Job Description
PV/Safety Study Officer

Reports To
Head of Program Operation

Job Responsibilities
The PV/Safety Study Lead is responsible for the oversight of safety studies including EU Post-authorization safety studies (PASS), surveillance studies and other activities to ensure compliance with safety regulations, requirements, commitments in Risk Management Plans.

Job Duties
- Acts as Qualified Person for Pharmacovigilance (QPPV) for the Foundation.
- Accountable for the oversight of ongoing and planned post-marketing safety studies, (including PASS), for monitoring study progress and reviewing aggregate reports as needed.
- Collaborates closely with the study teams, in support of safety studies, surveillance studies, registries, Pharmacovigilance programs and other activities undertaken by the Foundation.
- Liaises effectively with study teams and local partners in the understanding of local and country regulations which affects post-marketing commitments.
- Lead set up of safety procedures within Penta sponsored studies
- Represents Penta on cross functional teams and interfaces with the multidisciplinary study team as needed.
- Contributes to Health Authority inspection and audit support for safety studies.
- Participates in other activities, teams and committees as assigned.

Skills and Qualifications
- Knowledge of global regulations and guidance related to Post marketing studies Pharmacovigilance, risk management
- Experience in: review of serious adverse event (SAE) reports received from post marketing sources for review; regulatory compliance during pharmacovigilance of the new drug; expedited safety reports, or periodic safety reports during clinical research; assist project management activities related to drug safety
- Working knowledge of MedDRA terminology and practices.
- Ability in solving problems and achieving objectives.
- Ability to work with interdisciplinary, highly matrixed team
- Proficiency with electronic search engines of the medical literature.

- Ability to read and analyze scientific and medical literature.
- Requires strong attention to detail in composing and proof-reading materials, establishing priorities, scheduling and meeting deadlines.
- Excellent written, oral communication and presentation skills.
- Must be able to work in a fast-paced environment with demonstrated ability to simultaneously manage multiple competing tasks and demands.
- Ability to work independently, take initiative and complete tasks to deadlines.
- Good working knowledge of MS Word, Excel, PowerPoint and Outlook.
- Excellent knowledge of written and spoken English language
- Up to 5% travel required.

Education

- Higher Degree or Master's degree in life-science or healthcare related disciplines
- 3+ years of experience in conducting Post-approval safety studies or other studies in the pharmaceutical industry or CRO.

Salary

45K euro + Welfare Package

How to apply

You can send by email:

1) a signed CV including the following statement: *I hereby agree for the processing of my Personal Data included in my application for the needs of the recruitment process in accordance with the General Data Protection Regulation EU 2016/679*

2) a cover letter outlining why you wish to apply and how you meet the specified requirements in this job description.

3) one reference in either your cover letter or CV. Please indicate whether we can approach your references prior to an interview.

Send all materials to recruiting@pentafoundation.org with 'PV | Safety Study Officer' in the subject of the email

If you have any queries, please email at recruiting@pentafoundation.org