

Position Title: Regulatory Affairs Leader

Reports to: Regulatory Affairs Director

Department: QA, RA and Clinical

Job description:

Responsibilities:

- Coordinate, review and maintain efforts associated with the preparation of regulatory documents for submissions such as CE, FDA, etc.
- Coordinate, prepare, or review regulatory submissions for domestic or international projects.
- Work and communicate closely with company members to assist in obtaining regulatory approvals for the company's products.
- Interpret regulatory rules or rule changes and ensure that they are communicated through policies and procedures.
- Review product promotional materials, Social media and labeling for compliance with applicable regulations and policies.
- Write or update standard operating procedures, work instructions, or policies that support regulatory activity.
- Participate in product development, as required, to ensure the product is in compliance with regulatory requirements
- Support cross company processes as CAPA, NCRs, ECOs and customer complaints.

Qualifications:

- **Education and exeperience:**
 - A Bachelor's degree in a relevant field
 - 3-5 years experience in regulatory Affairs, at a Medical Device Company
 - Good Communication skills both verbally and in writing
 - Good analytical skills
 - High ability to work independently
 - Self-motivated and proactive
 - Fluent in English with excellent writing skills
 - Excellent computer skills, including a working knowledge of Microsoft Office applications.

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