



Project Manager – Research & Development

Position / Title

Project Manager - Research & Development

Department / Area

Research & Development (R&D)

Reports to

Team Leader/Head of R&D

Language

English, German

Education

- Bachelor of Science or Engineering or equivalent.
- Master's degree preferred.

Experience

- Minimum 3-5 years of experience in medical device development
- Exposure to ISO 13485 & ISO 14971.

Primary Tasks and Responsibilities

General

- Leading the development of projects from concept to market launch as per QualiMed's 12 step/5 stage methodology.
- Planning, reporting and execution of project deliverables with best effort to stay on time and in budget: Key figures (execution in time, in cost with planned resources).
- Responsible for completing the design and development of QualiMed's and/or the customer's product according to the project timeline and budget.
- Support / Execute product and process development as well as product transfer.
- Assisting in coordinating bench testing and product studies with in-house and/or outsourced testing facilities.
- Working closely with Procurement, Production and Manufacturing Engineers to forecast and procure components (i.e. stents and delivery systems) and/or products for feasibility, prototyping and testing purposes.
- Working according to all the applicable QualiMed internal procedure.
- Shall follow the ISO 13485, MDR as well as FDA guidelines.
- Write and execute protocols, reports, work instructions and drawings / specification.
- Complete Project documentation tasks in relation to Design History Files of projects entrusted.
- Participate in CAPA, NCR and Risk Management activities

Skills / Competencies

- Experience in project management;
- Prior catheter and stent design experience required
- Effective troubleshooting and problem solving skills
- Ability to work both independently and in conjunction with a team
- Working knowledge of MS-Office and CAD software

Working conditions

Permanent, full time (40 hrs/week)

For more enquiries, please contact:

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