Job Title:

Regulatory Affairs Specialist - Medical Devices

Work Mode: Hybrid

Location: Warsaw

Employment Type: Full-time

Type of Contract: Employment contract, service contract, B2B contract

RESPONSIBILITIES:

Regulatory Affairs Specialist - Medical Devices will be responsible for creating, implementing, overseeing, and continuously updating documentation related to the market approval and maintenance of innovative medical products in the field of cardiology.

In particular, the responsibilities will include:

- Verification of the existing Quality Management System (QMS), including policies, standard operating procedures (SOPs), etc., to ensure compliance with formal and competitive requirements, proactive proposal of modifications (CAPAs), their implementation, and continuous oversight.
- Coordination of the development and execution of regulatory strategies for the company's existing and developing products, taking into account the formal requirements of target markets, their relative attractiveness, capital constraints, logistical aspects, and engineering requirements.
- Acting as the Person Responsible for Regulatory Compliance (PRRC), ensuring that the company's activities in R&D, medical, production, and other areas are compliant with regulatory standards, as well as representing the company in this aspect in relationships with external partners (authorities, notified bodies, subcontractors, clients, investors, etc.).
- Development and oversight of quality documentation, including verification of actions that require documentation and archiving.
- Willingness to maintain documentation under multiple certification regimes simultaneously (e.g., EU MDR and FDA).
- Proactive participation in the planning of clinical trials and other studies verifying the safety and usability of developing products (e.g., in terms of preparing documentation for a Pre-submission meeting).

REQUIREMENTS:

- Documented experience and results in the industry (track record of products approved for market in the medical field and/or completed external audits; please specify in the application at least the class of the device(s) and the regulatory pathways used). Additional assets include experience working with products classified above Class I and qualifications as an internal auditor.

- Relevant education in the biological-medical and/or engineering fields and/or quality management systems.
- Documented knowledge in the registration of medical devices and the application of relevant quality standards (please provide detailed information in the application regarding mastered standards and regulations; we expect knowledge of at least basic European standards and ISO-13485). Familiarity with standards regarding the development of software as a medical device, biological safety, and electronic medical devices is welcomed. Additional assets include experience working with products subject to clinical trials and the “breakthrough device designation” procedure.
- Familiarity with or willingness to learn about the process of obtaining medical device market approval in the USA. Openness to understanding regulatory requirements in East Asian countries.
- Experience working in an R&D team.
- Proficiency in English at a level sufficient for creating professional documentation.

WHAT WE OFFER:

- Competitive compensation commensurate with experience and responsibilities, in the form of an Employment contract, service contract, or B2B contract
- Opportunity to participate in an option program based on warrants as part of the incentive program.
- Hybrid model of work.
- Possibility to co-create globally innovative medical products of a first-in-class nature.
- Direct reporting to the company's Management Board with a high degree of autonomy and responsibility.
- Opportunity to expand contacts and experience by collaborating with a wide range of experienced managers, investors, consultants, and analysts.

HOW TO APPLY:

Please send your CV to both of the following email addresses simultaneously, using the email subject line: *Regulatory Affairs Specialist - Medical Devices*.

e.lembryk@simplicardiac.com

a.bialkowski-miler@simplicardiac.com