Sr. Post Market Surveillance Specialist

Occlutech is the leader in developing innovative products for the treatment of structural heart disease. The Company manufactures, develops, sells and markets Class III medical devices for the transcatheter repair of structural heart defects, including a range of specialized devices for patients with atrial fibrillation or heart failure, in over 90 markets around the world. Occlutech operates facilities in Germany, Turkey and Sweden. For additional information please visit our website at www.occlutech.com.

Location: **Hybrid in Maple Grove, MN**

The Sr. Post Market Surveillance Specialist is responsible for adherence to Good Manufacturing Practices, Good Clinical Practices, etc. (GMP, GCP, GXP)) and proper complaint handling and FDA Medical Device Reporting per the Code of Federal Register (CFR) and other governmental regulations, and will communicate event investigation results via regulatory reports and written communications, as appropriate. Responsible for the reportability of customer complaints, compliance with FDA regulations and regulatory follow-up(s), guidelines and ensuring on time reporting for the United States.

Your work will focus on:

- Complete complaints initial assessment and report FDA Medwatch Reports as needed.
- Review complaint communications and assess for regulatory compliance, reportability, and potential impact to patient safety and business operations.
- File malfunction Medical Device Reporting as identified.
- Escalate complaints to the MDSO (Medical Device Safety Officer) Team when new failure modes are encountered.
- Apply clinical knowledge, as related to product application, to evaluate identified complaints. Investigate complaints by gathering sufficient data from clinical staff, field representatives, internal employees, and laboratory analysis.
- Determining the classification, review, and disposition of adverse events and medically related complaints for on-market products, including decisions on seriousness, reportability, and potential causality.
- Complete FDA MDR and other outside competent authority regulatory reports as applicable.
- Analyze customer complaints to determine which are regulatory reportable and coordinates activities with internal, field, and end use customers.
- Trending of all reportable complaints into the Quality System.

The working conditions for the Sr. Post Market Surveillance Speicalist are:

- Hybrid in Maple Grove, MN

We are looking for a candidate, who

- Has a B.S., B.A.or RN in a related field (science, engineering, nursing/medicine, regulatory, quality).
- Has a minimum of 5 years' experience in a Clinical/QA/Post-Market Surveillance/Regulatory in FDA Class III environmnent.
- Has a fundemental working knowledge of FDA regulations.
- Has experience with complaint handling systems.
- Has prior FDA Class III experience.
- Has the ability to accurately communicate complex information to a wide variety of people.
- Has strong oral and written communication, analytical skills, and organiation skills.

Are you interested?

We look forward to receiving your application (cover letter, CV, including qualifications and references - all documents in one pdf file), your salary expectation and the earliest possible date for start of work to vanessa.weber@occlutech.com. Only applications in English will be evaluated.