

JOB TITLE:	Quality Assurance Administrator
DIVISION/DEPARTMENT:	Quality
REPORTS TO:	Quality Department Leader, Management Representative
JOB CODE:	14796-5

PREFERRED QUALIFICATIONS/ REQUIREMENTS:

- Education** High School Diploma or equivalent, Documented ISO Quality Auditor Training required
- Work Experience** Background with FDA & ISO 13485 is beneficial.
- Candidate **must** have a minimum of 3-5 years experience in a manufacturing environment in a quality control/assurance capacity, preferably working with medical devices. This experience **must** involve a company(s) maintaining an ISO Certified QMS.
- Candidate **must** have a minimum of 2 years experience in QMS auditing.
- Candidate **must** have a minimum of 2 years experience in CAPA associated activities.
- Candidate should have inspection experience in the areas of Receiving, In-Process, and Final Product Inspection.
- Candidate should be familiar with various test/inspection tools (i.e. micrometers, calipers, gauges, voltage meters, scales, tape measures).
- Candidate should have a solid background with analyzing quality data and reporting findings to Management.
- Knowledge of Good Manufacturing Practices (GMP's) and applicable quality system standards (i.e. ISO) required.
- PPAP, FMEA and Process Validation experience required.
- Computer Skills** Candidate must be proficient in MS Word and Excel. Knowledge of PDM Works and Visual Manufacturing would be beneficial.
- Physical** Standing, walking, talking, hearing, sitting, reaching, grasping, pushing, and pulling. May occasionally be required to handle items that weigh up to fifty (50) pounds.
- Hours** Typical work-week is 40-55 hours; 1st shift, Monday – Friday, some Saturdays will be required.

SUMMARY OF PRIMARY DUTIES AND RESPONSIBILITIES:

- Internal Process Auditing of FDA registered, ISO certified medical device manufactures' QMS and Supplier Auditing. This includes:
 - Planning, scheduling and conducting audits per procedure against documented requirement
 - Uncovering objective evidence of compliance or non-compliance with internal and external requirements
 - Writing and publishing audit reports
- Maintenance CAPA program This includes:
 - Correct and accurate problem description and recording
 - Implementation and verification of containment (temporary) actions
 - Organize and conduct CAPA meetings for root cause definition and verification as well as program status meetings with management
 - Determination and verification of corrective actions
 - Implementation and verification of (permanent) corrective actions
 - Report writing

ADDITIONAL DUTIES AND RESPONSIBILITIES:

- Utilize and comply with the Quality Management System.
- Utilize/read blueprints and work orders to verify product and process quality.
- Inspect and test In-coming, In-Process and Final product.
- Generate QC Reports (1st article, non-conforming, material review, process control reporting, etc.).
- Identify/Record/Report any product quality problem to management
- Collect data, as required, for tracking and reporting purposes. Manage this data, including Manufacturing inspection results, and provide information in a useful format to Management.
- Assist Engineering and Manufacturing with product design verifications and process qualifications/validations.
- Initiate and/or make suggestions to improve working processes or product.
- Perform other Quality related activities as assigned.

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Eligible candidates must possess excellent communication, investigative and reporting skills. This is a high profile position requiring an exceptional level of professionalism, integrity, motivation, commitment and people skills.