Manager Regulatory Affairs (m / f / d)

Our mission is to protect the eyesight of patients with retinal diseases. For this purpose, the international team of OD-OS has been working closely with physicians and clinical experts worldwide for more than 10 years. Our unique navigated laser therapy system Navilas® sets a new standard for retinal treatment.

Our next generation treatment device will offer a therapy to millions of people who don't find access to treatment, yet. Join our team and have an impact in making this vision come true. Join our cross-functional development team to implement innovative solutions for automated high-quality medical treatment.

Your role:

- The area of your responsibility comprises successful approval of medical devices in the European(Class IIb), US (Class II) and other markets
- Work in close interaction with the Development team and other stakeholders for the developments and changes of already marketed devices
- Compile, prepare and maintain documentation for EU MDR Technical File, US FDA 510k submissions, and other regulatory submission dossiers for new medical device registrations and changes to existing products, in accordance with regulations
- Evaluate and submit changes for international regulatory approvals
- Monitor new legislations, policies, standards and guidelines that affect the assigned product portfolio.
- Conduct post-market surveillance and report adverse events/field safety corrective actions to the authorities
- Communication with Notified Bodies, US FDA and other authorities world-wide
- Support internal and external audits
- Deputy PRRC
- You will report to the Head of Regulatory Affairs

Your profile:

- Completed higher degree in Engineering or Natural Sciences, or sufficient professional experience in the RA field
- Minimum 3 years experience with Regulatory Affairs for Medical Devices and/or In Vitro Diagnostics (preferably with Active Devices and/or Software as Medical Device)
- Solid knowledge of
    - EU MDR 2017/745 (or EU IVDR 2017/746), US FDA, further jurisdictions are an advantage
    - Successful submission and clearance achievement with US FDA
    - Compiling and maintaining Technical documentation
    - Other processes such as Post Market Surveillance, Vigilance, Usability and Risk Management are an advantage
- Problem solving ability, and the ability to think analytically and strategically

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- Good team work and project management ability
- Very good writing and communication skills in English, German is an advantage
- Customer oriented way of working

Our offering:

- We offer an exciting and diversified job in a growing, innovative company in a startup mode
- An interesting and varied job in a collegial, highly motivated team
- Working in a fast-growing, innovative company with flat hierarchies and transparent communication
- Flexible working hours, performance-related remuneration and bonus system
- Technical equipment such as company cell phone and laptop
- Social events (e.g.: Christmas or summer party)

Are you interested?
Please send us your application documents consisting of your curriculum vitae and references, stating your salary expectations and your earliest possible availability date. exclusively via E-Mail to: Jobs@od-os.com

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