MEDICONTUR

Material. Design. Optics.

ADVANCING IOL TECHNOLOGIES

Medicontur Medical Engineering is an independent European company in existence since 1989. With a true focus on patient needs and numerous advances in material, design and optics, the company has emerged as a global tech-leader in providing advanced IOL systems for the treatment of cataract and other ocular diseases. With more than 6 million intraocular lenses implanted in over 60 countries, the company is proud of its established network, partners and employees.

To support the growing market demands, **Medicontur** is now looking for an ambitious

Clinical Affairs Manager

- Responsible for clinical studies from writing of the clinical investigation study plan to the final clinical study report in compliance with the applicable standards and rules.
- Medical writer for regulatory documents and scientific publications

Tasks:

- Writing and review of clinical investigation plans, consent form, CRF, study documents
- Direct involvement in clinical studies – writing protocols, study centre meetings, data collection and analysis, clinical report writing
- Selection and coordination of service providers: CRO, study material etc.
- Management of TMF
- Review and/or submission of research ethics committee/regulatory documentation.
- Identify, select, and monitor performance of investigational sites for clinical studies; prepare accurate and timely visit reports from all site interaction visits.
- Train/Educate study centers
- Monitor clinical trial progress through a combinationof data review and on site monitoring visits.
- Ensure the Sponsor, Investigator, and study team adhere to current regulations and adherence to protocol and GCP.
- Audit & Verify that trial data is consistent with patient clinical notes and other source documentation (source data verification/review).
- Maintains frequent contact and motivate investigators, KOLs and work effectively with investigators and coordinators and manage Investigator meetings.
- Review and resolve discrepancies in clinical data with clinical sites
- Review key study quality metrics (e.g., eligibility, primary endpoint data, etc.) and determine appropriate action in conjunction with study team
- Writing of scientific publications
- Collaboration with internal and external partners

Requirements:

- Excellent knowledge of ISO 13485 and MDR requirements, with experience supporting regulatory submission
- University (MD, Dr. Pharma, MSc, optometry) degree (preferably a scientific/medical background)
- 3-5 years work experience in a similar position, preferably in the medical device sector
- Fluent English in written and spoken form, MS Office strong user-level
- Professionalism, proactivity, precision, endurance, flexibility and prioritization skills
- Ability to work independently, problem solving and communication skills

What we offer:

- Dynamically developing area of activity
- Competitive salary, other benefits (SZÉP card, private healthcare service, Schooling, nursery, kindergarten benefits)
- Opportunity to participate in conferences, trainings, exhibitions and professional events
- Young, energetic team

Workplace:

- Budapest

If you are interested in the position, please send your CV with your salary expectation to career@medicontur.hu.

The applicants agrees with their job application, that the participants (who are participating in the examination of the applicants) recognizes the application and contributes for the personal data processing. If the application was unsuccesful, after notification the application will be destroy.