Clinical Affairs Manager

Basic Job Purpose:

The Clinical Manager is responsible for leading all clinical activities related to the development, pre-market, marketing and post-market of one or more Lumenis products. The Clinical Manager should gain a thorough understanding of all clinical aspects for products under his responsibilities by interacting with internal (R&D, Marketing, Clinical Peers, Quality, Regulatory) and external (literature, Physicians, KOLs, competitors etc) stake holders. The CRM will be able to share his knowledge and understanding of the clinical aspects of his Lumenis products with other stake holders. The clinical research manager will be responsible for extending the clinical data and evidence of products under his supervision and sharing that knowledge with other stake holders.
Location: Yokneam

Main Duties:

- Full support to Regulatory / Clinical Strategy, including
- Design a clinical and regulatory strategy for lumenis product and their indications for use
- Writing and reviewing regulatory documents such as SOP, CER, validations etc
- Support product regulatory submission to FDA, cFDA and EMEA
- Preparation of clinical knowledge scientific documents
- Development and execution of Post-marketing clinical plan
- Planning and execution of clinical trials and different clinical activities (Sponsored, IITs, pre-market and post-market studies) according to GCP(ISO-14155/MDR/CFR) and following company SOPs including:
- Contract negotiation, preparation of trial related documentation, IRB, study initiation visits, site monitoring and training, data collection, analysis and reporting, collaborating with physicians towards publication of study results,
- Support Business Units activities from the scientific/medical point of view in strategic thinking, planning and execution including:
- Supporting the writing and review of marketing materials and white papers
- Contact person in any communication with leading physicians, KOLs and consultants
- Literature search and providing clinical publication supporting materials
- Active participation in scientific meetings / lectures / congresses.

- Support of R&D process of medical devices, including:
- Planning and execution of ex-vivo, in-vivo and clinical trials
- Clinical application requirements
- Risk management process
- Support in training according to internal and external needs
- Active participation in scientific meetings / lectures / congresses
- Support complaints investigations and vigilance report review
- Ability and willingness to travel abroad (10%-20%)

Required Qualifications:

- PhD (preferable) or Master's degree in life sciences
- Experience of at least 3 years in clinical research in and outside of Israel (Must)
- Regulatory/Clinical documents writing (Preferable)
- Ability to independently lead clinical research
- High interpersonal skills
- Fluent in English
- Excellent teamwork skills
- Strategic thinking
- Presentations skills
- Leadership skills

Please apply by email- lumenis.5C.71C@applynow.io