

Clinical and Regulatory Affairs Manager

AnX Robotica is looking for a Clinical and Regulatory Affairs Manager. Our commitment to quality and regulatory compliance is at the heart of our brand and is vital to our growth and success.

Summary:

The successful candidate will be experienced in working within the medical device industry, preferably startups, with knowledge in clinical and regulatory affairs of medical devices. They will ensure that regulatory and clinical projects and practices are aligned with business objectives while maintaining compliance with all applicable rules, regulations, and requirements.

Responsibilities:

- Coordinate the development of clinical study protocols and related clinical study documentation.
- Coordinate the activities for implementing company sponsored clinical studies (e.g., ethic approval, registration in clinicaltrials.gov, finalizing contracts and agreements, etc.)
- Supervise the execution of company sponsored clinical studies.
- Coordinate the preparation and submission of regulatory applications.
- Provide regulatory guidance to development project teams regarding design, development, and evaluation of the company products.
- Provide regulatory guidance to department teams regarding marketing and sales of the company products.
- Coordinate the development of regulatory strategies and implementation plans for the preparation and submission of new products.
- Investigate product complaints and prepare documentation and submissions to appropriate regulatory agencies, as required.
- Monitor emerging trends regarding industry regulations to determine potential impacts on organizational processes and company products.
- Serve as the contact point for colleagues within the company in terms of all questions concerning the technical documentation and the approval/clearance of the company products.
- Provide staff training on regulatory affairs issues and good clinical practice.
- Oversee documentation efforts to ensure compliance with domestic and international regulations and standards.
- Review materials such as marketing literature, user manuals, instructions for use, etc. to ensure that regulatory requirements are met.
- Manage/Coordinate activities such as regulatory agency inspections, product recalls, reporting





adverse events to regulatory authorities, etc.

- Perform other duties as assigned.

Qualifications:

- A bachelor's degree in life sciences or a technical field
- RA certification (RAC) in the U.S. and/or EU
- At least 3 years of working experience in a regulatory/clinical department of a medical device company
- Basic knowledge of FDA, EU, and other regulatory agencies rules and regulations, including GCP for medical devices (e.g., ISO 14155, 21 CFR 812, ISO 13485, CMDR, MDSAP)
- Attention to detail
- Good computer skills with knowledge of Microsoft Office and QMS Systems
- Fluent in English with strong verbal and written communication skills
- Fluent in Chinese is a plus but not a requirement

Working Conditions:

- Primarily in an office environment
- Domestic and international travel up to 20%

About AnX Robotica

AnX Robotica is a medical technology company dedicated to advancing gastrointestinal diagnostics through innovative, minimally invasive solutions. The company develops and commercializes next-generation capsule-based technologies designed to improve the detection, evaluation, and management of GI diseases across the esophagus, stomach, small bowel, and whole gut. Its growing portfolio includes the NaviCam™ family of capsule endoscopy systems, AI-assisted diagnostic software, and emerging technologies focused on motility assessment and advanced imaging. By combining engineering innovation with clinical insight, AnX Robotica is committed to expanding access to high-quality diagnostics while helping physicians deliver more efficient, patient-centered care.

