Regulatory Affairs and Quality Assurance Manager (m/f/d)

About Us:
BTT Health GmbH is a German medical technology company specialized in the production of medical devices for bone healing. Our primary products, the bone4ce ultrasound bone growth stimulator and the osteoporosis therapy system MARODYNE LiV, offer safe, effective, and drug-free treatments. Our commitment to improving health and well-being drives our innovation and excellence in the field. Join our dedicated team at our headquarters in Greifenberg near Munich.

Job Description: As a Regulatory Affairs and Quality Assurance Responsible, you will play a critical role in ensuring our medical devices meet regulatory standards and maintain the highest quality throughout our manufacturing processes. You will define and implement regulatory strategies for international markets, with an immediate focus on the USA, and manage quality assurance programs to ensure our products comply with industry regulations and customer expectations. This role involves direct communication with authorities and notified bodies on all matters related to medical devices.

Responsibilities:

- Develop and execute regulatory strategies for global markets, with immediate focus on EU (MDR), and later the USA (FDA).
- Ensure compliance with national and international regulations, including MDR, ISO 13485, and 21 CFR Part 820.
- Prepare and manage technical documentation for medical devices for submission to Notified Bodies and the FDA.
- Conduct internal and supplier audits to ensure compliance with quality management systems.
- Oversee market surveillance activities and manage Corrective and Preventive Actions (CAPA).
- Implement product and process-based risk management strategies.
- Maintain and improve the quality management system in line with relevant standards and requirements.
- Act as the primary point of contact with regulatory authorities and notified bodies.
- Ensure continuous improvement of quality assurance processes and systems.
- Provide regulatory guidance and training to internal teams.

- Prepare and submit regulatory filings and ensure timely approval of medical devices.
- Manage and resolve regulatory and quality issues efficiently.

Qualifications:

- Completed scientific training or studies in a relevant field such as engineering, medical technology, biology, chemistry, pharmacy, or similar.
- Minimum of 2-3 years of professional experience in medical device certification within a national and international context.
- Proven experience in establishing and maintaining quality management systems compliant with MDR, ISO 13485, and 21 CFR Part 820.
- Proficient in managing technical documentation for medical device.
- Skilled in conducting internal and supplier audits.
- Experience in market surveillance and CAPA management.
- Strong understanding of product and process-based risk management.
- Proficient in using common Microsoft Office programs.
- Excellent communication skills in both German and English.
- Ability to work independently and manage multiple projects simultaneously.
- Detail-oriented with strong analytical and problem-solving skills.

What We Offer:

- A dynamic and innovative work environment within a growing company.
- Opportunities for professional development and career advancement.
- A collaborative and supportive small company environment.
- Located at beautiful surrounding close to Munich.

If you are passionate about regulatory affairs and quality assurance and have the expertise to help us maintain the highest standards in medical device manufacturing, we would love to hear from you. Apply now to join our team at BTT Health GmbH and contribute to our mission of improving patient health and well-being at:

personal@btt-health.com

BTT Health GmbH

Beurer Str. 25A

86926 Greifenberg / Germany