REGULATORY AFFAIRS SPECIALIST

Full time, Sydney NSW

360 Med Care is an innovative Australian company operating in the medical device, health care, and biotechnology sector specialising in total joint arthroplasty. We are real people, combining knowledge and technology to deliver positive patient outcomes.

360 Med Care is looking for a Regulatory Affairs Specialist to join a collaborative local team. In this role, you will apply your knowledge of regulatory requirements and actively contribute to product regulatory approvals and maintenance activities for applicable markets including Europe, Australia and US.

KEY RESPONSIBILITIES:

- Participate in developing and realising regulatory strategies;
- Actively contribute to product regulatory approval projects;
- Ensuring that the company's products are compliant to regulatory requirements; at a minimum for key markets including Australia, Europe and US.
- Ensuring that product realisation activities conform with the company's QMS;
- Coordinating regulatory strategies and product realisation activities with project teams using the company's project management frameworks;
- Providing leadership, ensuring a high performing culture within areas of responsibility;
- Acting as primary or secondary contact, as appropriate, with regulatory authorities and 360 Med Care's strategic partners
- Maintaining device and facility registrations e.g., FDA, AR, TGA
- Leading Post-Market Surveillance and Post-Market Vigilance activities

PROFESSIONAL AND TECHNICAL CAPABILITIES:

Essential

- Qualification in Engineering (preferably biomedical) or similar
- 1 - 5 years of professional experience in regulatory affairs or in quality management systems relating to medical devices (preferably orthopaedic).
- Experience working in an ISO 13485 regulated environment.
- Experience with regulatory processes for medical devices in key markets, including Australia, Europe and US.

- Experience in reading, understanding and implementation of standards for a variety of standards organisations e.g., ISO, IEC, ASTM.

Preferred

- Experience with regulatory submissions for software as a medical device.
- Experience working in a MDSAP regulated environment.
- Project management experience, specifically within Agile frameworks such as Scrum or Kanban.
- Experience in leading and managing individuals and / or small teams.

KEY ATTRIBUTES

- Proactive, dependable, self-motivated and takes ownership of work
- Logical, systematic and conscientious when approaching projects, tasks and problems
- Professional, clear and strong communication skills with an ability to address a variety of stakeholders
- Team-oriented with an ability and desire to collaborate within cross-functional teams promoting problem-solving and best outcomes
- Solution oriented with an ability to influence internal and external stakeholders
- Big picture thinker with an ability to prioritise and adapt based on current direction within an agile and fast-paced company

At 360 Med Care, our People ambition is to have an exceptional team, who challenge the status quo, are growth focused and help lead our purpose of optimising the episode of care.

If you feel you are up for a great challenge, please send your resume to hr@360med.care