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Principal Regulatory Affairs Specialist

Hiring organization
BioLink 360

Employment Type
Full-time

Industry
Medical Devices

Job Location
Mountain View, CA
Remote work possible

Date posted
July 15, 2023

Description

Reports to: Senior Director of Regulatory and Quality

Salary Range: 140-160K

Location: San Jose, CA (hybrid position)

This is an established privately held medical device company with a focus in delivering innovative navigation diagnostic and therapeutic technologies. Their reach is global and they are the industry leader in their specialty, with a second location in Asia. The investment into R&D is significant with several products in the pipeline at various stages and their financial standings are strong.

The Principal Regulatory Affairs Specialist hired will report to the Senior Director of Regulatory and Quality, with sights to build out an RA team as needed.

Responsibilities

- Support and prepare all regulatory submissions for FDA, Health Canada, Notified Bodies, and other regulatory agencies, with limited guidance and direction.
- Provide guidance and approval regarding regulatory strategies and approaches.
- Develop, Maintain and update regulatory documents such as technical files for CE marking, device master records, GSPR checklist, risk analysis, and design history files.
- Participate and Support new product development teams to provide regulatory support to the project.
- Assess regulatory impact of post-market changes on labeling, design, materials, manufacturing process, sterilization or packaging and notifying regulatory agencies and NB of substantial changes.
- Support post market activities and reportability to regulatory agencies.
- Required to support communication with FDA and the Notified Body, preparing responses to questions or deficiency letters from regulatory agencies, and serve as the RA Representative during FDA and NB site audits.

Qualifications

- 5-10 years experience in regulatory affairs within the medical device industry
- Strong experience in EUMDR Regulations (Medical Device directives (93/42/EC)
- Authoring experience in FDA product submissions (IDE, PMA, 510k)
- Experience in writing/maintaining CE Technical Files preferred
- Experience with ISO 13485:2016 and ISO 14971