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Job Description: Senior Quality / Regulatory Compliance Engineer

Position Summary

We are currently seeking an independent, self-starter with 3-5 years of experience to drive continuous quality improvement through development and use of NPI activities, KPIs, effective root cause analysis, problem resolution, and implementation of quality programs such as ISO 9002. The Quality Engineer will also be responsible for product environmental, safety and regulatory compliance. This position reports directly to the Director of Quality.

Key Responsibilities:

- Develop and maintain the QMS system. Work with teams to develop and revise procedures that comply with ISO 9001:2015 QMS requirements while maintaining lean operations.
- Conduct QMS audits to drive process standardization, waste elimination, and compliance to ISO 9001:2015 standard.
- Provide support for product development and NPI, including technical benchmarking and capability assessments
- Perform compliance reviews, as part of NPI, including safety, regulatory, environmental compliance (RoHS, REACH, Conflict Minerals) and risk assessment of potential sources of supply.
- Collaborate with design engineers to develop robust inspection and verification test strategies to ensure safe, reliable products are implemented.
- Review user documentation to ensure that required warnings, labels and symbols are properly documented as required by standards.
- Develop IQ/OQ/PQ for new equipment and fixtures and execute verification / validation qualifications.
- Review design inputs (specifications) and design outputs (reports, prints, etc.) to assure that appropriate design requirements are specified and to evaluate/confirm quality requirements prior to successful design transfer to manufacturing and suppliers.
- Lead and/or participate in complaint investigations, failure analysis of returned products, and issues resulting in a stop ship/stop production; document findings, provide reports and analysis; apply root cause analyses using 5Why, Fishbone diagram, DMAIC; drive implementation of solutions to prevent recurrence of root causes.
- Participate in Engineering Changes (ECO) and New Product Introduction (NPI). Develop quality control plans and risk assessments reviews.
- Maintain Calibration program. Ensure tooling and equipment is scheduled for calibration at defined intervals. Maintain calibration records.
- Monitor, communicate and improve key Quality KPI's, DPPM and waste.
- Aid manufacturing in the evaluation and qualification of new suppliers and materials.
- Drive "Zero Defect" mentality within the manufacturing and supply base.
- Ensure established material and product certifications are in conformance with updated and current standards.
- Submit required compliance reports to safety agencies and review 3rd party technical files and documentation.

Minimum Requirements and Qualifications

- Bachelor's degree in Electrical and /or Mechanical Engineering or similar technical field.
- 5-10 years related quality experience in a manufacturing environment.
- Knowledge of quality system methodologies including 8D, Lean, 5 Why's, Pareto Analysis, Six Sigma, 8-D, DFMEA, DMAIC preferred.
- Knowledge of ISO 9001:2015 or ISO13485 and other recognized international quality system standards.
- Working knowledge of domestic and international regulatory and compliance schemes: UL, IEC, CE, GSA, CSA, FCC, CB Scheme, CE Directives (LVD, EMC, RoHS, REACH, CA65, Energy Efficiency).
- Ability to read mechanical drawings and prints. Knowledge of machining, sheet metal fabrication, circuit board assembly, and assembly practices.
- Must work well with diverse groups of people and be able to function independently or collaboratively in a team setting.
- Strong problem-solving skills.
- Strong organizational skills.
- Project management skills.
- Attention to detail.
- Strong written and verbal communication skills.
- Advanced computer skills using Microsoft Office applications.
- Must have a valid driver's license in good standing and the ability to travel.

Preferred Qualifications

- Knowledge of IEC based safety standards: IEC/EN/UL 60601-1, and EN 60601-2-52 and the ability to maintain necessary technical and certification files for agency review and approval.
- Solidworks experience.
- Prior experience of working in laser and/or optical products.

Physical Requirements

- While performing the duties of this job, the employee is regularly required to sit, stand, and walk.
- Must be able to examine assemblies and subassemblies using a microscope and work in clean room.
- Employee must occasionally lift and/or move up to 50 pounds.
- Comfortable in gowning up clean room attire.
- Some travel required as needed.