



Regulatory, Clinical, and Lab Support for **Structural Heart and Mechanical Circulatory Support Devices**



Structural heart and mechanical circulatory support (MCS) programs depend on rigorous evidence and long follow-up windows. RQM+ supports manufacturers of transcatheter and surgical valves, occluders, and circulatory assist devices across regulatory, clinical, laboratory, and reimbursement work. We combine former FDA and notified body experience with specialized structural heart trial and materials capability.

Services at a glance

Regulatory & Quality

Regulatory strategy for structural heart devices advancing on novel, no-precedent TAVR and TMVR pathways and complex Premarket Approval (PMA) submissions



Lab & Material Science

Specialized bioprosthetic-tissue chemistry alongside synthetic materials characterization for occluders and assist devices



Clinical Trials

Trial design built around independent event adjudication, echo, and CT core lab review, the operational backbone of a credible structural heart study



Reimbursement

Reimbursement strategy that accounts for the long follow-up windows structural heart durability data requires



Service details



Regulatory & Quality

RQM+ develops regulatory strategy for structural heart devices, including the novel, no-precedent transcatheter aortic and mitral valve (TAVR and TMVR) pathways that make for the most complex Class III submissions. Former FDA and notified body reviewers build the path for both U.S. and EU markets.



Clinical Trials

Structural heart studies are designed around independent event adjudication, echo, and CT core lab review, the operational backbone of credible evidence. Clinical events committees and data monitoring committees operate strictly according to their charter, with imaging review standardized and blinded.



Lab & Material Science

Jordi Labs, an in-house, FDA-recognized laboratory, provides specialized bioprosthetic-tissue chemistry, including glutaraldehyde residual quantitation and biological material identification, alongside synthetic materials characterization for occluders and assist devices. Lumo™, our neural-network response-factor prediction platform, flags biocompatibility and extractables and leachables (E&L) risks early.



Reimbursement

Reimbursement strategy accounts for the long follow-up windows, often 5-10 years, that structural heart durability data requires. Health economics planning is built to match the multiyear evidence these devices generate.

Long-term follow-up and post-approval study support are built to match structural heart's multiyear evidence requirements, where durability data plays out over five to 10 years.

Want to learn more about RQM+ support for structural heart and mechanical circulatory support 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.

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