

## Job Description – QC Inspector Level II

### Reporting to: QC Team Lead

The position requires an experienced, highly motivated person with a background in Quality Control and Quality Assurance. Previous experience within a GMP environment is necessary. Candidates must have at least 3 years of experience in the Medical Device Industry within a Quality role.

### Quality Control Responsibilities

- Become proficient on techniques / processes associated with role and train other resources
- Complete incoming inspections on raw materials and components in line with controlled procedures
- Review and approval of raw material inspection records.
- Perform In-process and Final product inspections
- Review and approval of in process work orders / batch records
- Provide quality support to the rework/ reprocessing process.
- Maintain documentation and records in a compliant state
- Conduct and Report environmental particulate monitoring
- Complete Certificate of Compliance related activities for final product release
- LALs sample processing
- Bioburden sample processing
- Support process changes as the QC representative
- Support Stability study activities as the QC representative

### Quality Assurance Responsibilities

- Review and update QC-related documentation
- Collate, Trend and Present Key Performance Indicator Data for the department
- Customer Complaint / Manufacturing Investigation processing
- Engineering Change order processing
- Documentation control management
- Support & participate in internal / external audit
- Execute GMP audits
- Support Documentation Control Archiving Process

### Other

- Performs other related duties, as assigned.

### Minimum requirements:

- Previous experience in a GMP regulated industry is required - Medical Device or Pharmaceutical industry.
- Previous work experience in Quality Control **AND** Quality Assurance environment, coupled with basic knowledge of the regulatory requirements for the Medical Device industry.

**Education:** a Minimum Certificate level in Science, Engineering or Quality Management is required.

**Additional Information:** The candidate must be proficient with excel, Microsoft word, PowerPoint.