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 hybrid working model in Garching as soon as possible

Director, Early Development Regulatory Lead (f/m/d)

Your role

Your profile

- Serve as Regulatory Affairs expert for early-stage development projects within the radiopharmaceutical pipeline, with a primary focus on upcoming IND/CTA submissions, reporting directly to the Head of Clinical Regulatory Affairs
- Act as the primary regulatory contact with key Health Authorities (FDA, EMA), holding operational accountability for regulatory interactions and submissions in close collaboration with subject matter experts and the Global Project Team (GPT)
- Lead the preparation and conduct of scientific Health Authority meetings (Pre-IND, Type A–D, EMA Scientific Advice, Protocol Assistance) and oversee timely preparation, submission, and approval of original and amendment filings (INDs, CTAs) in the US, EU, and other regions
- Develop and implement global regulatory strategies for assigned product candidates in alignment with the clinical development plan and overall program objectives
- Plan, organize, and manage regulatory activities in line with global development plans and regulatory milestones, including identification of risks and implementation of mitigation strategies for complex radiopharmaceutical products
- Coordinate timely, high-quality responses to Health Authority requests and ensure the use of appropriate regulatory pathways to optimize submission strategies
- Successfully completed scientific studies (Bachelor's or Master's degree) in pharmacy, chemistry, biochemistry, biotechnology, or a related field; a post-graduate degree is an advantage
- A minimum of 7–10 years of experience in regulatory roles within the pharmaceutical or biotechnology industry or at a regulatory authority
- Profound knowledge and hands-on experience with regulatory requirements for pharmaceutical development, with a strong focus on IND and CTA regulations applicable to clinical development
- Proven ability to understand, interpret, and strategically integrate oncology drug development regulations and guidelines into comprehensive development plans; experience with radiopharmaceuticals is a strong asset
- Experience in direct interactions with regulatory authorities, in particular with the FDA and EMA
- Excellent written and spoken English skills; fluency in German is a plus

- Provide regulatory input, review, and approval of key clinical and non-clinical documents, including study protocols, Investigator's Brochure (IB), Clinical Study Reports (CSR), and non-clinical reports
- Author and review high-quality, product-specific regulatory documents (e.g., meeting requests, briefing books, iPSPs, orphan annual reports) in close collaboration with cross-functional experts, ensuring compliance with regional regulatory requirements
- Provide clear, proactive regulatory guidance to clinical trial teams using an "out-of-the-box" mindset, maintain strong cross-functional stakeholder collaboration, stay current with evolving regulatory guidelines, and support non-program-specific initiatives (e.g., business development, departmental projects, training)

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. EGYM Wellpass, subsidy for local fitness studio, sponsorship of sporting events, various lifestyle coaching sessions)

ITM is an employer that ensures equal opportunities. Qualified applicants are encouraged to apply and will be considered during the selection process regardless of gender, age, national or ethnic origin, religion or belief, disability, sexual orientation, gender identity, or any other characteristic protected under the German General Equal Treatment Act (AGG).

If you are a qualified individual with a disability or are otherwise covered under applicable law and are unable to apply through our online application process, you may request a reasonable accommodation. Please contact career@itm-radiopharma.com.

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

Anastasia Dauns

career@itm-radiopharma.com

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People & Culture
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85748 Garching/München, Deutschland

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