ZURICH, SWITZERLAND

Risk Manager

KRISTINA@ELEMED.EU

COMPANY

Come and join a well-established, commercial-stage company that continues to grow each year as their NEW Risk Management Specialist! To support their continuous growth, this company is expanding their QA/RA team and creating brand new roles such as this risk management specialist. This is a fantastic opportunity for someone who is tired of working in large, slow-moving corporations to step into a newly created role and really make an impact.

This company is designing, developing and producing an innovative Class III active-implantable medical device that is already CE marked and changing the lives of patients. If you enjoy working in a fast-paced and highly dynamic environment, this could be the place for you!

OPPORTUNITY

This is an exciting time to be joining the company as they grow in all areas including people, product indications and markets. It is an opportunity to step into a brand new position and be the main “go-to” person responsible for risk management. You will work collaboratively across all operational departments of the business, including engineering, clinical and manufacturing, in a young and dynamic team on a complex AIMD product with 1300 components.

As Risk Management Specialist you will:

- Manage all tasks related to Risk Management activities such as Risk Management Team meetings, coordinating Risk Management updates
- Collaborate cross-functionally to coordinate, plan and facilitate Risk Management activities within the organisation
- Create and review Risk Management documents according to ISO 14971 including Risk Management Plan, Risk Analysis, Benefit/Risk Analysis and Risk Management Report
- Lead and document dFMEA & pFMEA assessments and include updates based on product design information and production/manufacturing information
- Be responsible to regularly incorporate post-market surveillance data
- Support the monitoring of Risk Management development globally

REQUIREMENTS

As Risk Management Specialist you will have:

- A minimum of 3 years demonstrated Risk Management experience
- Experience working in the medical device industry
- Hands-on working experience with ISO 14971
- Fluent reading, writing and speaking in English

INTERESTED IN FURTHER CONVERSATION?

PLEASE SEND YOUR CV TO KRISTINA@ELEMED.EU TO ARRANGE A CONFIDENTIAL CAREER DISCUSSION.