Job Description



Title: QA Associate Department: Quality Assurance

Reports to: Director of Quality Assurance **Date Prepared:** January 2022

Broad Function

To support the Director of Quality Assurance in the implementation and maintenance of the Quality Management System in accordance with ISO, ICH, Eudralex, FDA guidance and applicable regulatory guidelines.

Principal Responsibilities

- Assisting in the creation, maintenance and archiving of quality documentation.
- Maintaining the nonconformance process and helping to drive improvement.
- Supporting the audit schedule both internal and external.
- Data gathering and analysis.
- Generating quality metrics and trend reports.
- Supporting the delivery of internal quality training.
- Upholding and fostering a strong positive quality culture across the company.

The above duties and responsibilities are not an exhaustive list, and you may be required to undertake any other reasonable duties compatible with your experience and competencies. This description may be varied from time to time to reflect changing business requirements.

Principal Relationships

- Accountable to Line Manager.
- Liaise with internal personnel at all levels of the business as required.
- Liaise with the wider team including site staff, consultants and other external third-party organisations as required.

Education & Experience

- Educated to degree level in a relevant Engineering or Science-based subject.
- Experience of quality management obtained in a drug development environment.
- Experience of working in a commercial pharmaceutical setting.

Skills and Attributes

- Competent and organised self-starter with the ability to perform multiple tasks concurrently.
- Is diligent and possesses a strong attention to detail.
- Is enthusiastic, persuasive and demonstrates a positive outlook.

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- A good understanding of quality techniques including RCA and improvement.
- Is methodical and organised and can adapt according to changing priorities.
- Can work alongside personnel at all levels in the organisation.
- Excellent verbal and written communication, planning, team working and organisational skills.
- Strong IT skills, including Microsoft Word, Excel, Outlook, and PowerPoint.