

Senior Human Factors Specialist

Deadline:
30-05-2025

Contact person:
Callie Ebben

Job area:
Usability Engineering

Position type:
Full time

Want to develop the medical devices of the future, work with user needs and ensure patient safety throughout development processes? If so, we offer you the chance to be a part of an innovative and vibrant company, where being nice and nerdy is a superpower!

The role and what to expect

When working at Technolution, you will have extensive contact with the elite of Danish and **international** MedTech companies, across industry segments and disciplines. You will be a part of a company, where professionalism and unity are keywords, and where initiatives are welcomed. We have regular events of both professional and social character—and hey, we even have our own band.

We have a safe, trusting and, developing culture and recently implemented “New Ways of Working,” which is a framework that facilitates efficiency, collaboration, and contribution across the organization. It enables everyone to engage, influence, and drive responsibility in a flat organizational structure, where you will have plenty of opportunities to contribute to the continuous improvements.

To strengthen our Human Factors Engineering team even further, we are looking to hire a seasoned colleague, who has experience leading, executing, and documenting HFE activities in all phases of product development. You will become a part of a rapidly growing company, where you will boost your professional experience and knowledge, and find great opportunity for professional sparring with highly skilled colleagues. You will manage projects and relationships with our clients in efforts to get new medical devices approved by regulatory authorities, as well as assisting and advising them on development of medical devices, combination and IVD products.

Key Responsibilities

- Leading and executing HFE activities in compliance with regulatory standards for medical device development, e.g., IEC 62366-1, ISO 14971, FDA
- Applying Human Factors and usability engineering to medical devices
- Preparing, executing, analyzing, and reporting formative and validation studies of medical devices and combination products
- Identifying and analyzing use errors using relevant HFE documentation and methods
- Building client relations and identifying new project opportunities
- Developing HF documentation, including use-related risk analyses, use specifications, known use problems analyses, etc.
- Continuous improvement and optimization of HFE procedures and templates
- Sharing knowledge and experiences with the HFE team to ensure continuous growth for both senior and non-senior colleagues.

We have a few wishes too

To be the right candidate for this position, we expect you to have a relevant educational background at BSc or MSc level, or received a training, that makes you capable of mastering the role. We imagine that you have at least 6+ years of experience working with Human Factors Engineering within medical device and/or combination products development. If you have experience with Design Control and ISO 14971:2019 it is seen as an advantage. You have extensive experience with HFE studies incl. the creation of test protocols, moderator guides, HFE reports and documentation. You have created use specifications, task and use-related risk analyses, and are an expert in use error analysis and design change rationales. Experience with IEC 62366-1:2015 and FDA's Guidance “Applying Human Factors and Usability Engineering to Medical Devices” is a must, but we don't expect you to have every line memorized.

As a person you are outgoing, open-minded, a great communicator. You have a structure mind-set, and the ability to work efficiently both alone and in groups. A limited amount of traveling in connection with study activities, primarily in Denmark and the US must be expected. It's a requirement that you are fluent in English, verbally and in writing.

Let's Talk...

For more information about the role and why working at Technolution will make you part of an absolute rockstar team, please reach out to Magnus Krygell-Gottschalck, Talent Acquisition on mail: magnus.krygell@technolution.dk. We will be conducting interviews continuously and therefore urge interested candidates to reach out as soon as possible. We can't wait to hear from you!