Job Title	Head of Quality Assurance and Regulatory Affairs (QA/RA)
Reporting To	Technology Director
Accountable To	Technology Director

Role (Summary)

The Head of QA/RA is responsible for quality and regulatory activities of the organization including its Quality Management System (QMS) and products in accordance with international standards, best practice and customer requirements.

Key Responsibilities

Duties

- Establish and maintain an effective Quality Management System (QMS) in accordance with all applicable medical device regulations, including ISO 13485, US FDA Quality Systems Regulation (QSR) and Medical Devices Single Audit Programme (MDSAP).
- Lead Continuous Improvement of the Quality Management System.
- Input to regulatory aspects of technology & product opportunity evaluation.
- Lead quality and regulatory aspects within the product development process e.g. standards identification and interpretation, and quality and regulatory resource and activities planning.
- Work closely with internal and external multi-disciplinary product development teams to ensure project success.
- Plan and conduct internal audits and provide guidance regarding best practices and continuous improvement.
- Lead supplier management process including Quality agreements, auditing, etc.
- Promote audit readiness and lead facilitation of audits of Medovate and partner facilities by external regulatory authorities.
- Lead engagement with global regulatory authorities regarding the QMS and product certification.
- Contribute to development and achievement of Quality Objectives and Key Performance Indicators, reporting to the senior management team during Quality Management Review Meetings
- Compile and maintain product documentation for initial and ongoing certification.
- Oversight of post-market activities e.g. surveillance, vigilance, customer feedback, failure analysis.
- Significant contribution to strategic planning and implementation of Regulatory and Quality aspects of the business.
- Maintain a current expert knowledge of US FDA, EU MDR and other applicable regulations, legislations, best practices and guidelines related to QA/RA, monitor changes to applicable laws and regulations, identify impact to the business, and in collaboration with other stakeholders, develop response strategies and/or a work plan and complete according to deadline.
- Be responsible for training on the QMS for existing and new staff, and external parties.
- Management of the customer feedback/complaints systems and processes.
- Supporting and approving CAPAs, root cause analysis and non-conformance investigation activities, validation activities, risk management and design review. Support the senior management team understand the QA/RA framework in which the business is expected to operate.
- Promote a high level of Quality both within the business and with external providers.
- Participation in company's Health & Safety activities and support compliance.
- Line management of the Quality Assurance and Regulatory Affairs team
- Any other duties to support company business activities as required.

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Person Specification

Knowledge & Experience

- Minimum 5 years working in the Medical Device industry.
- Managing an ISO 13485 Quality Management System (QMS) under the Medical Devices Directive (MDD)/Medical Devices Regulation (MDR) for product development and/or manufacturing in the UK/EU is essential.
- Knowledge of US FDA 21 CFR 820 Quality Systems Regulation is essential, and experience is highly desirable.
- Knowledge and experience of the medical device EU MDR conformity assessment process to obtain CE mark is essential.
- Knowledge of the US FDA product approval process e.g. 510k is essential and experience is highly desirable.
- Knowledge of other global quality & regulatory obligations is desirable.
- Experience of Class I and II devices is essential.
- Experience of sterile single-use devices including process validation is highly desirable.
- Experience of a wide variety of device technologies and clinical specialties is desirable.
- Working with external contract design and manufacturing organizations is essential.
- Project Management experience and knowledge of good project management techniques.
- Strong interpersonal and negotiation skills.
- Excellent attention to detail is essential.
- A strong team player who is motivated by the success of the business.
- A self-starter committed to making things happen.
- Able to work independently and lead relevant aspects of the QA/RA function.
- Experience of managing people.
- Ability to travel independently to venues around the UK at times and for durations required by the role. This may require the post holder to be away from the main base of operations for overnight periods and may also include international travel.

Education

- A degree or higher degree in an Engineering, Science or Regulatory discipline.
- Member of a professional body would be advantageous e.g. RAPS, TOPRA, CQI.