



<https://www.biolink360.com/job/ra-dir-sf/>

Regulatory Affairs Director

Description

Company Location: Bay Area

Comp: 150K-220K

Position Reports to: VP of Regulatory and Quality

Director of Regulatory Affairs -San Francisco

We are seeking a highly motivated and experienced Senior Director of Regulatory Affairs for a Medical Device Orthopedic Portfolio. This person will lead interactions with regulatory agencies globally and help develop & execute regulatory strategy. The person in this role manages a team over RA and QMS.

Responsibilities

This person will represent the regulatory function on manufacturing and product development teams to provide input on regulatory requirements, review and approve protocols, reports, and other product development and manufacturing documentation to ensure compliance with regulatory requirements.

- Manage the EUMDR transition to ensure continued business with existing products and timely new product CE marking.
- Work closely with research and development, clinical, quality and marketing teams to ensure regulatory considerations are integrated into product development and launch plans.
- Develop and plan strategies and contingency plans for projects related to NPD.
- Provide direction and guidance to project teams to execute complex regulatory affairs projects & initiatives.
- Will include preparation of documentation packages for submission to regulatory agencies globally.
- Interact with regulatory agencies as part of submission review and on-site audit support.
- Oversee team members in RA and QMS, to execute business plans and strategies for RA success.

Qualifications

Education/Experience Requirements

- Bachelor's degree required with a concentration in life sciences, technical, engineering or related field
- Advanced degree strong preferred
- 10+ years of experience in Regulatory Affairs submissions in a Senior/Principal/Program leadership function.
- 3+ years in a management capacity
- 3+ years of experience in medical device, drugs, biologics, and/or combination products, preferred

Hiring organization

BioLink 360

Employment Type

Full-time

Job Location

San Francisco, CA

Date posted

July 8, 2023

- RAC and/or PMP preferred