



Regulatory Affairs Specialist, North America (m/f/d)

Occlutech is the leader in developing innovative products for the treatment of structural heart disease. The Company 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 50 markets around the world.

Position: Regulatory Affairs Specialist, North America (m/f/d)

Location: The successful candidate will be based either in Istanbul, Turkey or Jena, Germany

Reports to: Director International Registrations

Primary responsibilities of the successful candidate include supporting Occlutech's International Registration Team in managing, implementing, maintaining and improving the Company's North American Regulatory Affairs procedures and objectives. This will include working together with staff across functions and across sites the organization. Moderate travel may be required.

Your principal responsibilities:

- Support the coordination of all regulatory affairs related activities pertaining to North American within the organization (all sites)
- Supporting the preparation of regulatory affairs plans, budgets and timetables
- Maintaining close and effective working relationships with the staff in other, involved departments in the Company (R&D, Quality and others)
- Drafting of procedures, protocols, reports, and integrated summaries, as necessary
- Providing reports to superiors and Company management concerning the status of registration activities, new regulatory requirements and identification of issues that may be found.

Selected, specific tasks will include:

- Support North American registrations of Occlutech products in accordance with applicable standards & regulations in order to obtain necessary permits (PMA, 510(k))
- Together with internal, interdepartmental resources, create, compile and manage North American registration dossiers (including PMA, 510(k)), and manage submission processes
- Support communications with relevant agencies during the process of registrations (U.S FDA, Health Canada)

We are looking for a candidate, who has

- Bachelor's Degree in Engineering or Life Sciences
- Minimum of 3 years' experience in North American registration processes e.g. (PMA, 510(k)) with U.S.FDA Class III and II medical devices regulatory affairs,
- Proven experience with U.S. FDA regulated Class III cardiovascular devices
- Thorough knowledge of U.S. FDA and safety guidelines related to Class III & II medical devices.
- Expertise in establishing and/or managing a ISO 13485 and FDA QSR compliant Quality Management System
- Excellent interpersonal and communication skills

- Ability to manage multiple projects effectively & excellent organizational skills
- Managerial/supervisory experience a plus
- Fluency in English a must

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 jobs@occlutech.com.

www.occlutech.com