

Head of Clinical & medical Affairs

Job description:

- Lead Global clinical strategic planning activities and translate strategic decisions into actionable plans.
- Provide oversight of site selection, initial contract negotiations and patient recruitment programs.
- Provide oversight of CRO selection and budget to ensure timely implementation of clinical studies in accordance with GCP regulatory requirements.
- Collaborate cross-functionally with internal departments such as Marketing, Regulatory Affairs, R&D and Quality to ensure clinical program compliance.
- Provide input into clinical protocol design and associated budgets.
- Oversight progress of clinical studies and ensure adherence to the protocol, timelines, and budget. This includes reviewing site recruitment, initiation and patient enrollment progress, also reviewing and acting on trending reports.
- Achieve enrollment rates consistent with company goals.
- Medical worldwide conferences plan oversight and management
- Initiate and manage good relationships with leading KOLs, study physicians, company consultants and leading physicians in the company's medical area.
- Medical support for clinical studies staff, customers or marketing distributors for the use of the medical devices and their procedures.
- Provide oversight of the clinical process ensuring compliance with / and training for good clinical practices (GCP), good documentation practices, and regulatory guidelines, ensuring adherence to domestic and global regulations.

Skills and Experience:

+5 years of ophthalmology corneal medical experience. In addition, experience in the medical device industry, running multinational clinical studies or related activities.

Excellent working knowledge of FDA, and global medical device regulations, GCPs, ICH guidelines, and all phases of clinical device study development.

Strong leadership abilities and marketing orientation for initiating good relations with leading physicians and the ability to profound new leading contacts for the clinical and marketing department. . Ability to lead under pressure, manage and resolve conflicts and successfully implement new initiatives.

Highly motivated, accountable individual with excellent organizational, interpersonal and communication skills and experience working in geographically distributed teams and interacting with all levels of the company.

Position includes at least 35% travel

Excellent knowledge of medical device business, global device development, clinical and regulatory process.

Ability to respond to complex medical operational challenges with innovative solutions supported by appropriate tactics.

Proven track record of both strategic and tactical capabilities, demonstrating both the ability to innovate and execute

Proven track record in building and leading teams

Strong English - written and verbal communication abilities

CV to: michal@insighthr.co.il