



## Project Engineer – Research & Development

### Position / Title

Project Engineer - Research & Development

### Department / Area

R&D

### Reports to

Team Leader/Head of R&D

### Language

English and German

### Education

Minimum Bachelor of Science in Mechanical/Biomedical Engineering or equivalent. Master of Science preferred.

### Primary Tasks and Responsibilities

- Assist project manager on development projects
- Support development of projects from concept to market launch as per QualiMed's 12 step/5 stage methodology
- Creating product / component drawings and discussion with component suppliers
- Write and execute protocols, reports, work instructions
- Create and execute test protocols and engineering studies
- Assisting in coordinating/conducting 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 ISO13485, MDR as well as FDA guidelines
- Complete Project documentation tasks in relation to Design History Files of projects entrusted
- Support CAPA, NCR, DCN and Risk Management activities.

### Skills / Competencies

- 0-2 years of experience in medical device development
- Strong design skills with CAD Softwares such as Solidworks, AutoCAD or Inventor
- Strong understanding of metals/polymers and their processing techniques required
- Effective troubleshooting and problem solving skills
- Prior medical device experience especially in catheter and stent design is preferred
- Ability to work both independently and in conjunction with a team
- High efficiency with MS-Office

### Working conditions

Permanent, full time (40 hrs/week), Work location – Winsen (Luhe).

**For more enquiries, please contact:**

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