



Regulatory Affairs Specialist

(Post Market Surveillance and Vigilance)

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 80 markets around the world. Occlutech operates facilities in Germany, Turkey and Sweden. For additional information please visit our website at www.occlutech.com.

Location: **Jena, Germany**

Reports to: Director International Registrations and COO

Position Description:

Broad Function

Support the Quality Assurance & Regulatory Affair department by reviewing, evaluating, and performing Post Market activities on our medical devices, determining if they require vigilance reporting, trend reports, identifying supporting data and notifying regulatory agencies as necessary.

Your work will focus on

- Work with R&D team to support closing complaints in a high quality and timely manner
- Perform high quality and traceable documentation on Adverse Event, CAPA and Complaint Proceeding
- Collect, trend and escalate data related to Post Market Surveillance
- Preparation and presentation of Post Market Surveillance Report to the Management
- Generate, maintain and complete the Post Market documentation (Periodic safety update report, PMS report & Plan) subject to review by regulatory agencies

We are looking for a candidate, who has

- Successful Bachelor's or Master's degree in life science or engineering (or related field)

- Proficient experience within QMS (ISO13485:2016/MDSAP/U.S. FDA QSR) and MDD / MDR; 3 years in post-market surveillance and complaint management of medical devices (Complaint Evaluation / Safety assessment / Medical Device Reporting / Compliance)
- Excellent oral English with very good English writing skills
- Strong organizational, planning and analytical skills, results oriented
- Excellent communication and interpersonal skills, ability to work in international environment with cross-functional team
- IT Tools: Excel (advanced), Word, Power Point

If you are

- a team player who likes challenges
- a confident user of standard office software
- excellent in leadership, communication, organization and time management
- open to international travel

then we can offer you an interesting job in a team of people who like to work together and always focus on helping our customers to save and improve patient's lives with innovative and highest quality products.

Are you interested?

We look forward to receiving your application (cover letter, CV, references - all documents in one pdf file), your salary expectation and the earliest possible date for start of work to bewerbung@occlutech.com.

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