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).

In the United States, ITM is expanding to support our growing portfolio and pipeline. We are building a high-performing commercial team to bring innovative radiopharmaceutical therapies to patients and strengthen our presence in oncology.

Qualified Person for Pharmacovigilance (QPPV) Office Expert, US

Your role

- Act as a primary point of contact (US-based) for all official communications between the FDA and ITM, including active participation in the preparation of response documents to FDA inquiries and safety-related requests in cooperation with cross-functional teams
- Act as a safety contact for the DSPV team on U.S. matters, ensuring alignment with the global PV team and supporting other U.S.-based internal PV Stakeholders (e.g., Medical Affairs, Sales) and external PV Stakeholders in PV matters
- Support the collection of ICSRs from U.S, and perform follow-ups upon request
- Ensure compliance with FDA pharmacovigilance regulations
- Reconciliation of safety information with internal and external US PV Stakeholders
- Involvement in designing and optimization of training curricula for internal PV Stakeholders in collaboration with Global Quality department
- Support regulatory intelligence processes by screening, analyzing, and providing inputs on U.S.-specific regulatory updates
- Participate in the development and update of U.S.-specific SOPs, contributing expertise to ensure compliance with FDA requirements

Your profile

- Master's degree or higher in Life Sciences, Pharmacy or Medical Sciences
- 3-5 years of experience in US pharmacovigilance in an industry setting, previous experience in a similar role is an advantage
- Demonstrated knowledge of FDA PV regulations and adverse event reporting requirements, familiarity with ICH & GVP guidelines
- Experience with working in a cross functional team within a matrixed environment
- Excellent analytical, problem-solving, strategic planning, and interpersonal skills
- Strong organizational and time-management skills, applied in different and complex assignments
- Experience with pharmacovigilance systems such as Argus, including case processing and safety data management
- Demonstrated capability to assess processes, identify gaps, and implement improvements through updated procedures; open to changes, suggestions, and innovations, continuously seeking opportunities for process optimization
- Strong ability to interpret FDA regulatory updates and translate them into clear, actionable presentations

- Assist in the implementation of US compliance standards and facilitate the regular collection of compliance metrics (as required)
- Maintain readiness for FDA PV inspections and audits; participate in inspections/audits and ensure timely responses to findings
- Have oversight on and conduct PV Training for external US PV stakeholders, assist in defining and maintaining the PV Training strategy on an affiliate level
- Experience with Veeva systems is a plus
- Work both independently and collaboratively and use own initiative
- Communicate effectively both locally and globally, internally and externally
- Collaborate with technical teams and deliver high-quality results within established timelines
- Thrive in a fast-paced environment while providing appropriate attention to details

Our offer

- Competitive base salary.
- Comprehensive health benefits, including a medical plan with no employee premium and 100% company-paid dental and vision coverage.
- Annual bonus opportunity.
- 401(k) with company match.
- Generous paid time off and company holidays.
- An entrepreneurial environment with the opportunity to shape a high-growth U.S. business.

Salary Range (US) $110,000-$140,000

The compensation range for this US role is listed above for a full-time employee. Actual salary will vary based on factors such as candidate's qualifications, skills, competencies, and demonstrated experience.

ITM is an equal opportunity employer. Qualified applicants are encouraged to apply and will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity or expression, age, national origin, disability, veteran status, marital status, or any other characteristic protected by law.

If you are a qualified individual with a disability or a disabled veteran and are unable to apply for a position through our online application process, you may request a reasonable accommodation. To request assistance, please contact us at careersus@itm-radiopharma.com.

Apply now

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