

SENIOR MANUFACTURING ENGINEER

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

ABOUT US

We are Salvia: an innovative startup active in the emerging field of bioelectronics. We derived the name Salvia from the Latin word *salvere*, which means to stay healthy. In addition, the Salvia-herb has been used to treat headaches, pain, and mental disorders over centuries. Our mission is to deliver bioelectronic solutions that restore health for people suffering from chronic migraine. Salvia is ambitious: we want to provide drug-free solutions that are effective and inherently side-effect free and make our novel solutions widely accessible.

THE CHALLENGE

We offer a challenging position for an experienced Manufacturing Engineer with opportunities to grow with the organization. Working together with R&D, Quality and Operations you will set-up new manufacturing processes for our innovative active implantable medical device. You are responsible for the design, procurement, and realization of Salvia's production line. You will develop and execute required validations in line with regulatory requirements, including Equipment, Process & Product validations (IQ/OQ/PQ) and will drive process reliability and yield optimization from initial pilot production towards commercial scaling. You will assist with resolving issues e.g. arising from internal quality assessments/audits, regulatory inspections, or post-market findings, and aid in driving closure of findings by contributing to CAPAs and preparing appropriate responses. Whenever needed, you will provide day-to-day support to operators and technicians. You enjoy working at the heart of a multi-disciplinary and dynamic start-up environment. Most importantly, you bring a can-do attitude and have a sharp eye for quality, partnering up with the team to ensure timely realization of Salvia's manufacturing line.

RESPONSIBILITIES

- Establish and maintain manufacturing documentation including, Equipment Documentation, pFMEAs, Manufacturing Work Instructions, Control Plans, Maintenance and Qualification routines.
- Provide engineering leadership to our cross-functional team, external development partners, and component suppliers.
- Characterize and evaluate critical process parameters and lead process development to enable production of units for clinical investigation initially and support the scale-up to commercial product builds.
- Support and train operators and technicians, enabling them to efficiently execute product builds.
- Grow with the organization to enable Design Transfer to commercial-stage operational processes and provide continued engineering leadership in scale-up phase.

YOUR PROFILE

- Minimum 4 years medical device engineering / manufacturing experience.
- Strong technical understanding of set up and maintenance of manufacturing processes and equipment design. Experience in Lean Manufacturing is highly desirable.
- Experienced with working under cleanroom conditions (\leq Class 7). Prior experience in medical device assembly including cleaning, silicone molding, and interconnect technologies, is considered an advantage.
- Proven ability to organize and prioritize multiple tasks.
- Pragmatic team player with excellent technical, communication and coordination skills.
- MSc or BSc degree in engineering.

CONTACT

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