Advanced Bionics, with headquarters in Stäfa/Switzerland, belongs to one of the three worldwide leaders in research and development of Cochlear Implant (CI) systems for children and adults. The company has more than 900 employees worldwide with the distribution of its products in around 30 different countries in the world. As a member of the Sonova group Advanced Bionics has access to the leading technology and know-how of the world-leading hearing aid manufacturer Phonak AG regarding acoustics and micro system technology as well as complex audiological algorithms. The goal is to improve the hearing ability of people with profound hearing loss, thus adding to their quality of life.

In Hannover, Germany, Advanced Bionics runs the **European Research Center (ERC)**, founded in 2009. The ERC coordinates a variety of clinical projects, including feasibility, regulatory, pre- and post-market studies in Europe and beyond, with particular focus on signal processing, fitting procedures, new stimulation concepts and electrode development, in order to improve the benefits obtained by CI recipients. The ERC works in close cooperation with international clinics, technology providers and universities. Around 25 researchers and audiologists work for the ERC, 15 of them permanently based in Hannover. To support our Regulatory Clinical Research team we are looking for a:

Regulatory Clinical Project Manager (m/f/d)

Our Offer for your Engagement:

- Sonova and our brands offer very good perspectives and career opportunities
- Atmosphere of mutual trust in a highly motivated team
- Modern work environment and equipment
- You contribute to improve the quality of life of millions of people with hearing loss
- Opportunity to share your ideas with us.

Main tasks and responsibilities:

- Development of Post-Market Clinical Follow-up (PMCF) plans and execution of PMCF activities as defined in the plans
- Design, implementation and conduction of regulatory clinical studies for PMCF purpose: study design and documentation, interaction with clinical partners, hardware/software-setup, monitoring of study progress, data analysis and reporting
- Ethics committee and competent authority submissions
- Support preparation of Clinical Evaluation Reports (CER)
- Support regulatory requirements for pre- and post-market studies
- Support maintenance of departmental procedure in compliance with regulations.

Your profile:

- University Degree in Audiology, Physics, Engineering or equivalent fields
- At least 5 years' experience in regulatory clinical research in a medical field, ideally in the auditory implant area
- Willingness to travel internationally (up to 20%)
- Knowledge of medical terminology and clinical study design, including ethics and competent authority submissions
- Expertise with regulatory compliance guidelines (e.g. new MDR, ISO 14155…) and study monitoring
- English: excellent written and oral communication skills; fluency in one or more additional European language(s)
- IT skills: Microsoft Office, statistics software.

In return, we offer an exciting and challenging position with great potential for personal development, with a unique organization in a fascinating and fast-growing medical industry. If you want to work in an enthusiastic, motivated team and help launch the hearing implants of the future then send us your online application in English.

We favour disabled applicants over non-disabled applicants if they have the same qualification.

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