MEDICONTUR

Material. Design. Optics.

ADVANCING IOL TECHNOLOGIES

Medicontur Medical Engineering is an independent European company group ever growing 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 refractive ocular conditions. 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 Study Specialist/Manager

Main responsibilities:

- 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.

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
- Writing and review of clinical evaluation reports, PMCF and PMS plan and reports and its implementation into CER, Instruction For Use: for CE Mark, renewals and annual updates
- Supporting the creation of scientific publications, scientific newsletters, scientific lectures, educational materials, articles
- Collaboration with internal and external partners
- Review of promotional materials
- SOP review and development for sc. department:
  - Gap analysis of the current SOPs
  - Identify the responsibilities
  - Review and renew the organigram of how the Clinical trials are built /flow
    - Define this structure through SOPs
  - SOP writing of all the steps concerning clinical trials set up – connecting regulatory/Q&A, scientific departments and close out of the clinical study and CSR
- Synchronization and implementation processes into Q&A Medicontur system
- Medicontur clinical studies list – clinical evidence/claims available for regulatory and marketing purposes
  - Gap analysis; Create/finalize listing the Medicontur clinical studies; Meeting with Regulatory and Marketing to standardize this file and share it with them, as a reference of all clinical evidences /claims available

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

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What we offer:

- Dynamically developing area of activity
- Competitive salary, other benefits
- Opportunity to participate in conferences, trainings, exhibitions and professional events
- Young, energetic team

Workplace:

- Budapest XI. district

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

The applicants agree 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.