Project Manager

As a Project Manager, you will bring strong practical
experience of project management in a rapidly evolving, cross-functional, highly regulated environment. This role also requires strong cross-functional business acumen, including technical, manufacturing, finance, quality, clinical, and regulatory-based knowledge.

Responsibilities:

• Overall responsibility of all technical aspects of the device: Design, development, prototype manufacturing and assembly, test planning and conduction, documentation in DHF
• Developing and managing project plans: Scheduling, risks and mitigation, resourcing, budgeting
• Preparing, presenting and archiving all Design Control reviews and other deliverables to support project objectives
• Championing continuous improvement: evaluating project for opportunities to improve performance; continuously monitors risk and mitigates as appropriate
• Project administration – accounting activities associated with projects, including monthly reporting as required for grants accounting and services billing
• Demonstrating excellent interpersonal and communication skills, in a persuasive and inspirational style that is timely, proactive, concise, candid, accurate, and clear, with all projects' members [including OEMs]

Qualifications and Skills:

• A Bachelor's degree in a Mechanical OR Biomedical engineering OR equivalent work experience (Required)
• A minimum of 5+ years of related work experience in the medical device field (Required)
• Demonstrated skills in managing medical device development projects to produce effective and differentiated products meeting customer expectations and internal business goals (Required)
• Must have experience working through all aspects of medical device design/development including design V&V and process validation/technology transfer (Required)
• Working knowledge of design controls regulatory requirements (US, EU, Other) and experience defending product information or processes in a regulatory audit preferred

• Experience developing designs and testing via a phase-gate analysis (Concept, Feasibility, Verification) using a risk-based approach compliant with 21CFR/ISO-13485

• Extensive knowhow in V&V procedures and QA materials: writing protocols and reports

• Familiarity with manufacturing technologies

• Proficient in CAD/Solid works

• Excellent time management and organizational skills

• Outstanding written and oral communication

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