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

If you are a team player with excellent interpersonal, communication and leadership skills, have as strong sense of ownership and a proven track record of professional and / or academic accomplishments, you should submit your CV with a cover letter indicating the position you are applying for, and highlighting your motivation, skills, background to bewerbung@occlutech.com

Location: The successful candidate will be based in the US

Position Description:

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 and QMS procedures and objectives. This will include working together with staff across functions and across sites the organization. Moderate travel may be required.

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, submission files, 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, IDE, 510(k)), and manage submission processes, such as response to deficiency reports.
  - Support communications with USFDA during the process of registrations)

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

Requirements:

- Bachelor's Degree in Engineering or Life Sciences
- Minimum of 5 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 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 is a must

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 bewerbung@occlutech.com . Only applications in English will be evaluated.

www.occlutech.com

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