ST GALLEN REGION OR BAAR REGION, SWITZERLAND- WITH FANTASTIC HOME OFFICE OPTIONS

Senior Design Quality Engineer

TAMANNA@ELEMED.EU

elemed

The company

Are you looking to join a growing medical device company where you will play a critical role within their Quality department?

Are you looking for a role where you will be the first expert brought into develop projects around design assurance within QA?

This company is globally leading in providing some of MedTech's top companies with excellent medical devices from Class I through to Class III. A great collaborative environment with global offices and a great international feel. This specific role can be based from either their St Gallen or Baar site- with fantastic home office options up to 60%. Providing for a fantastic opportunity that provides flexibility and great work/life balance.

Due to the size of the company there are great opportunities to work alongside other divisions and have an influence across RA/QA and R&D to ensure smooth new product development and introduction.

The opportunity

This is a unique one of a kind opportunity. This is the first role of its kind in this global company; thus allowing you to be the first expert to develop and provide guidance on key design and new product development projects.

This will also provide you with the perfect platform to progress your career as an expert in this field. Your key role will be to develop key design assurance projects and be the bridge between R&D, RA and product launch. A great role to be part of all the key steps of new product development.

Your responsibilities

- Manage in cooperation with R&D, Marketing, Medical Science and Clinical Affairs, the design validation of new products
- Prepare and maintain the Technical File documentation for new products or modified products and cooperate with the Regulatory Affairs team to prepare regulatory submissions

Your responsibilities

- Direct all the regulatory pre- and post-market activities related to technical aspects
- Support the R&D area to formalize the development plan, the development phase gate documentation, the design verification documentation and the design validation.
- Be responsible to develop quality documentation to support new product development projects and regulatory submissions
- Work in project teams and lead design changes
- Be responsible to evaluate predicate products for quality issues and determine potential impact of existing products in development
- 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

Your qualifications

- Minimum 5 years of experience in Quality for medical devices
- Specific expertise minimum of 3 years of experience within design assurance for medical devices
- Great experience of working across cross-functional teams, specifically RA and R&D
- An independent expert who likes bringing forward ideas and directing projects
- Scientific mindset, with ideally an engineering degree
- Fluent in English; fluency in German would be a bonus

INTERESTED IN FURTHER CONVERSATION?

IF YOU ARE INTERESTED IN THIS EXCITING ROLE, PLEASE SEND YOUR APPLICATION DIRECTLY TO:

TAMANNA@ELEMED.EU

Would you like to find out more about our open opportunities? Visit https://www.elemed.eu/vacancies/

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