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Quality Control – Quality & Validation Specialist

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Quality Control – Quality & Validation Specialist Job Title: Validation Associate Level 2 Employment Type: Full Time, Temp Location: Parkville, Australia Summary of Role: The Validation Associate Level 2 is responsible for performing validation activities associated with changes to existing plant, equipment, and processes, as well as the revalidation of processes and equipment for the Seqirus Australia business. Additionally, this role encompasses project validation and routine revalidation activities, as directed by the Validation Senior Associates or Validation Managers. The position will be assigned to one of three dedicated workstreams, each focusing on specific facilities of priority. Reporting Structure: This position reports to one of the Validation Senior Associates or Validation Managers. Delegation: In the absence of the Validation Senior Associate, other validation associates, or the Validation Manager in the same workstream, additional duties may be delegated. This role may also take on activities from another Validation workstream when necessary. Responsibilities: Execute validation activities related to changes in existing plant, equipment, and processes, as well as project validation activities to achieve successful validation outcomes for the Seqirus Australia business. Perform validation activities in compliance with the Quality Management System, Site Validation Master Plan, Business Improvement, and Validation procedures, ensuring adherence to all relevant codes, regulations, and policies. Prepare, implement, and maintain departmental documentation for validation activities and regulatory submissions, such as Validation protocols and reports, Executive Summaries, and Validation Master Files. Establish and maintain collaborative relationships with key stakeholders. Participate in internal (e.g., Quality Compliance, Safety, and departmental) and

external (e.g., TGA, FDA) audits as required. Actively engage in problem-solving and identify opportunities for process improvement to optimize validation activities. Ensure all training and certification requirements are up-to-date. Follow documented procedures to maintain a safe work environment in compliance with Seqirus policies, procedures, and statutory obligations. Assist with EHS Risk Assessments and the implementation of safety improvement initiatives. Prioritize health, safety, and security at work for oneself and others. Key Relationships (Internal and External): Quality Group Operations (Manufacturing) Group Regulatory Affairs Project Management Research and Development (R&D) Manufacturing Science and Technology (MS&T) Analytical Science and Technology (AS&T) Logistics and Supply Chain Human Resources and Environment, Health, and Safety (EHS) Suppliers, Customers, and External Contractors Position Specification: Essential Qualifications/Experience: A relevant science or engineering tertiary qualification. Preferred Qualifications/Experience: Experience in the pharmaceutical manufacturing industry is highly desirable. Solid knowledge of cGMP. Familiarity with industry guidance documents and standards, along with a good understanding of validation principles. Strong verbal and written communication skills. Proficiency in presentation, interpersonal, and time management skills. Computer literacy, experience using Microsoft applications, and familiarity with SAP, eQMS, GLIMS. Strong problem-solving and negotiation skills. Preferred Skills, Knowledge & Attributes: Ability to work effectively with changing priorities and manage multiple tasks. Collaboration skills to ensure successful business operations. Ability to meet deadlines and ensure timelines are met. Job Title: Senior Validation Specialist Level 5 Employment Type: Full Time, Temporary Location: Parkville, Australia (with occasional travel to other manufacturing sites) Summary of Role: The Senior Validation Specialist is a subject matter expert in testing methodology, proficient in troubleshooting technical issues, developing current and existing methods, and staying up-to-date with the latest analytical testing technologies. This role includes leading and coordinating cross-site activities for method improvements as necessary, executing intra-site method transfers, and providing subject matter expertise for regulatory filings and audits. Reporting Structure: This position reports to the site AS&T Senior Manager and is responsible for Quality Control method validation lifecycle management and method standardization/robustness. Delegation: Not applicable. Responsibilities: Ensure the compliant status of QC method validation lifecycle. Lead troubleshooting investigations for technical challenges with QC test methods, delivering solutions for implementation through the quality system (CAPA, Change Control). Provide guidance and subject matter expertise oversight for

the execution of method standardization and robustness programs. Develop current and new test methods and stay engaged with the latest testing technologies. Take a lead role in coordinating the execution of intra-site method transfers and providing SME input into regulatory filings/audits. Be responsible for experimental design in key projects involving new technologies and processes for QC. Review data generated from validation activities and report detrimental trends or deviations to management. Plan own work and activities of others during the execution of method validation/development and transfer studies. Influence QC leadership on direction for method improvements/replacements. Stay updated on industry knowledge and new methods, equipment, and techniques. Develop new methods and identify improvements that positively impact the business. Key Relationships (Internal and External): Quality Assurance Quality Control Leadership Team Technical Development Manufacturing Position Specification: Essential Qualifications/Experience: Bachelor's degree in a science-related field. Minimum of 2 years' experience in a pharmaceutical or biopharmaceutical company in roles with increasing responsibility in quality management. Fluency in English. Background in cGMP in the pharmaceutical industry. Experience with Quality Control testing techniques and industry practices. Proven time management skills for planning and scheduling work. Strong communication skills, both written and verbal. Knowledge of continuous improvement techniques and advanced root cause analysis techniques. We're the only national recruitment agency committing 100% of it's profits to disability and community services. #J-18808-Ljbffr

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