

**Natural Scientist, Engineer as QM & Regulatory Affairs Manager - Medical Devices (m/f/d)**Cellbox Solutions GmbH  Hamburg**CELLBOX.
NOW
BOARDING.**

Cellbox Solutions GmbH is a young technology company focusing on new innovative solutions for the global BioTech industry. The company, founded in 2016, is a spin-off from Fraunhofer Research Institution for Marine Biotechnology and Cell Technology in Lübeck. We're aiming at improving the lives of others by providing innovative and new cell logistic solutions for the correct handling of living cells and biologic structures.

To support our team in Hamburg we're currently looking for a

**QM AND REGULATORY AFFAIRS MANAGER
(FULLTIME)****YOUR RESPONSIBILITIES:**

- Development of new products in cooperation with R&D and production
- Close collaboration with R&D and Production to assure compliance of locally manufactured products to international regulations
- Responsibility for product registrations on national and international level
- Establishment of QM system
- Creation and maintenance of Technical documentations for CE-certifications of laboratory and medical equipment (according to MDR)
- Elaboration of requirements for international markets
- Development of internal strategies for elaborating respective regulatory approval documents
- Correspondence with national/international authorities
- Preparation and control of export registrations
- Participation in audits

WHAT YOU'RE OFFERING:

- Degree in Regulatory Affairs, MedTech, Natural Sciences, Engineering or equivalent
- Several years of professional experience in the area of Medical Devices Regulatory Affairs or Quality Management for Medical Devices or Product Management of innovative technologies in Life Sciences
- Profound knowledge in Quality Management (ISO 13485) and Risk Management (ISO 14971)
- Ideally experienced in legal directives (according to MDR/IVDR)
- Experienced in regulatory approval processes of laboratory and medical products
- Excellent communication and presentation skills
- Hands-on mentality
- Fluent in German and excellent English language skills

WHAT WE'RE OFFERING:

- The opportunity to shape and build the QM department of a promising and growing technology company
- Permanent contract
- Motivated and experienced team, flat hierarchies
- Office in the heart of Hamburg, sports facilities and fresh fruit

READY FOR BOARDING?

Drop your application at [jobs\(at\)cellbox-solutions.com](mailto:jobs(at)cellbox-solutions.com). In case you have questions get in touch with Hans Nagels at +49 176 10 350 320.

We're looking forward to receiving your application.



 Full-Time, Permanent  Specialist  Updated on 02.12.2019