US PROGRAM LEAD – CLINICAL TRIALS

Posted on 28 februari, 2020

Company Name Sedana Medical

Location Stockholm

Job Description

Sedana Medical has developed and commercialized the medical device AnaConDa, for the administration of volatile anaesthetics to mechanically ventilated patients. Sedana is now poised to also become a pharmaceutical company. Currently, a pivotal clinical study is ongoing to obtain regulatory approval in Europe for inhalation sedation in intensive care units with the pharmaceutical IsoConDa® (isoflurane).

In addition , Sedana will perform a clinical program in the USA in order to obtain FDA approval. We therefore announce the role of a **US Program Lead** in the Medical Department. The US Program Lead will be responsible for the management and coordination of all relevant functions leading to a successful execution of the program leading to the approval and launch of of AnaConDa and volatile anesthetics for ICU sedation.

The Program Lead will be responsibe for the overall budget and the resource planning, coordinating and overseeing all functions of the integrated Clinical Development plan such as regulatory , clinical development and clinical operations.

The US Program Lead will report to the Chief Medical Officer and be based at the headquarters in Stockholm. International travels, in particular to the US will be part of the job in order to work closely with the US Agent, to manage the CRO oversight , attend FDA meetings, meet coordinating investigators of the clinical trial(s) and other Key Opinion Leaders and stakeholders in the program.

In the role of US Program Lead, several parallel critical activities towards the approval of the AnaConDa and volatile anaesthetics for ICU sedation will be supervised, such as the toxicology program, the clinical trials and the Human Factors Engineering Program.

Major/Key Responsibilities

Leading and managing the US registration program for the AnaConDa device
Leading and managing the US registration program for the drug candidate IsoConDa®
Responsible, together with the senior clinical research managers, for RFP and outsourcing activities i.e identifying the right CRO
Interacting with current US Agent and benchmarking for further work

Managing and preparing authority interactions and FDA meetings
Interacting with and ensuring timely deliverables of the Human Factors Engineering Program leader in Sedana, as well as from the Toxicology project team, in relation to the US registration program
Interacting with US Clinical Leads and Coordinating Investigators for the Clinical Trial(s)
Program management such as Gantt charts
Budget and resource planning for the program

Joining Sedana Medical will give the right candidate the opportunity to significant personal development and the opportunity to lead a cross-functional project team, managing the full process towards approval of a drug and a device in the US.

Your background as succesful candidate

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Experience from the pharmaceutical industry is mandatory, as well as US experience and a proven track record of project management. Strong communication skills are important as is a strong command of the English language. This role requires flexibility and a creative and entrepreneurial spirit. Collaboration and team building skills are core values for Sedana.

The role is based out of the HQ in Danderyd, and openness to travelling is essential.

Education/Learning Experience

University degree (Medical/Healthcare training or other Science-oriented)
PhD or other research experience is meriting
Project management/leadership training and/or significant experience is mandatory

Work Experience

Experience from international work in the Pharmaceutical Industry
US regulatory experience, including FDA and US agent interactions
Project leadership skills

Skills/Knowledge

Experience in leading cross-functional project teams, including external parties like agencies and KOLs, delivering results timely and within budget.
Open to work in an entrepreneurial organization, where ownership and own drive is of greatest importance.
Strong communication skills in English with ability to efficiently and productively communicate orally and in writing.

Languages

Fluency in written and spoken English and Swedish.

To apply, please send your CV and cover letter to daniel.kremer@moveup.se, as soon as possible.

Genom att skicka din ansökan ger du också ditt samtycke till att vi lagrar dina personuppgifter, inklusive CV & personligt brev samt att vi äger rättigheten att dela dessa uppgifter med tredje part (vår uppdragsgivare). Samtycket kan du återkalla när du vill.

Om företag

Sedana Medical is a Swedish Medtech company with a globally leading and unique position in its field of inhaled anesthetic delivery in the intensive care unit (ICU) setting. The company headquarters are in Danderyd, Sweden with R&D operations in Ireland with 45 employees. The company currently has direct sales in the Nordic, Germany, France, Great Britain and Spain as well as external distributors in Europe, Canada, Australia, Japan and South Korea.

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