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/onsite working model in Garching/Neufahrn as soon as possible

Senior Global PV Operations Expert (f/m/d)

Your role

Your profile

- Investigate, configure and implement Safety System functionality to support efficient case processing such as use of Work Lists, Prioritisation, Field Validations and Automation functionalities
- Implement and manage the connections to Safety systems from external systems, such as E2B import and export of electronic files
- Support the day-to-day running of applications to sustain Drug Safety objectives, including Argus Safety, MedDRA, WHODD etc
- Assist with quality review of configuration of PV Safety Systems for products, studies, user privileges and workflow
- Perform programming, validation, and generation of custom reports for data analysis to meet internal business requirements based on contracted timelines
- Understand regulatory changes as they impact the company
- Ensure all project safety activities are completed in accordance with SOPs, Safety Systems Protocols (SSPs), and other applicable regulations
- Work directly with business users in workshops/ sessions to share database activity expertise

- Minimum 5 years of experience within Pharmacovigilance is required, of which at least 3 years of experience must be with Argus Safety systems and applications in terms of advanced level configuration and maintenance of product and licence information, reporting rules, clinical studies and user information
- Understanding of FDA/EMA/MHRA regulations supporting the submission of adverse events for post-marketing and investigative drugs
- Understanding of ICH guidelines, MedDRA structure
- Understanding and application of guidelines detailed in FDA 21 CFR Part 11, including system validation requirements
- Advanced skills in report generation using business intelligence tools (Argus Safety Database)
- Advanced understanding of database architecture (Argus Safety Database)
- Ability to troubleshoot complex problems, involve multiple teams/departments in the investigation and assessment of the problem and proposed solutions and good communication skills
- Familiar with Drug Safety business processes for case processing and reporting and with database schema for leading safety solutions (Argus Safety)
- Experience with data migration projects is good to have
- Be a self-starter who can meet goals with minimal supervision

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