



Title
Quality Assurance Assistant

About SMART-TRIAL

SMART-TRIAL is a young and ambitious international company that caters to a niche in the global MedTech industry.

SMART-TRIAL is helping MedTech to comply with regulations on clinical evidence, by simplifying the collection and management of clinical data. We offer a do-it-yourself Electronic Data Capture software for pre- and post-market clinical studies, registries, and surveys.

Our mission is to make it easy and cost-effective to collect and manage clinical data in compliance with industry regulations, so safer and better medical devices can reach patients faster.

SMART-TRIAL is used by SME's and larger MedTech companies around the globe (Europe, Israel, USA) in clinical operations.

Role

As Quality Assurance Assistant you will be involved in various tasks pertaining SMART-TRIAL ApS's Quality Management System (QMS). You will work closely together with the Quality Assurance Manager on ensuring that the product is always of high quality and in compliance to applicable standards and legislations

Responsibilities

Assisting Quality Assurance in:

- Continuous maintenance and development of SMART-TRIAL ApS's QMS system in accordance with relevant standards that might be applicable for SMART-TRIAL from time to time.
- Quality Assurance of the SMART-TRIAL product and all associated products, ensuring compliance with our QMS and all relevant standards.
- Completing/Answering vendor qualification questionnaires from potential/current clients.

Ideally, you should bring with you

- Knowledge of clinical trial and med-tech standards
 - Relevant standards
 - ICH-GCP
 - FDA 21 CFR part 11
 - HIPAA
 - ISO14155
 - ISO27001
 - ISO9001
 - PIC/S Standard for Computerized Systems in GxP Harmonized Environments
- Experience with a modern EDC system
- Experience in a customer facing job

What we offer

- Flexible work hours
- Become a part of a young international software company that caters to the global MedTech industry with ambitious growth plans
- Opportunity to take part in the growth of an international team
- Create and develop high-tech software solutions for a niche industry
- Opportunity to influence the company development strategy
- Competitive salary

Working at SMART-TRIAL you will tackle a wide array of challenges while experiencing a myriad of cultures, geographies, and technologies.

One of the cultural pillars is a strong winner mentality, and the staff are mainly made up of specialists within their field, some would probably call them geeks. At SMART-TRIAL the term "geek" is considered a compliment because they are all obsessed with the newest, coolest, trendiest things that their subject has to offer.

Employment Type

Part time

Industry

Software, Life Science

Location

The position is located at SMART-TRIAL offices at K. Christensens Vej 2L, 9200 Aalborg

Contact

Send your application or feel free to ask any questions about the position to QA & Compliance Manager, Amalie Rosenlund, through amalie.rosenlund@smart-trial.com by 15th January 2022.

Website

www.smart-trial.com