HEAD OF QUALITY MANAGEMENT & REGULATORY AFFAIRS IN INNOVATIVE MEDTECH STARTUP (100%)

Are you tired of the complications of the new MDR for class II and higher class products? Are you interested in learning more about international regulations and would you like to get class I and I(s) products on the market globally? Do you appreciate short administrative paths and like getting things done? Then Aison Technologies is the right company for you.

We are looking for a motivated Quality and Regulatory Affairs professional who will be responsible for regulatory compliance at Aison Technologies AG. Starting date is immediately or as soon as possible in Schlieren, Switzerland.

Your Role:

- You will report directly to the Chief Executive Officer (CEO)
- You will be responsible for the implementation and maintenance of the Quality System processes, in compliance with ISO 13485 and FDA 21 CFR, Part 820, Quality System Regulation
- You will manage all aspects of regulatory compliance:
  - Correspond with FDA, Swiss and other notified bodies
  - Prepare and maintain international product registrations
  - Maintenance of regulatory files, consistent with state, federal and international regulatory requirements
- You will provide knowledge and support to the company to enable Aison to operate within regulatory guidelines
- You will develop regulatory strategies for international markets
- You will host regulatory agencies audits
- You will review and interpret regulatory rules as they relate to company products and processes
- You will conduct ongoing company-wide trainings on FDA and ISO requirements
- You will assess need for regulatory registrations and act accordingly
- You will define needed quality metrics and coordinate data collection from various functions
- You will perform Management Reviews and advise management of any product or process related issues and make recommendations for improvements
- You will plan and manage internal audit activities and coordinates audit corrective actions
- You will manage the CAPA process and ensures corrective actions are established and that root-cause elimination is completed for identified issues
- You will manage Medical Device Reporting activities
- You will administer and manage supplier qualification activities and monitor suppliers' performance
- You will promote a positive working environment conducive to a team atmosphere

Requirements:

- Medical degree, Master in Engineering/Science, or an equivalent of the same in working experience
- Exhibit skills in project management, leadership, communication and presentations
- Identify issues and minimize regulatory risks through structured analysis
- English (fluently), any additional language is a plus

What you will get:

- International, exciting and fast-paced work environment
- Placing products on an immediately global market
- A supportive team that highly values quality
- Many opportunities to grow

Interested? Please send your CV along with a motivational letter to Sophia Borowka
ceo@aisontechnologies.com .