

Regulatory, Clinical, and Lab Support for **Implantable Neurostimulator Devices**



Implantable neurostimulators combine active-implant complexity with a device platform that often expands into many indications over time. RQM+ supports manufacturers of spinal cord, deep brain, sacral, and vagus nerve stimulators across regulatory, clinical, laboratory, and reimbursement work. Regulatory, laboratory, and clinical teams work together on the same program, coordinated from the start.

Services at a glance

Regulatory & Quality

Regulatory strategy across the full range of neurostimulation device types, including serial label-expansion programs as one device platform reaches new indications



Lab & Material Science

In-house polymer and silicone lead extractables and leachables (E&L) expertise, with validated analytical methods for lead and implantable pulse generator (IPG) housing materials



Clinical Trials

Trial design that accounts for sham-control architecture and patient-reported outcome (PRO) validation specific to neuromodulation studies



Reimbursement

Reimbursement strategy engaged from day one of program planning, addressing coverage and coding early in development



Service details



Regulatory & Quality

RQM+ supports regulatory strategy across the full range of neurostimulation devices, including serial label-expansion programs where a single platform is applied to new indications over time. Each indication brings its own submission, and RQM+ plans for that sequence from the start.



Clinical Trials

Neuromodulation studies are designed around sham-control architecture and patient-reported outcome (PRO) validation, which are specific to this field. Trial teams bring neurostimulation experience across pain management and movement disorder programs.



Lab & Material Science

Jordi Labs, an in-house, FDA-recognized laboratory, performs extractables and leachables (E&L) on polyurethane and silicone leads and implantable pulse generator (IPG) housing materials, with validated analytical methods in inventory. Lumo™, our neural-network response-factor prediction platform, flags biocompatibility and E&L risks early.



Reimbursement

Reimbursement strategy is engaged from day one of program planning, so coverage and coding are addressed early in development. This is important for platforms that will pursue several indications, each with its own coverage pathway.

The MedTech CRO

Former FDA and notified body experts on staff

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

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1,000+ MedTech clients

Regulatory, laboratory, and clinical trial capability work together on the same program, coordinated as one team from early planning through submission.

Want to learn more about RQM+ support for implantable neurostimulator 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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