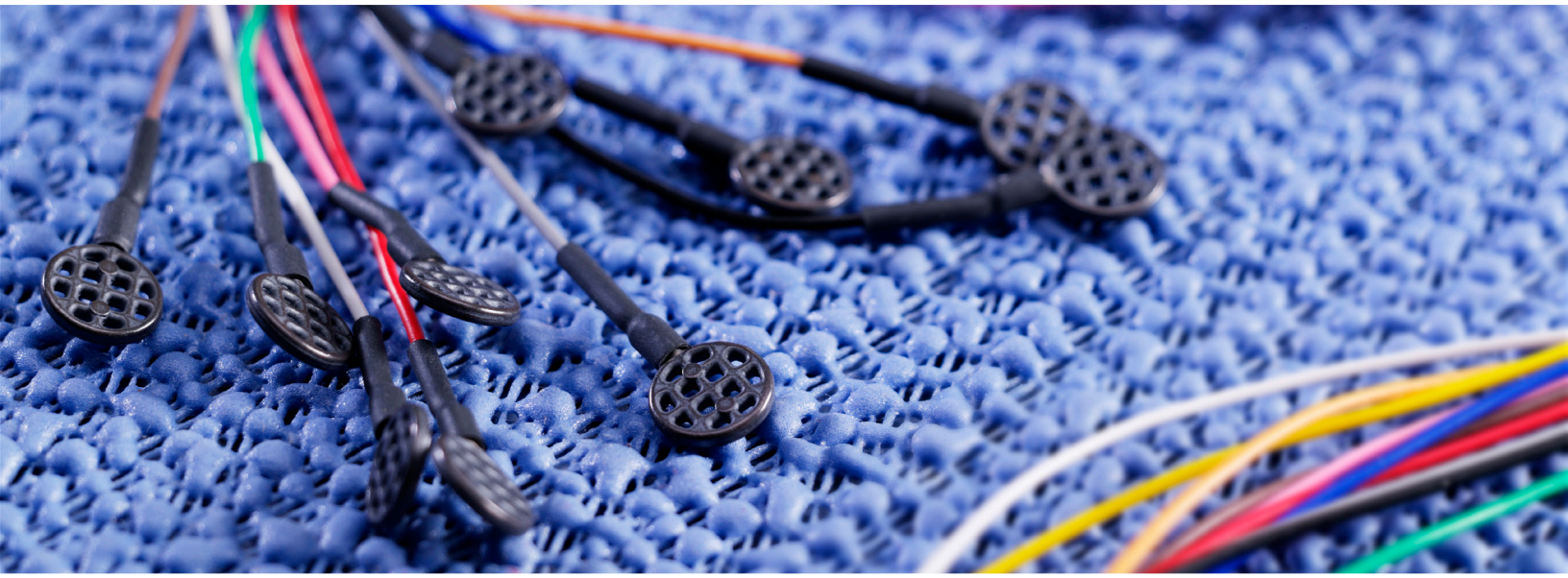
INNOVATIVE SOLUTIONS WITH RESULTS

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 & Registration Strategy Support
- Premarket Notification [510k] Guidance
- Master File Creation & Expert Report Preparation
- Medical Device Reporting [MDR] & Complaint Handling
- Product Development Protocol [PDP] Assistance
- Regulatory Assessment & Gap Analysis
- Risk Management Assessment
- Quality Systems Regulations [QSR] Implementation
- Quality System GMP Compliance
- Documentation & Presentation Coaching
- Validation Guidance
- Regulatory Due Diligence Support
- Advertising & Promotional Materials Review
- Product Information & Labeling
- Clinical Trial Applications & Trial Support



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.

OUR EXPERIENCE WORKS FOR YOU

8 Years - Medical Device Design & Development and Medical & Technical Writing
10 Years - Data Managment, Monitoring & Consulting Clinical Trials
11 Years - Filings, Audits & Inspections
15 Years - Registered Lead Auditor for QMS
30+ Years - Product, Quality & Reliability Engineering

8 510k Submissions
8 Manuscripts for Medical Journals
10 Compositions for Clinical Protocols
20 Abstracts & Posters for Tradeshows
40+ Drug & Medical Device Trials

Rhythmlink®

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