CLINICAL AFFAIRS MANAGER

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 Clinical Affairs Manager professional. Working closely with Salvia’s chief medical officer, you are part of the Salvia development team where you take ownership for setting up, driving and execution of the clinical trials, supporting CE mark and FDA clearance. You design the study documentation (protocol, informed consent, electronic CRF and patient diaries), obtain approvals of the ethical committees and competent authorities, initiate the studies and ensures timely study execution. You are the first contact with the study sites. You work closely together with and manage the contract research organization. You work in compliance with internal processes, local regulations, FDA requirements and GCP. You enjoy working in a multi-disciplinary start-up environment and have a can-do attitude. You realize that quality and respect of timelines are of paramount importance and you are passionate about delivering solutions that truly stand out.

RESPONSIBILITIES

- Oversees Salvia's clinical trial program (first in human, pilot trials and pivotal trials) in the EU and the US,
- Manage all study aspects in accordance with timelines, budget, applicable standards and regulations,
- Contributes and takes ownership to prepare all clinical documents, e.g. protocol, investigator brochure, case report forms, annual report updates, clinical study reports, monitoring plans, budgets,
- Proactively identifies potential barriers to project completion and data integrity and proactively implements effective strategies to correct and prevent such barriers.

YOUR PROFILE

- Profound knowledge of Good Clinical Practice and FDA requirements for human clinical trials, experience with (active) implantable medical devices is a plus,
- Minimum 5 years' experience in the medical device industry, in a clinical affairs role,
- Pragmatic team player with good communication skills,
- Detail oriented and problem-solver,
- Fluent in English,
- You are a motivator and can inspire.

CONTACT

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