

TÜV UK Ltd. is member of TÜV NORD Group, one of the world's leading service companies in the areas of Technical Inspection and Certification. TÜV NORD's 10,000 employees are serving clients in more than 70 countries worldwide. TÜV UK Ltd. operates mainly in the UK and Ireland. As our Certification business is growing, we are looking for an experienced Medical Devices Lead Auditor on a contract basis.

**Responsibilities:**

- Practical planning experience and conducting third party audits taking into account the requirements of Directives 93/42 / EEC, and the Standards ISO 9001 and ISO 13485.
- Preparing audit reports in a timely manner and in compliance with the requirements,
- Supporting certification decisions by providing clear recommendation on the audit outcome
- To lead the audit team and check compliance with the applicable requirements
- To establish a clear communication with the client and making sure he/she is aware of the requirements.

**Required background:**

- To have successfully completed medical, scientific or engineering university in relation to medical devices
- A min. 4 years of full-time employment with relevant practical experience, in the medical device or pharmaceutical industry, science, laboratories, testing bodies or institutions which test or manufacture medical devices themselves, of which at least 2 years of employment in the field of quality management.
- To have successfully completed an IRCA training
- In-depth knowledge of the development, manufacture or quality control of the medical devices subject to the quality assurance system under assessment and of the relevant technologies described in the system
- Verifiable knowledge of the product-relevant standards or monographs of the pharmacopoeias, Common Technical Specifications (CTS) for medical devices and EN ISO 13485.
- Verifiable knowledge of the MDD 93/42/EEC
- Demonstrable knowledge of risk management methods, in particular the EN ISO 14971 standard
- Additional skills required to lead an audit, such as planning, organization, communication and leadership.

**Skills required:**

- Be a self-motivated individual with a customer and solution oriented personality and have unquestionable and precise work ethics.
- Customer oriented.
- Personality with precise work ethics.
- Excellent communication skills in written and oral form, ability to converse – at all levels on certification matters.
- Be proficient in all Microsoft office packages.
- Eligible to work in the UK, a clean driving licence and the facility to work from home.
- To be willing to follow to required training to maintain the knowledge up to date and to follow the training on MDR 2017/745.

**We are looking forward to your application.**

Please apply by email with your salary expectations

Clearly specify the vacancy you are applying for in the subject heading.

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