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Senior Manager/Director of Regulatory Affairs-Drug Delivery

Hiring organization
BioLink 360

Employment Type
Full-time

Industry
Medical Device/Pharma

Job Location
San Jose, CA

Base Salary
$ 160,000 - $ 200,000

Date posted
March 29, 2023

Description

Company HQ: San Jose/San Francisco, CA
Position Reports to: VP of Regulatory and Quality
Direct Reports: None
Salary Range: 160-200K

This is a company pioneering drug delivery technology to help patients with heart and vascular disease. This company is an established organization with a rich R&D pipeline. The person hired into this role will be responsible for all Regulatory submissions for the product portfolio. Working closely with the VP of Regulatory and Quality, the person in this role will develop and implement global regulatory strategies that support clinical research and marketing approvals. They will work directly and interactively with cross functional teams during product development phases interpreting regulations, analyzing risks, and providing direction on test strategies and reviews. This person will define strategies to mitigate risks and provide regulatory guidance to company throughout the research and development process.

Qualifications

- 10+ years of regulatory work experience, to include Class III Risk Devices
- Subject Matter Expertise with strategy and authoring of IDE/PMA submissions
- Experience with MDD and MDR
- Background in Cardiology/Class III Medical Devices and/or drug delivery
- Bachelors degree in Science or Engineering, with advanced degree preferred.

Contacts

For further information, please apply here. Qualified candidates will be contacted by a member of our recruitment team within 7 business days. If you need additional assistance, please reach us at Connect@BioLink360.com