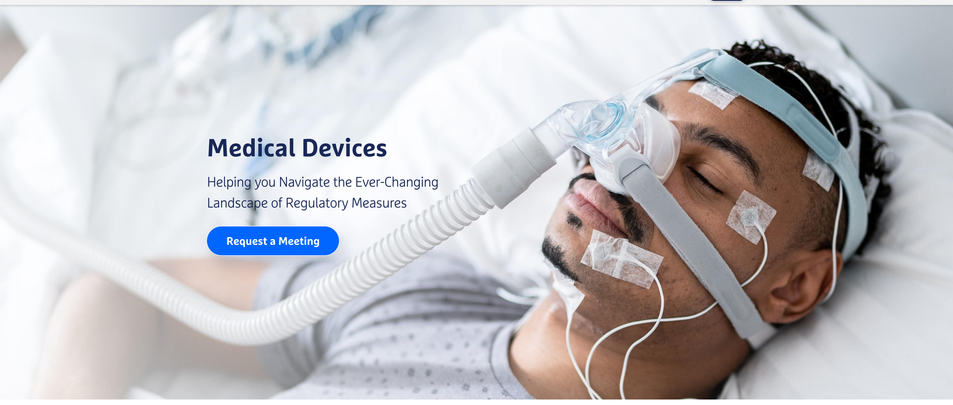

Medical Devices

Helping you Navigate the Ever-Changing Landscape of Regulatory Measures

Request a Meeting

Together, we can help you overcome the unique challenges medical device development presents. As your partner, we can guide you through the ever-changing landscape of regulatory measures, new technologies, and healthcare economics.

We bring the disciplined approach that characterizes successful product development paths, thoughtful regulatory, economic and development strategies, and a meticulous approach to clinical trial execution.

From device classification through to market surveillance on your approved product, our experts work to mitigate risk by navigating applicable regional or global regulations.

Medical Device Services

Our global CRO development and commercial services can advance your medical device from development to deployment in the market.

Development and Testing

Your ultimate resource, we have the specific expertize and experience essential to developing and testing medical devices.

As your full-service, global CRO, our knowledge can guide your project from the initial design stages through the clinical trials and every step of the way, including preparing and filing regulatory documents.

As medical equipment manufacturers, we can ensure that products and medical instruments are fully vetted and verified as safe and effective.

- Clinical investigation management
- Protocol development and study design
- Site monitoring services
- Drafting investigational plans
- Data collection, management and analysis
- Development of the vigilance system
- Statistical analysis and reporting
- Regulatory consulting and strategy
- Preparation of all essential regulatory documents
- Regulatory filing and publications
- Communication with regulatory authorities and ethics committees
- EU Authorized Representative

CE Marking

We can help you to get the CE marking that is essential for marketing medical devices in the European Union. In fact, our experience in this area is some of the best in the industry, making us the top choice for medical device manufacturers wanting to market their products overseas.

To help ensure medical devices for sale in the EU conform to all requirements, we can help with:

- RA/QA Consulting
- EU Medical Device Classification
- EU Authorized Representative
- Compilation of Technical Documentation
- Clinical Evaluation Reports
- Post-marketing surveillance
- ISO 13485 Implementation

Development and Testing

- Laser systems for glaucoma
- Minimally invasive glaucoma shunts (MIGS)
- Influenza vaccine/device combination
- Advanced macular degeneration monitoring device
- Diabetic retinopathy AI software
- Reagents for ex-vivo T-cell depletion for GVHD
- Drug coated balloon PTA catheter for treatment of dysfunctional native and synthetic AV fistulae
- Systems for treatment of symptomatic drug-refractory paroxysmal atrial fibrillation
- Systems in patients with central sleep apnea
- Tempered infusions for induction and maintenance of normothermia in refractory febrile patients
- Catheter ablation vs. standard treatment for left ventricular dysfunction and atrial fibrillation

As a medical devices company, you benefit from our industry-leading qualifications, dedication to the highest standards of clinical safety and vigilance, and long experience of developing and testing everything from medical alert devices to implantable technology.

We have completed **more than 2,000 clinical studies since 1977**, and our knowledge base covers a broad range of therapeutic areas. We share the private and public sector industry knowledge we have accumulated to best serve our clients.

Request a Meeting

Connect with our Medical Devices team to learn more.

Request a Meeting

Fact Sheet

Medical Devices Factsheet.

Learn More