



*Quintiles is the only fully integrated bio and pharmaceutical services provider offering clinical, commercial, consulting and capital solutions. More than 24,000 Quintiles employees in 60 countries helped develop or commercialize all of 2010's top 50 best-selling products or compounds. If you thrive on work that has a broader purpose, you've come to the right place. As the world's largest bio pharmaceutical services provider, we've spent more than 30-years changing millions of lives for the better – all over the world. Work doesn't get much better than that.*

*You can be among the more than 24,000 employees around the world providing clinical, commercial, consulting, capital services. We invite you to join us as we continue on our quest to shape the New Health Landscape.*

We are currently looking for **Senior/Associate Specialist, Lifecycle Safety (Singapore)**

**Job Responsibilities:**

- Receive, triage, review and process drug safety data according to applicable regulations, guidelines, Standard Operating Procedures (SOPs) and project requirements. Perform data entry into tracking and safety databases, code relevant medical terminology, write safety narratives, generate queries pertinent to the case, perform quality control, assist with reconciliation, drive case closure, coordinate translations and ensure reports are sent to the customer within assigned deadlines.
- Assess drug safety data for reportability to relevant authorities, track reportable cases and report to regulatory authorities, ethics committees, institutional review boards, and investigators per legislation, within timelines and in a format compatible to requirement.
- Provide oversight and maintain a thorough understanding of project protocol, therapeutic indication, budget and scope of work for assigned projects; set up and maintain project files, standards, templates, electronic forums, databases and workflow.
- For assigned projects, proactively identify issues, propose solutions and provide technical support, reports, metrics, statuses, identifying scope of work changes and potential change orders, delegation of client requests and installation of new initiatives.
- Establish and maintain effective team project service operations communications; feedback effective project performance to junior members of team.
- 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.
- Build a positive, collaborative team environment with team members, lead by example, provide training and mentoring for less experienced team members, and assist with appropriate allocation of resource.
- Perform other duties as assigned.

**Requirements :**

- Bachelor's Degree in Pharmacy, Nursing or a Health Science.
- For Senior Specialist position, in depth knowledge of pharmacovigilance processes and understanding of applicable global, regional, and local clinical research regulatory requirements (i.e. Good Clinical Practice (GCP) and International Conference of Harmonization (ICH) guidelines) and SOPs is required.
- Excellent attention to detail and accuracy.
- Excellent organizational skills and time management skills with proven ability to meet strict deadlines and manage competing priorities.
- Excellent written/verbal communication and report writing skills.
- Demonstrate effective project management and leadership skills.
- Proven ability to work independently and autonomously with policies and practices.
- Demonstrate a flexible and receptive approach to changing demands.

For interested applicants, please apply on-line at <http://www.quintiles.com/careers/>. Only shortlisted candidates will be notified.