Quality Assurance Consultant

REMOTE

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The company

With a strong heritage in research and innovation, this Medical Device company is heavily investing in new product development projects. They are already making headway within the Medical Device space with a range of products and by injecting lots of investment into innovation, this company is expanding their quality systems department and requires support to drive systems improvements.

The opportunity

In this role as a Quality Consultant, the main aspect is to design, implement and maintain their Quality Management System to ISO 13485-ready processes and documentation. You will be working with quality and regulatory to ensure the compliance of the new innovation.

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Responsibilities

- Drive compliance of both products and processes to applicable standards and regulations globally
- Drive projects to improve the reliability and quality of products by establishing effective control mechanism in operations and supplier management
- Drive accountability towards effectiveness of the QMS
- Implementing quality management systems
- Continued regional compliance and regulatory change management
- Responsible for documentation, update, and procedural management

Requirements

- Experience working with FDA approval process for medical devices, covering European MDR approval process ISO 13485, 14971
- Experience creating and updating QMS
- Design History File
- Risk Management

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Get in touch

If you are interested in this exciting role, please send your application directly to

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