**Solutia Life Sciences (recruitment division of Solutia) specializes in technical and middle management profiles in the pharmaceutical, biotech, and medical device sectors.**

We are currently selecting a **RA&QA Manager** for a medtech startup deeply committed to delivering top-notch cutting-edge respiratory care technology that pushes the boundaries of innovation to the future of healthcare, located in Barcelona.

**What will you do?**
We seek an experienced professional in quality assurance and regulatory affairs, with experience in Medical Devices.

The candidate will oversee all aspects of product compliance, including documentation and processes, to meet regulatory requirements and interact with institutions to keep scaling the product until it is ready to market. The main functions are as follows:

- Support all QMS maintenance-related activities (Document control, non-conformities CAPA, change control, audits, and potential inspections).
- Develop the Risk Management Plan, working with tech partners and medical and tech teams to ensure compliance with the QA RA requirements.
- Participates in preparing, reviewing, and maintaining procedures, quality plans, work instructions, forms, specifications, inspection plans, validation plans, qualification plans, templates, or any other quality document.
- Work with internal and external stakeholders on identifying and documenting product-related complaints and non-conformities and developing CAPA plans.
- Work on CAPA's investigations and follow-up with internal and external stakeholders.
- Participate in supplier's (product or service suppliers, subcontractors, CROs…) qualification and approval.
- Participate in the preparation and conduct of suppliers' audits and clinical audits.
- Participate in external and internal audits and regulatory authorities' inspections.
- Support quality metrics collection, analysis, trending, and reporting.

- Participate in the preparation/maintenance of establishment/operating licenses.
- Perform other duties as assigned.
- Comply with and enforce compliance with established information security and privacy policies and standards and act following instructions and procedures received.

**Requirements:**

- 2-4 years of experience in QA/RA in the medical device field.
- Knowledge of ISO 13485, CE marking, and FDA applied to medical device class IIA.
- Familiar with "good practice" quality guidelines and regulations.
- Knowledge of Quality Assurance tasks (e.g., Auditing, Change Control, Complaints, Deviations, CAPAs, Batch Record Review, Documentation management, Training, Supplier· Management, validations, qualifications, and calibrations).
- University degree in Engineering or life-science discipline. Ph.D. will be highly valued.
- Proficiency in English, both written and spoken.

Contacto
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