

# DESIGN V&V ARCHITECT

*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 an experienced design verification and validation professional. You will lead the overall test strategy for a highly innovative active implantable medical device, consisting of implantable and wearables devices, and therapy-apps. You take ownership to ensure compliance to relevant product standards and define and validate test methods covering the novel technical aspects of the Salvia product and ensure it meets FDA and MDR requirements. You will closely work with the system architect, the development team and test engineers to demonstrate the technical performance of our solution. Together with QA, RA you will interface with regulatory bodies to align Salvia’s overall testing strategy and ensure compliance to EU and US medical device regulations. You maintain a big-picture overview and oversee multiple technical disciplines, but you also can dive into details when needed and work hands-on. You realize that quality is of paramount importance and you are passionate about delivering solutions that truly stand out.

## RESPONSIBILITIES

- Technical leader for the testing of an advanced and innovative bioelectronic system, defining the test strategy and overseeing its execution:
  - Define Design Verification Plan.
  - Collaborate with technical specialists for Test Method definition and validation.
  - Interface with suppliers to support definition of product release tests.
  - Liaise with technical specialists and dive deep into technology when needed.
- Collaborate with QA, RA, and interface to regulatory bodies to release the Salvia products to the market.

## YOUR PROFILE

- Self-starter, naturally taking ownership.
- Critical thinker with strong scientific and analytical skills.
- Strong communicator; team player; solution-oriented; handles complexity.
- Substantial R&D experience in a regulated industry, e.g. medical, automotive or aerospace.
- Working experience with medical device product standards and safety standards is a benefit.
- Educated in a relevant discipline, e.g. electrical engineering, physics, mechanical engineering, chemical technology, etc.

## CONTACT

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