



Clinical Development Manager At Lumenis

What makes this opportunity so BIG:

The Clinical Manager will be responsible for leading clinical activities related to the development of an innovative minimally invasive surgical device. The Clinical Manager should have a thorough understanding of all clinical development activities and be familiar with the surgical environment. The clinical manager should have practical work experience in the OR environment preferably in plastic surgery. The CRM will be able to guide the development team based on his knowledge and understanding of the clinical aspects of minimally invasive surgery and will be able to communicate with physicians and engineers to develop product specification and perform practical pre-clinical and clinical testing of the new device. 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 stakeholders.

Here's what you'll be doing:

- Full support to R&D / Clinical Strategy, including
 - o Design a clinical and development vision and strategy for a new and innovative product
 - o Plan and execute pre-clinical studies in large animals
 - o Participate in surgeries and guide physicians on the correct surgical use of the device
 - o Writing and reviewing product requirements and specifications.
 - o Support regulatory documents such as CDP, CEP, CER, clinical validations etc
 - o Support product regulatory submission to FDA, cFDA and EMEA
 - o Preparation of clinical knowledge scientific documents
 - o Development and execution of Post-marketing clinical training programs
 - 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:
 - o 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:
 - o Supporting the writing and review of marketing materials and white papers
 - o Contact person in any communication with leading physicians, KOLs and consultants
 - o Literature search and providing clinical publication supporting materials

- o Active participation in scientific meetings / lectures / congresses.
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 - Ability and willingness to travel abroad (20%-30%)

What you will bring to the role:

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

Here's why you will LOVE this unique opportunity with Lumenis:

- Exercise your creativity while making a true DIFFERENCE in people's life
- Work with top talents in a company that is a market leader in its domains!
- Benefit from personal growth opportunities in a well-established global company
- **Enjoy** dynamic, never-boring environment, where no two days are alike!
- Drive multi-disciplinary technologies powered by innovation!

Location-Yokneam

Link to our website- <https://lumenis.com/>

CV → lumenis.13.D12@applynow.io