

- **Safety Operations Specialist / PhV analysts**
Grade 130

- **Job**

Overview

Review, assess and process Safety data and information, across service lines, received from various sources and distribute reports/data onwards to both internal and external third parties following applicable regulations Standard Operating Procedures (SOPs) and internal guidelines under guidance and support of senior operation team members.

RESPONSIBILITIES

- Receive, triage, review and process Lifecycle safety operational data from various sources on time, within budget and quality standards. Perform data entry for tracking and Lifecycle safety databases, coding relevant medical terminology, writing descript narratives, generating queries pertinent to the case, performing quality control, assisting with reconciliation, driving case closure, coordinating translations and ensuring reports are sent to the customer within assigned deadlines. Pre-process material for endpoint committee or core laboratory adjudication. Preparation of material for submission.
- Assess Lifecycle safety data for report ability to relevant authorities, track reportable cases and report to regulatory authorities, ethics committees, institutional review boards, investigators, oversight groups per legislation, within timelines and in a format compatible to requirement. Liaise with local Quintiles offices to facilitate expedited reporting. Liaise with systems manager for regulatory tracking requirements and electronic reporting.
- Contribute knowledge and expertise to or lead assigned deliverables in the field of Safety Publishing, Risk Management, Safety Surveillance and Medical Information or other service lines as appropriate.
- Receive and document incoming telephone calls, faxes or emails from investigative sites or other sources reporting operational data.
- Process Lifecycle safety data according to applicable regulations, guidelines, Standard Operating Procedures (SOPs) and project requirements.
- Build a positive, collaborative team environment with Lifecycle safety team members, lead by example, provide training and mentoring for less experienced team members and operations staff, assist Operations with appropriate allocation of resource.
- Provide oversight role and have a good understanding of operational team on status, metrics, productivity and initiatives.
- Provide and impart technical and process information to Lifecycle Safety Management (LSM) and members of operational team on project specific issues.
- Provide oversight and maintain a thorough understanding of project protocol, therapeutic indication, budget and scope of work (SOW) for assigned projects; set up and maintain project files, standards, templates, electronic forums, databases and workflow.
- Establish and maintain effective team project service operations communications i.e. provide regular feedback to operations team manager and Customer Delivery manager (CDM) on project metrics, out of scope work challenges/issues and successes; feedback effective project performance to junior members of team.
- Liaise with LSM contact in proactively identifying issues and proposing solutions, providing them with technical support, reports, metrics, statuses, identifying SOW changes and potential change orders, delegating client requests and installation of new initiatives.
- Ensure compliance to Quintiles high quality standards and works with LSM constructively in a matrix framework to achieve project and customer deliverables.
- Participate in training across Lifecycle safety process service offerings, participate in working groups as applicable in implementation of new initiatives, identification and implementation of process efficiencies.
- Liaise confidently with different functional team members, e.g. project management, clinical, data management, health care professionals e.g. investigators, medical monitors, site coordinators and designees to address operational project issues.
- Contribute to achieving productivity utilization and realization metrics.

- Read and acknowledge all necessary Quintiles standard operating procedures (SOPs) and customer SOPs as required.
- Ensure all required training is executed in a timely fashion and documented. Work towards ensuring your individual training plan and training transcript are reconcilable.
- Perform other duties as assigned.

REQUIRED KNOWLEDGE, SKILLS AND ABILITIES

- In depth knowledge of Lifecycle safety processes and willingness and aptitude to learn new skills across Lifecycle safety service lines.
- In depth knowledge and understanding of applicable global, regional, local clinical research regulatory requirements; i.e. Good Clinical Practice (GCP) and International Conference of Harmonization (ICH) guidelines, SOPs.
- Proven ability to meet strict deadlines; manage competing priorities.
- Demonstrate effective project management and leadership skills.
- Sound judgment; independent thinking and decision-making skills.
- Demonstrate a flexible and receptive approach to changing demands.
- Proven ability to work independently and autonomously with policies and practices.
- Effective mentoring and coaching skills.
- Excellent attention to detail and accuracy maintaining consistently high-quality standards.
- Excellent organizational skills and time management skills.
- Excellent written/verbal communication and report writing skills.
- Ability to establish and maintain effective working relationships with co-workers, managers and clients.
- Ability to work effectively on multiple projects simultaneously organize own workload and effectively manage competing priorities

MINIMUM REQUIRED EDUCATION AND EXPERIENCE

- Bachelor's Degree in a Health Science
- Experience:
 - For Semi Sr/Sr roles: at least +2 years' experience of Lifecycle safety (Pharmacovigilance, CEVA, Medical Information, Safety Publishing, Risk Management etc.)
 - For Junior roles: no Lifecycle safety experience is needed.
- English level: advanced. Mandatory.

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