

Regulatory, Clinical, and Lab Support for **Cardiac Rhythm & Electrophysiology Devices**



Cardiac rhythm and electrophysiology (EP) devices rank among the most demanding evidence and post-market requirements in MedTech. RQM+ supports manufacturers of pacemakers, defibrillators, and ablation systems across the full product life cycle, from regulatory strategy through long-term post-market follow-up. Former FDA and notified body reviewers work alongside electrophysiology clinical and laboratory experts on every program.

Services at a glance

Regulatory & Quality

Regulatory strategy and submissions for cardiac rhythm devices — from Class III pacemakers and defibrillators to novel ablation modalities entering PMA and CE Mark pathways under Annex IX



Lab & Material Science

Materials testing on lead insulation polymers, electrode coatings, and catheter tip materials, including validated extraction protocols for newer pulsed-field ablation (PFA) materials



Clinical Trials

Electrophysiology (EP) and ablation trial design and execution, supported by investigator and site relationships built specifically around EP studies



Reimbursement

Reimbursement and health-economics strategy that accounts for the parallel regulatory and payer requirements novel ablation technologies face



Service details



Regulatory & Quality

RQM+ builds the regulatory path for cardiac rhythm devices, Class III pacemakers and defibrillators, and the novel ablation modalities now entering PMA and CE Mark review. Former FDA and notified body reviewers who understand sensing, shock, and ablation endpoints shape submissions for both the U.S. and EU markets.



Clinical Trials

Trial design and execution are grounded in electrophysiology expertise, with principal investigators, KOLs, and sites experienced in EP and ablation studies. Clinical teams include CRAs trained on the implant procedure, so studies are run with people who understand the device.



Lab & Material Science

[Jordi Labs](#), an in-house, FDA-recognized laboratory, performs extractables and leachables (E&L), biocompatibility, and failure analysis on lead insulation polymers, electrode coatings, and catheter tip materials. Validated extraction protocols are already in place for the newer polymer sets used in pulsed-field ablation, and Lumo™, our neural-network response-factor prediction platform, flags biocompatibility and E&L risks early.



Reimbursement

Reimbursement and health-economics strategy runs alongside regulatory planning, which matters for novel ablation technologies that face payer and regulatory questions at the same time. Coverage and coding are addressed as part of the evidence plan.

The MedTech CRO

Former FDA and notified body experts on staff

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1,300+ regulatory, testing, and clinical development programs delivered

...

1,000+ MedTech clients

Post-market obligations for cardiac rhythm devices, including post-market clinical follow-up (PMCF), registries, vigilance reporting, and post-approval studies, are supported across the full device life cycle, which can run twenty years or more.

Want to learn more about RQM+ support for cardiac rhythm and electrophysiology devices?

Our team can walk you through regulatory, clinical, laboratory, and reimbursement support for your program.

[Connect with our team](#)

Let's make your MedTech program happen.



RQM+ is *The MedTech CRO*, accelerating innovation to patient impact. Our tailored solutions deliver regulatory and quality expertise, FDA-recognized laboratory services, clinical trials, and reimbursement strategies across device types and therapeutic areas to bring life-changing technologies to patients — faster, safer, better.

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