Celyad Oncology is looking for a **Pharmacovigilance Manager**. The successful candidate will be based in Belgium and will report into the **Pharmacovigilance Director** (or its Delegate).

Role & Responsibilities

- In line with Pharmacovigilance Director (or Delegate), ensure compliance for safety case management and reporting for the relevant projects.
- Engaged in preparing pharmacovigilance specific procedure and agreements (SDEA / SMP / SOPs / working instructions / template forms / template aggregate reports) relevant to the ongoing projects / studies.
- Ensure accurate data entry of identified adverse event information (Initial / Follow-up) and the timely processing and reporting of adverse events in alignment with regulatory requirements and in line with relevant system operation procedures and working instructions.
- Performs case file creation, tracking (case closure / Follow-up information / submission), archiving and maintenance (paper / electronic) as indicated in the relevant procedures and working instruction.
- Ensures current conventions are followed upon entering Safety cases (SC) into the Safety database (SDB, e.g., ARGUS database) and narratives writing for assigned SC as applicable.
- Manage coding as required in accordance with MedDRA and WHO Drug Dictionary obligations.
- Provide queries for the investigation sites; and follow-up on outstanding queries and requests.
- Handling safety case submission to regulatory Competent Authorities, as required.
- For SAEs, ensure data processing in safety database (vendor or internal), ensure SAE report follow-up, expedited reporting, reconciliation with clinical database, and archiving.
- Participation to answers for regulatory authorities in collaboration with other departments as applicable.
- Assists in reconciliation of the safety and clinical databases to identify database discrepancies according to project-specific requirements.
- Providing aggregate data (line listing and summary tabulation) as required, supporting safety report production, safety signal management.
- Participate to regular medical / safety monitoring with medical and clin ops teams for safety signal detection and evaluation, including preparation of intermediate safety report for internal review or review with external safety review committees.
- Organize and manage Celyad Oncology Safety Review Team (SRT) meetings (i.e., organize scheduling, agenda and capture decisions and meeting minutes) in collaboration with the Pharmacovigilance Director (or Delegate).
- Participate to safety aggregate report production, QC, distribution, archiving.

- Ensuring that all the required documents from reporting adverse events and aggregated reports (e.g. SLL, PSUR / PBEBR, DSUR, RM planning & reporting) are managed.
- Participate to clinical and regulatory documents creation and review (clinical study protocols, IB, study reports).
- Assists with generation/creation of presentation/training materials, as applicable.
- Participate to quality control of the handled safety data and liaising PV director (or delegate), Quality assurance (QA) department.
- Assist with the preparation of the audit/inspection and participate in the audit/inspection when appropriate.

Qualifications & Experience

- Biomedical Degree (Pharmacy, Medicine, Biology, Chemical Engineering etc.) or related working experience.
- Experience and knowledge of 5 years minimum in term of Pharmacovigilance Regulatory Requirements.
- Experience and knowledge of Good Clinical Practice (GCP) and/or Good Pharmacovigilance Practice (GVP), clinical safety documentation, reporting of adverse events from clinical trials, local regulatory requirements, and pharmacovigilance methodology; general understanding of worldwide regulatory requirements.
- Experience in oncology clinical trials and understanding of medical oncology and drug terminology are an advantage.

Skills & Competencies

- Excellent interpersonal, verbal and written communication skills.
- Ability to plan, organize, prioritize, and execute multiple tasks within assigned objectives.
- Ability to work effectively in an international matrix team and value the importance of teamwork.
- Advanced knowledge of safety databases such as Argus.
- Advanced knowledge of MS Office (Word, PowerPoint, Excel).
- Fluency in English and French (written and oral).

For more information about this position or about the Company, please contact us by email at job@celyad.com