUR INNOVATION, VERANEX IS YOUR DIFFERENCE

For a truly comprehensive solution from concept to commercialization, experience the Veranex difference

- Get in touch to learn more about our integrated MedTech solutions.

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Human Factors and Usability Testing

We provide human factors engineering and usability engineering (HFE/UE) support and testing services to successfully meet the requirements of the FDA and IEC 62366. This includes usability engineering file planning and HFE/UE validation reporting. We also support design and testing of device labeling and packaging, and effective instructions for use and summative usability validation testing.

Design Validation and Preclinical Evaluation

Design validation testing is a key component of the evaluation of medical device safety and performance and we provide analytical services to meet chemical, microbiological, biocompatibility, electrical, and mechanical testing.

We also provide in vivo preclinical testing in large models (ISO 10993, ASTM International, EMEA guidelines, and FDA recommendations), including the earliest stage proof of concept studies, R&D stage studies during which product designs are iterated and perfected, and final regulatory studies intended for regulatory submissions. Macroscopic and microscopic pathology evaluation is performed in-house to provide further critical information regarding biological responses to a medical device or biomaterial. All studies intended to support regulatory submissions are performed according to GLP guidelines (21 CFR part 58, OECD). As required, those include the use of written protocols, standard operating procedures (SOPs), calibrated equipment, accredited facilities, study conduct by skilled and trained personnel, and proper data tracking, biostatistics, and preparation of formal study reports.

Interventional and Surgical Training

Interventional and surgical training is a must for many novel medical devices, and at Veranex we offer services for training of clinical investigators for human clinical studies, including hands-on acute procedures and wet labs, as well as conference room and auditorium space for didactic training. We can dedicate up to five operating suites simultaneously to training sessions that are tailored to the specific needs of our clients. We have the state-of-the-art, fully equipped technical platforms that replicate the hospital setting, thus providing a familiar environment and experience that can be applied to clinical use.

ABOUT VERANEX

Veranex is the only truly comprehensive, global, tech-enabled service provider dedicated to the medical technology industry. Offering expert guidance from concept through to commercialization and across the development continuum, Veranex enables accelerated speed to market, controlled development costs, development risk mitigation, and accelerated market viability assessment.

At every stage, Veranex customers realize efficiencies in cost and time, while our integrated and comprehensive solutions unify the entire development process. With Veranex as your end-to-end partner, you're well-positioned to deliver the safest, most effective devices to improve outcomes to patients everywhere.

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