



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

(Senior) Director, Head of Global Drug Safety (f/m/d)

Your role

Your profile

- Lead the global pharmacovigilance strategy, ensuring alignment with corporate and development objectives while providing senior leadership for benefit-risk evaluation across all development programs
- Oversee and strengthen the pharmacovigilance infrastructure, maintaining scalable systems, processes, and governance frameworks that support compliance and organizational growth
- Provide medical oversight of safety data, including the review and interpretation of ICSRs, signal detection, and aggregate safety data to ensure robust pharmacovigilance activities
- Lead signal evaluation, risk management, and benefit-risk assessments, proactively identifying and mitigating safety risks while supporting key development and regulatory decision-making
- Oversee end-to-end pharmacovigilance activities across clinical and marketed products, ensuring robust safety surveillance and high-quality safety deliverables (e.g., DSURs, PSURs/PBRERs, RMPs, IBs, and regulatory submissions)
- Ensure compliance with global pharmacovigilance regulations (FDA, EMA, ICH, GVP), maintain inspection readiness, and provide strategic safety support for regulatory submissions, including IND/CTA, NDA/BLA, and MAA filings
- Serve as the primary pharmacovigilance representative in interactions with regulatory authorities and health agencies,
- MD, PharmD, or PhD in Medicine, Pharmacy, Life Sciences, or a related scientific discipline
- More than 12 years of progressive experience in Pharmacovigilance/Drug Safety, including senior leadership responsibilities
- Strong expertise in oncology drug development across all phases of clinical development
- Proven experience spanning both clinical development and post-marketing pharmacovigilance
- In-depth knowledge of global pharmacovigilance regulations and reporting requirements (FDA, EMA, ICH, GVP)
- Demonstrated success operating in a small- to mid-sized biotech environment with a hands-on, strategic leadership approach
- Fluent in German and English, both written and spoken

providing expert safety leadership and regulatory guidance

- Lead and optimize pharmacovigilance operations by overseeing case processing, vendor/CRO management, KPI and quality monitoring, while mentoring and developing a high-performing, compliant safety team
- Collaborate cross-functionally with Clinical Development, Regulatory Affairs, Medical Affairs, Quality, and Biostatistics to integrate safety strategy across programs, while representing Drug Safety in governance forums, safety review committees, and executive leadership discussions

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

ITM Isotope Technologies Munich SE

People & Culture

Walther-von-Dyck-Str. 4

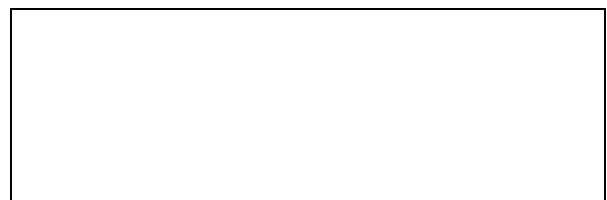
85748 Garching/München, Deutschland

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