Medical device technical expert

00023420

Company profile

Our client is a successful company in the pharma industry.

Work location

Area Basel

Main duties

- The Human Factors Engineer will be responsible for independently leading the planning, execution and reporting of human factors studies and user interface design, according to current regulations and guidelines within the medical device and pharmaceutical industries.
- Provides human factors support throughout the product development lifecycle including user needs identification, development of user profiles and use scenarios, task analysis, use-related risk analysis, generation of hardware and software design concepts (creation of physical models and prototypes, graphical user interfaces, and product graphics), user interface design and instructions for use.
- Plans and executes formative and summative user studies, reporting and presenting design recommendations to the project team.
- Defines appropriate sample sizes and statistical methods for analysis.
- Performs anthropometric, biomechanical, ergonomic, and systems safety analyses to identify and assess risk in product development.
- Cross-examines and optimizes developmental prototypes and provides ergonomic, usability and safety assessments for consumer healthcare products, medical devices and pharmaceutical packaging.
- Leads IFU design and development including validation.
- Closely collaborate with cross functional stakeholders (e.g. risk management, Drug Regulatory Affairs, clinical development…).
- Supporting Human Factors related documentation for Health Authority registration in collaboration with Drug Regulatory Affairs.
- Works independently against self-set targets when necessary.
- Management of external vendors.

Start of work

Immediately / by agreement

Education

Bachelor or Master degree in engineering, ergonomics, human factors, usability or related discipline.

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Experience

- At least 3 years of experience in applying Human Factors Engineering to medical devices development, preferably in the pharmaceutical industry, including.
- Good understanding of medical devices development processes in general.
- Specific knowledge on applying Human Factors Engineering processes to medical device development from concept generation to health authority submission.
- Experience in project / program management.
- Experience in developing and documenting Human Factors activities for medical devices as required by regulation.
- Proven track record of successfully managing interfaces to other functions.
- Experience in managing external suppliers for user studies (formative and summative studies)
- Good understanding of the risk management activities
- Good communication and problem solving in the team and across organizational boundaries.

Languages

Excellent skills in English, verbal and written are required. Other language skills, e.g. French, German are advantageous.

Are you interested? Please send your complete application documents by email.

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