

Director of Implant Development

Responsibilities

Leading and direct management of a group of material and mechanical engineers.

Responsible for the development of the next generation implant devices and support current implant activities.

Leading the design process of complex electromechanical devices including design reviews, requirements analysis, strict project timelines, problem solving and coordination of multiple subcontractors.

Define project scope, goals, projects plan, budget and deliverables in collaboration with senior management, subcontractors (domestic and abroad) and other departments (Operations, Finance, QA, Clinical, Regulatory and Marketing).

The Director of Implant Development will report to company VP of R&D.

Identify and analyse the project risks and to find the mitigations and controlling implementations.

Participate in writing of all project's life- cycle documents including design input, protocols, and reports.

Requirements

BSc Degree in Mechanical /Bio-Medical / Material Engineering (MSc advantage).

4 + years of experience in R&D team leader, project / program management, preferably of Class III medical devices.

Experience in direct management of R&D team – strong advantage.

Experience in conducting and managing project / program plan and budget.

Proven track record of delivering complex projects on time and in budget.

Leadership experience. The Director of Implant Development must be able to utilize a core internal team consisting, mechanical and material engineers and collaborate with the development team for the HW design of the implant.

Managing a large quantity of remote subcontractors from different functional and technological areas.

The role will include following a product development process with formal stage gate reviews. The ideal candidate will have experience with all phases of development of a medical device.

CE / FDA / design control of medical devices. The ideal candidate will have knowledge/exposure to CE & FDA requirements or design control for medical devices. Knowledge and experience with environment, safety, biocompatibility, and essential performance tests (EN 60601, ISO-10993 etc.).

- Hands on approach.
- Strong English skills
- Ability to conform to shifting priorities, demands and timelines through analytical and problem - solving capabilities.

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