Job Description – QA Inspector

Reporting to: **QC Team Lead**

Group: **Quality System – Documentation Control**

The position requires an experienced, highly motivated person with a background in Quality Assurance
Previous experience within a GMP environment is necessary. Candidates must have at least 2 years of experience in the Medical Device Industry.

Quality Assurance Responsibilities

- Process Engineering Change notifications for revision of existing documents
- Process Engineering Change notifications for creation of new documents
- Manage revision of master documentation files
- Support management of documentation archiving process
- Manage the ECN Log
- Manage the Master Log index
- Manage the Manufacturing Investigation Log
- Complete Device History record reviews as part of the Manufacturing Investigation process
- Create manufacturing investigation reports for customers
- Process customer documentation requests
- Support & participate in external audits
- Conduct and Report environmental particulate monitoring
- Maintain documentation and records in a compliant state
- Complete LAL and Bioburden sampling processing
- Become proficient on techniques / processes associated with role and train other resources

Other

- Performs other related duties, as assigned by Team Lead.

Minimum requirements:

- Previous experience in a GMP regulated industry is required - Medical Device or Pharmaceutical industry.
- Previous work experience in 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 preferred but not essential (depending on work experience).

Additional Information: The candidate must be proficient with excel and Microsoft word