Clinical Safety and Materiovigilance specialist

iSTAR Medical SA, founded in 2011 and headquartered in Wavre, Belgium, is a pre-commercial stage, medical technology company focused on the development of MINIject, a novel minimally-invasive ophthalmic implant (MIGS) for patients with glaucoma.

Reports to the VP Clinical Affairs and Regulatory Affairs

The Clinical Safety and Materiovigilance specialist will be responsible for all iSTAR Medical safety activities, management of adverse events reporting for all clinical studies, management of safety data in all clinical studies to help write clinical study reports and materiovigilance activities for iSTAR Medical products.

Responsibilities

- ***Safety Activities for Clinical Studies***
  - Provide inputs to safety specific study-related documents (Protocol, Patient Informed Consent, CRF, Data Review Plan, Clinical Study Report)
  - Write Safety Management Plan and other safety documents in collaboration with Safety Monitor
  - Perform remote safety data review and cleaning according to the data review plan and follow up on resolution of safety queries
  - Work with clinical sites to obtain additional information related to specific safety issues
  - Write narratives for applicable adverse events and device deficiencies (in collaboration with Safety Monitor if required)
  - Support Safety Monitor in Safety Monitoring Committee management (schedule meeting, prepare safety reports for meeting, draft meeting minutes)
  - Manage safety operational activities in order to keep Safety Monitor activities focused on strategy
  - Provide a monthly safety report for the Clinical Team, highlighting specific issues from all clinical studies for action.
  - Support quality control & assurance activities related to safety (Internal QC, CRO & study site audit and safety CAPA resolution)

- ***Safety Reporting of Clinical Studies***
  - Review and assess adverse events and device deficiencies reported by study sites in collaboration with Safety Monitor
  - According to local laws, report adverse events to National Competent Authorities and Ethics Committee(s) globally, either directly or in collaboration with safety reporting partners
  - Keep up to date all iSTAR Medical safety related pre and post licencing SOPs according to the state of art
  - Report on Safety KPIs

- ***Materiovigilance activities***
  - Review post-market incidents to assess need for reporting

- Submit serious incident reports to competent authorities and the notified body within the regulatory timeframe requirements and follow up as necessary until case closure
- Interact with regulatory authorities during the execution of a field safety corrective action (FSCA) (write and submit FSCA report form, FSN). Collaborate with QA for timely FSCA execution and follow up until case closure
- Write and submit trend reports and periodic safety reports to regulatory authorities
- Analyze and identify statistical trends in incidents and FSCAs
- Provide materiovigilance input for technical documentation (post-market surveillance plan, periodic safety update report, summary of safety and performance, risk management)

COMPLIANCE/LEGAL RESPONSIBILITIES

- Maintains the highest standards of ethics in all circumstances
- Ensure compliance with the Company quality system and all applicable guidance, standards and regulations.

Profile

Education

- Master degree in Life Sciences and / or a healthcare professional

Languages

- Fluent in English, written and spoken. Knowledge of another language is beneficial

Professional Experience

- At least 2 years of demonstrated experience in clinical safety and/or vigilance reporting of medical devices. Knowledge in MDR reporting requirements is essential.
- Solid knowledge on medical terminology (ophthalmology experience is beneficial)
- Basic knowledge of GCP (good clinical practices) and regulatory compliance guidelines for clinical trials
- Knowledge/understanding of statistics

Personal Skills

- Self-motivated, engaged and possess high quality leadership skills
- Thorough and pay attention to detail
- Can communicate effectively; set priorities and have time management skills
- Able to use a computer and the main software packages competently
- Team player with positive constructive attitude to solve problems
- Eager to learn, stress resistant and ready to work independently in a start-up environment (hands on)