Regulatory and Quality Compliance Officer

The Company

A Perth-based health technology company that has developed proprietary and multi-functional technology is expanding its product range and now seeks to expand into the medical devices sector.

The Role

This full-time role will report directly to the Chief Operations Officer and will be responsible for the regulatory and compliance function within the organisation in relation to medical devices design, development and manufacture.

The role will oversee the review, development and implementation of compliance against a regulatory framework for medical devices. The regulatory framework for medical devices spans the life of the device and includes pre-market assessment; conformity assessment; market authorisation; inclusion in the ARTG; post-market monitoring; and continuing compliance with all regulatory, safety and performance requirements and standards.

Duties and Responsibilities

- Implement and manage a quality management system that is compliant with ISO 13485 and 21 CFR Part 820.
- Obtain and maintain relevant QMS certification.
- Implement an effective risk management strategy that demonstrates sound governance and builds a robust culture in risk identification, improving decision-making and enhancing outcomes and accountability.
- Ensure all staff are provided with suitable compliance training and support a strong compliance culture across the business.
- Create internal controls to ensure compliance within the medical device regulatory framework and compliance policies and monitor adherence to them. Ensure application of compliance controls related to all transactions, products, and processes.
- Proactively audit processes, practices, and documents for each department.
- Keep up-to-date with applicable legal and regulatory compliance requirements globally.
- Stay abreast of any updated rules within the countries we are based as well as European changes on data protection legislation (GDPR).
- Coordinate with different department managers to review all departmental procedures, and ensure they are documented to the relevant ISO standard.
- Coordinate and support the business continuity and disaster recovery planning.
- Work closely with senior management, particularly when entering new markets, to understand regulations, compliance and risks and provide strategic advice for appropriate risk mitigation.
- Leading broad risk assessments and response strategies across the business, in partnership with key stakeholders, including the identification and prioritisation of risks and development of mitigation activities.
- Assessment of record management program’s effectiveness.
- Work with senior management to define and direct implementation of internal controls that impact regulatory compliance.

- Serve as coordination point and subject matter expert for internal audit activities.
- If needed, lead and participate in ethics or legal investigations.
- Coordinate responses to external regulators both on a regular basis as per Law prescriptions and upon request.
- On a case-by-case basis, provide advisory to the business for specific regional industry Legal, Risk and/or Compliance requirements.
- Contribute to the design and deployment record-keeping strategy and data integrity preservation.
- Establish compliance KPI's.

Qualifications and Skills

- Extensive experience with medical device certifications and ISO 13485 and FDA GMP Regulations.
- An analytical approach and the ability to provide practical solutions.
- Ability to work on your own initiative, reach decisions and work under pressure.
- Experience working in a corporate compliance program and implementing regulatory compliance frameworks.
- Experience in risk management frameworks, risk assessment and risk management and mitigation strategies
- Mature, confident professional who is adept at partnering with senior leaders and legal counsel as well as positively influencing leaders to understand and address potential compliance risks through mitigation strategies.

To Apply

This is an exciting opportunity to make your mark in a growing company.

To apply for this role, please email your CV and a cover letter to janet@biotechrecruitment.com.au. Confidential enquiries should be made to Dr Janet Preuss via the above email, or on 1800 BIO JOB (1800 246 562).