

stryker

Developer Lateral thinker Top colleague Lifesaver



Senior Specialist Regulatory Affairs (f/m)

RA/QA • Selzach (SO) • Start: asap • Position permanent

Your Talent – our passion as a Top-Employer in MedTec!



33.000+ employees



5.638 patents



\$ 11.3 Billion turnover



Various perspectives and possibilities for personal development



Flexible working hour arrangements



Unique and engaged colleagues

Our offer

- In your new role as Senior RA Specialist you organize and implement strategies and activities required to procure regulatory approval for new and revised product lines.
- You ensure compliance to all US, EU and international requirements and corporate policies and procedures regarding submissions and other requirements for market approval of medical devices/combination products.
- You apply scientific principles to understanding safety and efficacy on a wide range of products.
- You interface and coordinate with the FDA, Notified Bodies and other regulatory agencies on submissions, approvals or other issues.
- You support R&D, marketing and manufacturing teams in regulatory assessment of proposed changes or product transfers.
- Moreover, you participate in cross functional team activities from initial stages through securing government approvals for any initiative and project requiring Regulatory Affairs support.

Your profile

- You have a Bachelor's Degree in a scientific discipline. Ideally, you dispose of a RAC certification.
- You have a minimum of 4-5 years' experience in a highly regulated industry and you have working knowledge of Medical Device Regulations (FDA/MDD required, additional international a plus).
- You have gained experience with 510(k), EU MDD 93/42/EEC Technical File/Design Dossier preparation.
- You have successfully interacted with FDA and notified body reviewers/inspectors and you have a sound understanding of scientific principles.
- You are characterized by strong interpersonal and communication skills. Moreover, you have excellent organizational and planning skills.
- You are fluent in English and have ideally a good knowledge of German.

We are looking forward to your online application via our career page, reference number 27673BR.

Please notice that the title of this advertisement can differ from the position title.



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Apply now!