Medical Writer

To Clinical Laserthermia Systems AB (CLS) in Lund, Sweden

Clinical Laserthermia Systems AB (CLS) in Lund is a medtech company that develops, markets, and sells thermal ablation systems for treatment of mainly prostate cancer, brain tumors and epilepsy using laser ablation. Development in other treatment indications is also ongoing.

As part of our increasing clinical activities and commercialization we are looking for an experienced Medical Writer in full time to our headquarter in Lund, Sweden.

As Medical Writer you will be responsible for preparing and finalizing the clinical and regulatory documents under MDR guideline and other regulatory framework. The Medical Writer will report and collaborate with the Chief Product Officer and the Regulatory department in a proactive role in terms of content and regulatory/scientific strategy as well supporting our scientific and medical communications. The Medical Writer plays an integral role in the planning and execution of the product lifecycle documentation related to clinical activities such as post-market surveillance and clinical studies as well monitoring of publications for safety updates, competitor analysis and marketing communication. As a Medical Writer you will gain in-depth insights in CLS technology as well as clinical applications, and a good overview of the markets on which CLS operates.

Areas of responsibility

- Prepare, finalize and maintain the regulatory and clinical product life cycle documentation for CLS products, with special focus on Clinical evaluation report (CER), Post-market surveillance processes and Post Market Clinical Follow-up (PMCF).
- PMS data collection; literature search, analysing, summarizing, and reporting data.
- Monitor and keep the company Period Safety Update reports (PSUR) up-to-date.
- Develop and maintain technical documentation related to Clinical evaluation and PMS processes.
- Gather and maintain updated literature data, vigilance and safety data.
- Owning knowledge on clinical data available to the company to support clinical, quality, regulatory, development and marketing activities including sustaining current and potential new indications.

Competence profile

Experience

- Previous experience as Medical Writer is required, preferably from a CRO or the medical device industry.
- Proficiency in medical English is a requirement, additionally proficiency in technical English is preferable.
- Previous experience in writing and maintaining documents related to regulatory and clinical part of the product life cycle management such as clinical evaluation reports and post-market surveillance plan and reports.
- Experienced in regulatory work and/or clinical investigations for medical devices.

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Required skills

- Excellent scientific writing skills.
- Must be able to work well in a team environment as well as individually.
- Goal oriented, reliable, and extremely well organized with strong attention to detail.
- Familiar with data analysis for publications and reports regarding CER, clinical trials or similar.
- Previous experience in working within ISO 13485, ISO 14155, MDR and GCP frameworks.
- Preferably clinically relevant background or similar.
- Familiar with peer-reviewed publication writing.

The role implies also contact with international key opinion leaders in the field as well as our subsidiaries and partners in USA and Asia Pacific. You will work in close contact with the regulatory and clinical team and report to our Chief Product Officer.

The position is fulltime at CLS headquarters in Medicon Village in Lund. To be successful in this role you should be willing to work in an environment of encouragement, commitment, and trust within multidisciplinary teams but at the same time be able to drive processes and can work autonomously. To be able to fit organically in our team, we are looking for a dedicated, creative, and structured person that is able to handle multiple tasks in parallel, at a high pace if needed.

What CLS can do for you

Being part of a small but very ambitious organization you will be able to develop your knowledge and skills and grow together with the rest of the organization, as well as having the opportunity of creating and developing your own framework within your area of responsibility.

You will have the opportunity of working in close contact with leaders in the field of prostate cancer, brain tumors and epilepsy treatment and gain hands-on and literature-based knowledge in these subjects.

How to apply

If you have any additional questions regarding the position you are welcome to contact our Chief Product Officer Verena Knappe at verena.knappe@clinicallaser.com.

Send your application to verena.knappe@clinicallaser.com with object ”Application Medical Writer + your name”. Please include both CV and motivation letter in your application.

About CLS

Clinical Laserthermia Systems AB (publ) develops and sells the TRANBERG®|Thermal Therapy Systems, including Thermoguide Workstation and sterile disposables, for minimally invasive treatment of cancer tumors and drug-resistant epilepsy, according to regulatory approvals in the EU and the US. The products are marketed for image-guided laser ablation and used in studies for treatment with imILT®, the Company’s interstitial laser thermotherapy for immunostimulant ablation with potential abscopal effect. CLS is headquartered in Lund and has subsidiaries in Germany, the US and Singapore. CLS is listed on the Nasdaq First North Growth Market under the symbol CLS B. The Certified Advisor (CA) is FNCA Sweden AB, Tel: +46 8 528 00 399. E-mail: info@fnca.se.

For more information about CLS, please visit the Company's website: *www.clinicallaser.com.*