



Post Market Surveillance & Vigilance Specialist (f/m/d)

Occlutech is a leading specialist provider of minimally invasive cardiac devices, with a mission to improve the quality of life for people with heart conditions. The vision is to become a global leading specialist provider in cardiac devices, addressing congenital heart defects, stroke prevention, and heart failure.

Occlutech has a broad and proven portfolio, based on proprietary technology, and over 200 patents with more than 139,000 products sold. The company markets and sells its products in circa 85 countries and has around 300 employees.

Location: Jena, Germany

Your work will focus on

- Ensure compliance with the post-market process according to the regulations
- Collect, assess, and monitor trends and escalate compiled data during the post-market life cycle phase.
- Perform and support “corrective and preventive actions” and “change requests”.
- Generate, maintain, and complete Post Market Surveillance Plan, Post Market Surveillance Report / Periodic Safety Update Report (PSUR).
- Preparation and presentation of relevant post-market data to the Management
- Prepare and share Post Market documentation subject to review by regulatory agencies
- Interact with all departments the s involved in the post-market life cycle phase
- Interact, among others, with the Risk Management department Complaint Management department, Clinical department

Knowledge, Skills, and Abilities (KSAs)

- Experience with FDA Medical Device Reporting (eMDR).
- Strong organizational, planning, and analytical skills, results-oriented
- Excellent communication and interpersonal skills, ability to work in an international environment with cross-functional team

Background Experiences

- IT Tools: Excel (advanced), Word, PowerPoint
- Excellent oral English with very good English writing 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 the start of work to bewerbung@occlutech.com

For further information on Occlutech please refer to:

www.occlutech.com

www.occlutech-jena.de

Occlutech GmbH Jena
Winzerlaer Straße 2, 07745 Jena, Germany
Tel +49 3641 508 324
germany@occlutech.com, www.occlutech.com

