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Senior Regulatory Affairs Specialist-Remote Based-West Coast

Hiring organization
BioLink 360

Employment Type
Full-time

Base Salary
$ 140,000 - $ 170,000

Date posted
January 6, 2023

Description

Reports to: Global Regulatory Affairs Director
Salary Range: 140-170K
Location: Remote Based
Travel: Occasional travel to West Coast, Must reside in Pacific or Mountain time zone

This Senior Regulatory Affairs Specialist will have an opportunity to work on new to market technology that is improving the field of diagnostic imaging and saving patient lives. This is a long-standing team of 12 people globally. The position reports to a Global Director, who is well respected. There is very little turnover with this team.

The company is well established and has a product portfolio and the person hired will be focused on the diagnostic imaging sector, where there is a robust pipeline of AI and machine learning technology. Exposure and interest in SaMD is a must!

Responsibilities

- Work closely with development teams to provide guidance on technologies supporting software as a medical device (SaMD).
- Prepare regulatory submissions including 510(k)s, Design Dossiers, Technical Files, Device License Applications, Investigational Device Exemptions, and Pre-market Approval Applications

- Confer with other Regulatory Affairs subject matter experts regarding regulatory requirements of new product designs and/or changes to existing designs.
- Support and comply with the company's Quality Management System policies and procedures.
- Apply advanced regulatory knowledge to the evaluation and solution of submission problems and drives product change assessments and define regulatory impact of product changes.

Qualifications

• Bachelor's degree in Physical or Life Sciences or a field as outlined in the essential duties
• 5+ years RA experience in a regulated medical device, digital health, med tech or medical device environment
• Experience with AI, machine learning, digital health is a plus, interest in these products a must
• Experience with ISO 13485, FDA, MDR (Medical Device Regulation), and CMDR (Canadian Medical Devices Regulations) compliance requirements and training
• Experience with Risk Management per ISO 14971
• Experience with FDA remediation, Warning Letters, 483 Observations, and Recalls
• FDA regulatory submission experience (Pre-Submission, 510ks, De Novo, IDEs)

Keywords:
MedTech, machine learning, AI, artificial intelligence, diagnostic imaging, medical technology, medical imaging, Angiography, computed tomography, fluoroscopy, tadiation therapy Imaging, magnetic resonance imagine, mammography, surgical C arms, surgical navigation, ultrasound