

Quality Systems and Compliance Engineer

Necsel IP, Inc An award-winning global organization HQ in the Silicon Valley, Necsel is vertically integrated and designs and manufactures laser solutions in fields ranging from Cinema to AR, Medical Systems to Biomedical using high and low powered visible lasers. This is part of one of the three (3) Vertical Markets of Ushio Inc. which is one of the largest photonics solutions companies in the world. Necsel has become the leader in visible laser system solutions via its unique patented technology and multiple acquisitions

Is seeking an individual to join our company as a Quality Systems and Compliance Engineer. This position will be responsible for the support of the Quality System for all departments and all levels of the company. The successful candidate will be a self-motivated individual who is inclusive, accessible, and respectful, and who works successfully with all levels of internal and external stakeholders to reach mutually suitable results.

Applicants must possess the following additional skills:

- Strong interpersonal skills
- In depth knowledge of quality systems standards and regulations (ISO 9001, ISO 13485, 21 CFR Part 820)
- Working knowledge of product specifications (60601, 61010, 60825)
- Ability to understand and perform statistical techniques as they relate to quality control
- Previous audit experience

Responsibilities include:

- Ensure that the Quality System is in compliance with ISO 13485; participate in internal and external audits
- Perform the duties of the ISO representative and FDA correspondent
- Develop and maintain procedures to support the ongoing compliance and continuous improvement of the Quality System
- Develop and implement methods for sampling, inspection, testing and evaluation of products
- Develop and implement methods and procedures for disposition of non-conforming material and ensure that effective root cause analysis is conducted; track and implement corrective/preventive actions
- Audit documentation to verify internal specifications, supplier part specifications, and internal test methods
- Initiate process improvement projects to increase efficiency, reduce costs, simplify processes and improve quality
- Support engineering and manufacturing departments to ensure successful transition of products and processes from design to production
- Work with production team to support their needs / requirements
- Work as part of a design team on new product designs and improvement of existing products
- Interact with customers to discuss quality objectives and resolve quality concerns

Requirements:

- Minimum of Associate degree in related Engineering field, Bachelor degree preferred, or commensurate level of relevant experience
- Ability to interpret mechanical drawings and bills of material
- Ability to design and perform product and process verifications and validations
- Understanding of quality systems standards and regulations (ISO 9001, ISO 13485, 21 CFR Part 820)
- Working knowledge of product specifications (60601, 61010, 60825)

Preferred experience:

- Working with medical devices and ISO 13485 qualification
- Experience with drivers and control circuits for LEDs and lasers

Necsel offers a comprehensive benefit package. Interested applicants can apply at jobs@necsel.com and put the position you are applying for in the subject line.