

Safety Assistant

Job Title(s): Safety Assistant, Drug Safety Assistant, Safety Data Coordinator

Department: Safety

Organization Type: Contract Research Organization (CRO)-based

Status/Salary: Non-Exempt and Hourly (Range \$47,500–\$73,500)



SUMMARY OF ROLE The Safety Assistant performs a variety of safety monitoring duties within the department. Responsible for assisting with the smooth function of the pharmacovigilance department to ensure all adverse events are processed to the required standard and submitted to the client and regulatory agencies (if applicable) within agreed upon timelines. The Safety Assistant must adhere to all data protection guidelines, the Health Insurance Portability and Accountability Act (HIPAA), Good Clinical Practices (GCPs), regulatory guidelines, and study procedures.



ESSENTIAL DUTIES

- Manage all adverse event and endpoint source documentation in accordance with Standard Operating Procedure (SOP) specifications; escalate issues to management, as needed
- Scan received documents for unrequested personal identifiers and initiates appropriate actions to protect data privacy
- Perform file creation, tracking, retention, and maintenance—both paper and electronic; maintain industry reference documentation
- Assist in the preparation of safety-related meetings and prepare minutes
- Provide simple and complex administrative support, such as the appropriate distribution of incoming paperwork/inquiries and assisting in production of queries of safety data for clients



KNOWLEDGE, SKILLS and ABILITIES

- Medical terminology knowledge strongly preferred
- Ability to multi-task and deal with shifting priorities
- High proficiency with full Microsoft applications; database experience
- Strong spoken and written communication skills; fluency in English
- Strong interpersonal, collaborative, and time management abilities
- Excellent organizational skills; accurate and detail-oriented



EDUCATION and EXPERIENCE

- Associate's Degree in Nursing plus 1-2 years' experience, **or**
- Bachelor's degree in a life science-related field and 1+ year of related safety experience preferred



TRAVEL and PHYSICAL REQUIREMENTS

- Travel can range from 0 to 10%

CAREER PATHWAYS

- ▷ Safety manager 1 ▶ safety manager 2 ▶ senior safety manager
- ▷ Regulatory, post-marketing surveillance