

Innovative Solutions for Custom Results



At RhythmLink we are committed to customizing our services to meet your goals and objectives. Whether it's a single task or a complex project, you can count on our highly qualified professionals to move your products through the market approval process quickly, efficiently and effectively. Regardless of the amount of resources you choose, we will advocate for your product to achieve regulatory approval.

Regulatory Services

- Dedicated project management
- Development and registration strategy support
- Premarket notification [510k] guidance
- Master file creation
- Medical Device Reporting [MDR] and complaint handling
- Product Development Protocol [PDP] assistance
- Regulatory assessment and gap analysis
- Risk management assessment
- Quality Systems Regulations [QSR] implementation
- Quality system GMP compliance
- Documentation and presentation coaching
- Expert report preparation
- Validation guidance
- Regulatory due diligence support
- Advertising and promotional materials review
- Product Information and labeling
- Clinical trial applications and trial support

REGULATORY TEAMWORK THAT WORKS FOR YOU

RhythmLink employs a highly dedicated team, holding decades of expertise in a variety of areas. Under a dedicated project manager, our talented regulatory, quality and clinical teams work closely together to help you achieve product compliance within your desired market.

EXPERIENCE

- 8 years Medical device design and development
- 8 years Medical and technical writing
- 10 years Clinical trials including data management, monitoring and consulting
- 11 years Filings, audits and inspections
- 15 years Registered lead auditor for QMS
- 30+ years Product, quality and reliability engineering including processes and logistics

- 8 510k submissions
- 8 Manuscripts for medical journals
- 10 Compositions for clinical protocols
- 20 Abstracts & posters for tradeshow
- 40+ Drug and medical device trials