

## QA Specialist

Kneat is looking for a QA Specialist to work as part of our Quality Assurance team.

This is a Quality Assurance role largely responsible for governance of all aspects of Software Development and Delivery, and for the implementation and management of all aspects of the Quality Management System (QMS) within the organisation.

Candidates will work collaboratively with Software Developers, IT staff, Account Managers, other QA personnel and business stakeholders to ensure that Quality and Compliance are the cornerstone of all aspects of Kneat's operations and that all customer business and regulatory requirements are met to the highest degree of satisfaction.

Some of the primary responsibilities of this role include:

- Implementation and continuous improvement of Quality Management System (QMS).
- Generation of policies, procedures and guidelines as part of the QMS.
- Internal QMS audits and input into management reviews.
- Ensuring that all project documentation is delivered into the QMS.
- Approval and management of project documentation and other project deliverables.
- Regulatory and customer audit support; ensuring audit readiness at all times.
- Conducting external vendor audits.
- Ensuring that projects are audit-ready at all times. Maintain QA dashboard and metrics.
- Assessment of compliance systems on ongoing basis to identify opportunities for process improvement.
- Reporting to Management on the state of compliance based on internal audits.
- Managing the customer complaints process
- Tracking and monitoring the implementation of corrective actions to provide assurance that deficiencies have been corrected.
- Provision of training in compliance systems / methodologies to company personnel.
- Advising relevant personnel on the status of investigations and associated CAPA and commitments, as appropriate.
- Review and approval of qualification/validation documentation
- Monitoring relevant regulations for updates and reviews impact to QMS

### Position Requirements:

We are looking for a person that has:

- Diploma/Degree or higher in a science, engineering, IT or similar discipline.
- 5 years+ experience working in a Quality Systems or Quality Assurance related role.
- Understanding of ISO9001 requirements and/or requirements for Systems Qualification in a regulated environment.
- Experience in Change Control, Risk Analysis, Root Cause Investigation, Complaint Handling, CAPA, Non-conformances etc.
- Good writing and communication skills.
- A passion for quality in a leading-edge technology based organisation.
- Ability to work well independently or on a team

Preferred candidates would also meet the following criteria:

Experience within regulated Life Sciences or IT industries a preference.

- Proven knowledge and understanding of IT / Life Sciences industry regulations including FDA and GxP requirements.
- Experience of participating in customer audits
- Experience of participating in vendor audits

Experience with the following would be beneficial:

- Understanding of the new ISO9001:2015 requirements.
- Understanding of ISO27001 requirements and/or IT and data security.