Medical Devices
Technical file reviewer

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 Technical file reviewer on a contract basis.

Responsibilities:

- Checking the completeness of client Technical documentation
- Perform technically correct reviews of the client supplied Technical Documentation in the time allocated
- Identifying and documenting adequately issues to be addressed, if there is any.
- Lead and coordinate all assessors involved in the Technical Documentation review) when required
- Liaise with the client to communicate the issues and to get the answers in the required timeframe
- To provide a complete report and associated documents for the technical review to take place in a timely manner
- Liaise with the technical reviewer in case of additional information is required

Required background:

- Successfully completed medical, scientific or engineering university or university of applied sciences.
- At least 4 years of full-time employment with relevant practical experience, including at least 2 years of employment in the area of development, production, quality control or testing of the products to be certified or with the (production) technology to be assessed and the relevant subject (e.g., application, biocompatibility, clinical evaluation, risk management, sterilization, etc.)
- Successfully completed medical, scientific or engineering university or Relevant verifiable knowledge in the field of medical device regulation (Directives 93/42/EEC, UK MDR 2002, etc.) and related fields of regulation, as far as relevant for the area of application of the expert.
- Verifiable knowledge of the product, technology or subject-specific norms or monographs of the pharmacopoeias and CTS (common technical specifications). Additional criteria for the field of "EC design testing of Class III devices": at least 2 years of employment in the field of development, production, quality control or testing of the medical device to be certified.

Skills required:

- Be a self-motivated individual with a customer and solution oriented personality and have unquestionable and precise work ethics.
- Customer oriented, you manage efficiently the workload
- Personality with precise work ethics.
- Deliver accurate report and paying attention to details
- Being able to work under pressure
- 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 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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