

Quality manager wearables and medical devices

2M develops medical devices, industrial sensors and biometric wearables for e-health, sports and clinical applications. 2M has a vacancy for a quality manager who together with the rest of the team brings innovative solutions from idea to commercial product.

About 2M Engineering

2M Engineering is a high-tech SME that creates innovative (sensor) solutions for medical, industrial, e-health & sports products. With a small and dedicated team of 20 highly skilled international, tech-professionals, 2M realizes complete product developments, going from R&D through industrialization, (medical) certification and production. We create products that have an impact and add real value to people's lives. Our clients include large and small companies, startups, hospitals, knowledge institutions and research organizations. 2M Engineering is based in Valkenswaard, The Netherlands close to Eindhoven.

We are looking for..

We are looking for a quality manager who likes challenges and has a very broad interest in product quality, quality management systems and regulatory affairs. The candidate must be interested in working in applications ranging from wearable (consumer) devices to large industrial and safety critical installations and medical devices (CE-IVD, class 1m, class 2a). The quality manager will work closely together with the other technical disciplines such as electronics, software, optics, signal processing and mechanics to create the complete product. 2M is a project organization where you can work on one or more innovations at the same time: so always something new and constantly learning.

Function description

The quality manager should have a masters in biomedical engineering or similar and will be responsible for product testing and the complete (medical) CE approval process for a range of medical and non-medical products. The full QMS is in place and you will be supported by experienced people initially for as long as necessary. The candidate should have a good eye for detail while also able to maintaining the overview. Affinity with sensing biomedical products is a plus. We are looking for an energetic person with a positive mindset and a "can do" attitude who likes achieving the impossible together with the rest of the team.

The quality manager keeps track of new ways and tools to continuously bring the overall quality process within 2M to a higher level. Not by working harder, but by working smarter.

Personal characteristics: strong written and verbal skills, independent, eye for detail and quality, eagerness to deliver results, good team player flexible and constantly striving to improve to becoming the best in class product creation company.

Requirements

Knowledge:

- Masters in Biomedical Engineering or similar.
- 2-3 years' experience in the field of quality and regulatory (more is a plus). Medical Device CE, CE-IVD, 1m and 2a product certification, FDA and/or MDR experience is very relevant
- Affinity with medical, sport & industrial applications.
- Working knowledge of the English language.

Characteristics:

- Reliable energetic personality that delivers what is promised.
- Positive, can-do attitude.

- Able to build long term relationships with clients and within the 2M network.
- Able to work in a structured way an improve existing processes.
- Able to organize own work and work for others (planning, prioritize, deliver on commitments).
- Ability to work independently as well as, as part of a team. Open for feedback.
- Good understanding (reading and writing) of Dutch is a plus.

We offer:

- An exciting work environment where every day is different and challenges abound.
- Growth opportunities and paths for both personal and professional development.
- The chance to define your own development projects and realize your own ideas.
- A market conform salary.

If you think you are up to the challenge contact us ! info@2mel.nl

Job Type: Full-time