

QUALITY ASSURANCE ENGINEER

Salvia BioElectronics, High Tech Campus 41, Eindhoven, The Netherlands

ABOUT US

Salvia is an innovative and ambitious start-up company active in the emerging field of "BioElectronics" that is inspired by biology and electronics to provide novel therapeutic solutions. The name Salvia is derived from the Latin word salvere, which means "to stay healthy". We are driven to deliver bioelectronic solutions that restore health for people suffering from severe neurologic disorders; our ambition is to make these therapies widely accessible. The Salvia team consists of entrepreneurs, engineers and scientists with diverse professional backgrounds and extensive medical device industry experience (Sapiens, Medtronic, Philips, St Jude, etc.).

WHAT ARE BIOELECTRONICS?

The human body is controlled by patterns of electrical impulses transmitted through nerve fibers. In chronic disease, these patterns are different. Bioelectronics are tiny implantable devices that use mild electrical pulses to influence nerve activity. Electrical stimulation is nothing new – cardiac pacemakers have been used for decades – but scientists are just beginning to realize the possibilities of regulating nerve signals to treat disease.

THE CHALLENGE

We offer a challenging position for a Quality Assurance professional. Working closely with Salvia's director of quality, you are part of the Salvia development team where you take ownership for driving the compliance of our development process and the quality of products. You assess technical design documents, test strategies and (incoming) inspection plans, and work with the team to ensure compliance to product standards and safety regulations. Together with the team you audit our suppliers and ensure Salvia's quality requirements are fulfilled. You enjoy working in a multi-disciplinary start-up environment and have a can-do attitude. You realize that quality is of paramount importance and you are passionate about delivering solutions that truly stand out.

RESPONSIBILITIES

- Collaborate with the development team to embed quality in development processes and Salvia's products.
- Collaborate with the director of quality to implement and improve processes.
- Project manage all aspects of Change and CAPA processes and ensure timely execution involving crossfunctional resources.
- Release materials, components, equipment and processes.
- Liaison with manufacturing partners to ensure quality requirements are met.
- Help facilitate continuous improvement.

YOUR PROFILE

- Working knowledge of ISO13485, 21CFR820 and ISO14971.
- Minimum 3 years' experience in the medical device industry, working in a quality assurance role.
- Preferred working knowledge with product standards such as e.g. IEC60601, IEC62304, IEC62366.
- Pragmatic team player with good communication skills.
- BSc or MSc in an engineering discipline.

CONTACT