JOB DESCRIPTION

SENIOR QUALITY REGULATORY ENGINEER

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<tr>
<th>DEPARTMENT: Corporate QA - 82</th>
<th>SALARY LEVEL: SG - 03S</th>
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<tr>
<td>SUPERVISOR: Manager of Corporate Quality</td>
<td>EXEMPT (Y/N): Yes</td>
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<td>JOB CODE:</td>
<td>EEO CODE: 02 SUB CODE: 1</td>
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<td>APPROVED BY: Larry Bostwick</td>
<td>DATE: June 2, 2014</td>
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**JOB SUMMARY:** To provide leadership and technical expertise in the support of KeyTronicEMS Management Systems and Quality Policy. The methodology of support shall be defined as the application of statistical analysis, lean manufacturing practices and continuous improvement activities. The application of the methodology shall be in the role as practitioner, trainer and leader.

**ESSENTIAL FUNCTIONS** (Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.) Depending upon the specific assigned responsibilities for the department, some or all of these quality functions will apply.

**Technical Support**
- Posses and maintains the following statistical/quality skills in order to perform the responsibilities of a Senior Quality Engineer. Knowledge level shall be sufficient to perform skills as needed to maintain product quality and to assist other personnel in the use of these quality tools.
  - Design of Experiments
  - Root Cause Analysis
  - Develop Control Plans
  - Plastic Injection Operations
  - Develop Quality Plans
  - Inspection & interpretation of IPC regulations

- Trend Analysis
- Process Capability Studies
- Develop Process Diagrams
- Prepare PPAPs
- Application of Lean Manufacturing Practices
- ITAR Controls
- FOD Controls
- Statistical Process Control
- Develop Inspection Plans
- Facilitate FMEAs - IMQP
- PCBA mfg methods
- Six Sigma Methodology

- Conducts detailed failure analysis of KeyTronicEMS manufactured parts or purchased parts upon notification from the customer, external or internal. Summarize findings into major points, prepare reports and submit reports to management for review and action.
- Analyzes compiled inspection reports and special test data to statistically quantify data, i.e.; identify negative or positive quality trends, process capabilities. Summarize findings into major points, prepare reports and submit reports to management for review and action.
- Able to read and understand drawings for electrical, mechanical and molding fabrication. Provide assessment of drawing requirements (tolerances) in relationship to production capabilities. Resolve discrepancies between supplier capabilities and the Customer's critical functional and cosmetic requirements

Management Systems
- Develops and prepares procedures for inclusion into CDC system, and/or reviews and approves procedures prepared by others.
- Develops criteria for, and helps implement record keeping requirements for process control and inspection data collection. Record requirements are to be designed to facilitate identification of individual product/unit issues and general process trend analysis.
- Conducts audits of processes in order to facilitate continuous improvement. Auditing may encompass management systems (ISO Internal Audits), manufacturing process audits and vendor audits as requested. May also assist during customer audits of manufacturing facilities.
- Interacts with Procurement, Planning, Engineering and Customer on quality issues by conducting/reporting detailed defect analysis on specific issues.
- Reviews and approves NPI check-lists for Resume Build status. Responsible for issuing Stop Build/Stop Ships, creating quality documentation, verifying FAI acceptance and RoHS certifications to support the NPI process and controls.
- Reviews Material Purge Notices and assigns the proper Disposition per the designated QMS (AQS/AQS).
- Generates and facilitates the CAPA (Corrective Action Preventative Action) requests for Internal, Supplier and Customers. Ensures that they have effective and efficient resolution.
- Leads/facilitates review of company’s processes to drive continuous improvement programs through the methodology of Lean Manufacturing Practices and Six Sigma or data based decision making.
- When assigned specific Customer programs with Explosive Atmosphere – Equipment Manufacturer requirements, this Quality position will be designated as the “Ex” Representative and will be responsible for the following:
  - Responsible for the assigned “Ex” Product and/or Processes.
  - The “Ex” Representative has the responsibility and authority for reviewing the Products “Ex” certificate and the technical documentation and identifying any changes that affect product compliance with the certificate.
  - Is responsible for the daily oversight and management of the company’s “Ex” activities, including RFEC / TECN and ECN approvals for all approval “Ex” manufacturing site. “Ex” Drawing review and approval.
  - Is responsible for interfacing with any “Ex” customers and outside agencies on matters regarding “Ex” control.
  - Is responsible for conducting the annual NW training for KeyTronicEMS staff with regard to “Ex” compliance and turning in training records to Human Resources.
  - Is responsible for ensuring that all “Ex” compliance policies and procedures are enforced.
  - Is responsible for conducting regular audits of the “EX” processes, documenting the results and reporting them to the “Ex” Representative.
  - Is responsible for conducting continual risk assessment of KeyTronicEMS’ “Ex” policies / procedures and informing the “Ex” Management Representative of any findings.
  - Is responsible for drafting updates and improvements to the “Ex” policies and procedures for approval by the “Ex” Management Representative.
  - Is responsible is issuing “Ex” -authorized decals for the ID badges of those employees that have successfully completed training.
  - Is the prime point of contact for KeyTronic Engineering and Production staff on issues of “Ex” compliance.

**Manufacturing Systems**
- Develops criteria for, and/or reviews and approves inspection programs and statistical process control (SPC) programs for; incoming inspections, in-process inspections, final inspections and OOBAs. Development and review is based on inspection program meeting the requirements of KTC quality and continuous improvement requirements; recognized statistical methodology; industry standards, and customer requirements.
- Develops, recommends and may conduct inspection or training programs in such areas as measurement methodology, IPC inspections, statistical sampling and test fixture operations.
- Coordinates the development of test controls and criteria, process controls, and acceptance standards for new, modified or existing products with Engineering and Manufacturing departments.
**Customer Systems**

- Work with Program Management to identify/review customers’ quality requirements for assigned programs.
- Work with Program Management to identify / review Safety Agency requirements (UL, CSA, TUV) as well as an Regulatory requirements, (FDA, TS Automotive, AS Aero Space, ITAR, EPA etc….). Understand and implement all Regulatory requirements.
- Work with Program Management through NPI process to facilitate transfer of customers’ quality requirements to plants’ Quality Control Departments.
- Provide documentation support to manage customer programs from NPI process into sustained production. Responsibilities may include the issuing of weekly / monthly reports, requesting of waivers or Deviations, issuing of Purges/Stop Ships, and managing RMA requests.

**OTHER FUNCTIONS**

- Attends meetings as needed to support organization activity.
- Interfaces with customers as required.
- Performs other duties, as assigned, to achieve corporate and departmental objectives.

**SUPERVISION GIVEN/RECEIVED**

Supervision is received by the Manager of Corporate Quality, and may provide guidance and mentoring to lower level engineers, but will have no supervisory responsibilities.

**MINIMUM QUALIFICATIONS**

- A bachelor’s degree in a scientific or engineering related field.
- Seven years progressive experience in quality engineering, specifically ISO 13485 and FDA 21CFR 820.
- Equivalent combination of education and experience may be considered.
- Associates degree in engineering related field.
- Ability to apply advanced mathematical concepts such as exponents, logarithms, quadratic equations, statistics and permutations.
- Must be able to define problems, collect data, establish facts, draw valid conclusions, and demonstrate the ability to determine critical parameters and develop process controls.
- Ability to interpret an extensive variety of technical instructions in mathematical or diagram form and deal with several abstract and concrete variables.
- Must be able to read and understand PCA assembly drawings and technical notes.
- Demonstrated ability with technical writing. Ability to communicate effectively, both orally and in writing to management and technical staff audiences. Ability to stand in front of small to large technical audiences and provide training.
- Demonstrated organizational skills, with the ability to handle and prioritize multiple projects simultaneously in a timely manner in a fast-paced environment.
- Sound written and oral communication skills; must be able to write and understand routine reports, follow oral and written instructions, and speak effectively.
- Strong interpersonal skills; ability to relate to and work with diverse groups of people.
- Must have knowledge of use and operation of standard office equipment and be familiar with commonly used email, Internet, word processing, databases and spreadsheets.
- Must have a high level of interpersonal skills to handle sensitive and confidential situations and materials. Position continually requires demonstrated poise, tact and diplomacy.

**PREFERRED QUALIFICATIONS**

- Ten plus years experience with sr. level quality engineering experience in a manufacturing environment.
• Familiarity with IPC 610 guidelines.
• Experience with AS 9100.
• Experience in Contract Manufacturing and EMS industry desired with an emphasis in supporting an offshore manufacturing facility.
• Internal Audit experience in an ISO Certified Organization.

**PHYSICAL DEMANDS** The employee is regularly required to sit; use hands and fingers, handle or feel objects, talk, hear, and see. The employee must occasionally lift and/or move up to 25 pounds, stand, walk, climb, balance, stoop, kneel, crouch, crawl, or reach with hands and arms. The environment is fast-paced; time pressured, and requires accuracy. The employee will regularly multi-task between projects, be required to move throughout the office building, and effectively communicate. The normal environment is quiet and typical of an open cubical setting with some areas that may be louder at times. Quality Inspectors must have 20/20 vision or corrected lens and have color acuity.

The statements on this job description are intended to describe the general nature and level of work being performed by incumbents. They are not intended to be an exhaustive list of all responsibilities, duties, and skills required by all incumbents, and all job descriptions are subject to change to accommodate business necessity. In support of KeyTronicEMS’ goals some incumbents may perform other duties as assigned. In addition, all KeyTronicEMS employees are expected to:

- Promote teamwork and cooperative effort
- Help train and give guidance to other KeyTronicEMS employees
- Maintain a clean, safe, and unobstructed work area
- Provide customers with the highest quality of products and service
- Understand and apply appropriate quality improvement processes

Rev. June 5, 2014