Job Description:

Quality and Regulatory Affairs Specialist (m/f/d)

Start Date: ASAP
Type: Part-time/ full-time

Main Tasks and Responsibilities:

- Maintain and further develop the company's quality management system in accordance with regulatory requirements of ISO 13485:2016 and the European Regulation 2017/745 (MDR)
- Support and monitor quality processes to ensure compliance with internal and external regulatory requirements of the quality management system, quality policy, quality objectives, customer and regulatory requirements
- Conduct document and record management, change control, risk management, management review, supplier management, audit management, manufacturing and environmental control, complaint handling and training
- Back up of the quality management representative

Required Education Level and Professional Experience

- University degree in engineering or natural sciences
- Experience in quality management and/or regulatory affairs, preferably in medical devices
- Business fluency in German and English

Please send your application to
info@protembis.com

About Protembis

Protembis is an Aachen (Germany) based medical device company. The company's vision is to bring its novel cerebral protection technology into every interventional procedure which bears a risk of neurologic injury, thereby radically improving patient safety. For more information please visit www.protembis.com.

DISCLAIMER

The above statements are intended to describe the general nature and level of work being performed by employees assigned to this position. The statements are not intended to be construed as an exhaustive list of all responsibilities, duties and skills required of employees assigned to this position.