

## THE COMPANY

Are you interested in joining a company that really values you as a person? This company has been voted again and again as one of the top employers in Medtech! You'll be joining one of the best performing divisions of the business. Because of this great performance, there's a constant stream of investment in R&D, and so a new position has been created as Senior Manager Design Quality.

## **The Role**

As Senior Manager Design Quality, you will build and lead a team of design quality engineers, and be responsible for supporting new product development projects to ensure the design process adheres to the best quality possible. You'll create organizational strategies, goals, processes and processes to push forward improvements in the product development process. You'll work through the medical device product development lifecycle, covering risk management and design/process verification and validation. But it's not all about work! This company is known for building high performing teams who know how to have fun! You can have the chance to participate in company sport, social events and unusual team building activities ... like an escape room or cooking class!

## As Senior Manager Design Quality you will have these responsibilities:

- Be responsible to develop quality documentation to support new product development projects and regulatory submissions
- Work in project teams and lead design changes
- Establish annual budgets and quarterly forecasts
- Lead, train, coach and build a team of design quality engineers, taking responsibility for recruiting, onboarding and developing top talent
- Challenge new product development teams when defining design V&V test requirements to ensure design inputs and safety requirements are met
- Represent the quality process function in internal and external audits

- Be responsible to evaluate predicate products for quality issues and determine potential impact of existing products in development
- Collaborate with all business departments (Quality Assurance, Service, Global Supply, Finance, Sales, R&D, and Marketing etc.) to implement corporate strategies and goals
- Use your knowledge of advanced Advanced Quality tools such as (FMEA), Root Cause Analysis, Poke Yoke to address and resolve quality issues
- Before product launch, assess the overall residual risk and the evaluate final risk/benefit justification
- Present risks associated with the product use during Design Reviews and track the design, documentation, and manufacturing process to mitigate those issues throughout the development process
- Support the product design transfer to manufacturing

## WE WANT TO HEAR FROM YOU IF YOU HAVE:

- 7+ years experience in the Medical Device industry, in a quality engineering or R&D position
- A biomedical or biomechanical Engineering background, or other related discipline
- Experience managing a team of direct reports (engineers) and delivering high performance
- Experience with quality tools, ability to interpret CAD designs, process improvement experience, and understanding of Quality Concepts (e.g. CAPA, Audits, Statistics)

Apply now! hello@elemed.eu