About ITM

ITM is a privately owned biotechnology and radiopharmaceutical group of companies dedicated to the development, production and global supply of targeted diagnostic and therapeutic radiopharmaceuticals and radioisotopes for use in cancer treatment. We are developing a proprietary portfolio and growing pipeline of targeted treatments in various stages of clinical development addressing cancers such as neuroendocrine cancers or bone metastases. Our main objectives are to significantly improve treatment outcomes and quality of life for cancer patients through a new generation of Targeted Radionuclide Therapies in Precision Oncology. The headquarters are located in the heart of the research center of the Technical University of Munich (TUM).

We would like to fill the following permanent vacancy in a remote-based/hybrid/ working model in Garching as soon as possible

Global Medical Writing Team Lead (f/m/d)

Your role

Your profile

- Lead the Global Medical Writing team to ensure appropriate allocation of work across writers
- Direct manager of MW function, provide leadership, guidance, and mentorship to a team of medical writers. Set clear objectives, goals, and priorities for the team and individuals. Provide regular feedback to team members
- Assess efficiencies, help identify areas of improvement and initiate improvement processes in alignment with corporate goals/needs
- Oversee the creation of various medical writing content by the team
- Be available to coordinate, author and edit documents (on an as needed basis)
- Participate in relevant document subteam(s) and ensure effective planning and management of timelines for all components of assigned documents across all projects/MWs
- Participate in document strategy sessions, including messaging, document flow, logic, and consistency for assigned projects
- Maintain document prototypes and shells, proactively support developing and reviewing standard processes and templates
- Comply with internal and external processes and guidelines while managing the review process and, on an ongoing basis, resolve issues, errors, or inconsistencies with pertinent team members to ensure timely completion and high quality of assigned documents
- Stay updated on regulatory guidelines and industry best

- Candidates must have a BS, MS or science degree (e.g.: RN, NP, MSN, PharmD, PhD, MD)
- 10+ years of oncology clinical research experience as a clinical or regulatory medical writer within the pharmaceutical/biotech industry
- Prior experience leading a diverse Medical Writing team
- Familiarity with the oncology therapeutic area
- Experience writing/leading the writing of critical clinical documents in major regulatory filings (NDA, BLA, MAA)
- Proficiency in the use and understanding of computer software e.g. word processing, graphics, reference manager, EndNote, document management systems
- Familiarity with all phases of drug development processes (discovery to market), clinical study protocol design, CTA/IND submissions, investigator’s brochures, clinical study data collection and results reporting, post-marketing obligations
- Advanced knowledge of routine document content preparation, including the use of style guides, medical dictionaries, and regulatory guidance documents and templates
- Experience writing, at a minimum, protocols (Phase 1-3, in oncology TA), investigator’s brochures, clinical study reports, Health Authority briefing packages, and Health Authority responses. Experience with Paediatric Investigational Plans (PIPs) is preferred
- Advanced understanding/knowledge of regulatory requirements and drug

practices to ensure compliance in all medical writing activities
- Review documents as required
- Work effectively and lead in cross-functional working groups

development processes, Good Clinical Practice (GCP), Good Pharmacovigilance Practice (GVP), regulatory requirements and guidelines associated with regulatory documents (e.g., protocols, investigator brochures, and clinical study reports)
- Ability to interpret and summarize complex tabular and graphical data presentations
- Strong organization, documentation and communication skills with an ability to multitask

Our offer

- Exciting challenges in an up-and-coming and fast-growing company with a high degree of creative freedom
- An open working atmosphere in an international corporate culture with short communication channels
- Comprehensive onboarding programme
- Flexible working hours with home office options
- Attractive special payments
- Just a good salary? Not with us! We also offer you
    - Employee participation programme
    - Job bike or subsidised job ticket
    - Above-average contribution to the company pension scheme
    - Individually tailored further training programme (including German and English courses)
    - Health promotion programmes (e.g. subsidy for local fitness studio, sponsorship of sporting events, various lifestyle coaching sessions)

Do you have these qualifications, are you willing to develop yourself further and are you looking forward to becoming a key part of our future? Great! We should get to know each other!

When you apply, please let us know your earliest possible starting date and your salary expectations. You can submit your CV in German and English in docx or pdf format.

Apply now

Contact

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Note for recruitment agencies
Please note that we do not accept unsolicited applications or offers of assistance. The telephone number given in the advertisement is intended exclusively for applicants and should not be contacted for any other purpose. Thank you very much!

More about ITM

With us, you will have the opportunity to work in an international environment on ground-breaking projects that can have a significant impact on cancer care worldwide. We are looking for dedicated, talented and passionate professionals who share our vision and want to help shape the future of oncology. If this exciting challenge appeals to you and you would like to contribute to realising our common goal, please do not hesitate to send us your application. We look forward to hearing from you!

For more information please visit: www.itm-radiopharma.com