

JOB DESCRIPTION

POSITION TITLE: Quality Assurance Engineer

DEPARTMENT: QA Engineering

JOB CODE:

FAMILY: Quality

TRACK: A P M

BAND: III

EVALUATED BY:

DATE:

GENERAL SUMMARY STATEMENT

Under the direction of the Quality Assurance Engineering Manager, performs assigned duties and responsibilities in support of Thermo Fisher Scientific – Rochester’s ISO/cGMP Quality System. Duties and responsibilities include; 1.) Validation of molds, equipment, and processes, 2.) Lead Quality Assurance responsibilities on new product development and transition project teams, 3.) Support Quality Control inspection, schedule accomplishment, customer allegiance, and supplier quality management

SPECIFIC RESPONSIBILITIES

- 1.) Validation of molds, equipment, and processes
 - a. Determine need for validation of new or changes to molds, equipment or processes
 - b. Validation protocol development, documentation, and approval (IQ, OQ, PQ)
 - c. Validation close-out review, justification, and approval
- 2.) Lead Quality Assurance responsibilities on new product development and transition project teams
 - a. Actively participate on cross-functional teams
 - b. Build and execute verification plans to support new product development
 - c. Define inspection sampling plans and acceptance criteria
 - d. Develop, verify, and document product standard test procedures (STP's)
- 3.) Support Quality Control inspection, schedule accomplishment, and customer allegiance
 - a. Ensure the accuracy and adequacy of quality control inspection plans (QCIP's) and standard test procedures (STP's) for purchased and manufactured components and finished goods to meet the latest quality and system specifications
 - b. Communication of QCIP and STP additions and changes to Quality Control Department in a timely, efficient and practical manner
 - c. Research, recommend and implement new and improved gauging, measurement and data acquisition systems to improve inspection efficiency
 - d. Analyze process capability data and other quality metrics in order to propose specification or process changes to Engineering
 - e. Lead root-cause investigations (RCI) and corrective action and preventative action (CAPA) activities to address customer complaints, internal non-conformances and audit observations
 - f. Contribute to practical process improvement (PPI) / Lean as an involved team member
 - g. Lead and participate in internal and supplier quality audits
- 4.) Other duties as assigned

QUALIFICATIONS

Position requires a Bachelor’s of Science Degree in Engineering or equivalent, and 5 to 7 years direct QA/QE experience. Working knowledge of ISO, cGMP’s, Excel, Word, Access, quality software, and statistical methods (SPC, DOE, etc.) preferred. Candidate must have effective oral and written communication skills. Project planning and advanced computer skills a plus.

APPROVALS

Date:	
Date:	

Date:	
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