



Position Description for Quality Assurance Regulatory Affairs Manager

Company

The client is a multi-national medical device manufacturer whose mission is to improve the quality of life through the design, development and manufacture of high quality, affordable medical products, for the benefit of patients and health professionals and with respect to their employees.

Role summary

In this position as QA/RA Manager you would be responsible for managing quality systems development and maintenance and coordinating regulatory activities as they develop their site in Mullingar, ISO13485 quality system set-up, as well as product registration and compliance. A broad, working knowledge of key aspects of both disciplines will be required. The immediate need and focus will be in Quality Systems, with the Regulatory responsibilities increasing over time. Strong leadership and team skills will be important to guiding and aligning the internal team and external consultants. That would be an on-site job and a full-time permanent position. The location is Mullingar, Westmeath.

Responsibilities:

Quality Systems

- Broad understanding of key elements of Quality Systems
- Drafting/Support of quality documentation, including SOPs, test methods, change controls, deviations, corrective actions, out of spec investigations, etc.
- Working knowledge of device and Design Control and/or Quality by Design. Must be able to guide team through phases, understand documentation and testing requirements, and maintain files.
- Personnel Qualification



- Maintaining Equipment Certifications
- Organizing Document Controls to Capture Key Internal Supporting Docs and External Vendor Quality Specs
- Vendor Auditing
- Reviewing Manufacturing Documents for Material Qualifications and Products

Regulatory

- Maintain an excellent understanding of global medical device regulations for specific jurisdictions as assigned to support products.
- Develops in-depth understanding of EU MDR requirements and supports all functions in implementation of these requirements
- Develop global regulatory strategies for medical devices in collaboration with Quality, R& D and Clinical functions.
- Advise other functional units (R&D, Engineering, Marketing, Quality, etc. of the requirements in each target market.
- Plans and prepares regulatory submissions for specific target markets for new products, product changes, and re-registration as required.
- Maintains registration information (license numbers, expiration dates etc) and obtains re-registration approvals in advance of license expirations to ensure no disruption in product availability.
- Maintains and develops the post market surveillance process including gathering and presentation of data
- Ensures post market surveillance sources are identified and post market surveillance plan is available.
- Provision of Post-market surveillance data for CER Reports
- Communicates Regulatory requirements to countries, regions, Notified Bodies, Competent Authorities and other regulatory agencies.
- Management of the clinical requirements for regulatory registrations for products and work as part of a cross-functional team to ensure that they are adequately addressed.
- Performs additional duties as assigned.

Requirements:

- Bachelor's degree in a scientific discipline (e.g., Biology, Biomedical Engineering)
- 5+ industry experience with a similar role



- Strong knowledge of FDA / GMP regulations
- Strong organizational and communication skills, both written and presentation.
- Able to work with a diverse group of individuals and styles, internally (employees) and externally (consultants)
- Respect and adherence to timelines
- Excited for start-up culture: adaptability, occasional ambiguity, limited resources, willingness to do what is necessary to get the job done
- Self-motivated, willing to learn