QUALITY ENGINEER – R&D

This position is in Neolight's Scottsdale, AZ office.

ABOUT NEOLIGHT

At Neolight, we engineer and design empathy-driven solutions for newborns in need of neonatal medical care. What are empathy-driven solutions? Here's what we mean. While the medical device industry is focused on designing large, hospital-grade technologies that treat infant health conditions within the hospital, we focus on inventing devices that treat babies at home, under the care of parents. We've started with a phototherapy device that we expect will cure jaundice through in-home rather than in the NICU. We have big plans for more devices that help as many families as possible suffering through the experience of having a newborn with a health condition. By 2020, we plan on being seen as an industry thought leader in the neonatal healthcare sector, with our devices saving the lives of infants across the globe.

ABOUT THE ROLE

As the ideal candidate for this role of Quality Engineer – R&D at Neolight, you thrive in a mission-driven and fast-paced startup environment. Responsible for supporting individual projects for new product development, design changes, and maintenance of the Quality System in accordance with FDA and ISO requirements. This will include serving as the Quality Representative of quality and engineering programs for high priority and high visibility development activities. He/She will be responsible for planning, coordinating, and managing quality related deliverables through completion of assigned projects to ensure the development and production of products meets customer and internal quality deliverables. The Quality Engineer - R&D is also responsible for managing project validation, maximizing product and operating system quality and efficiency, and minimizing costs. The individual holding this position will work in a collaborative team environment involving hands-on work in the areas of design, design transfer, and manufacturing. He/She will be a key contributor to the product/program/project from initiation through delivery, interfacing with external organizations as well as fellow Neolight associates on technical matters as needed.

This position reports to the Quality Assurance & Regulatory Affairs Manager.

ESSENTIAL DUTIES

- Support new product development and design changes for quality assurance and ensure compliance with necessary regulations and standards.
- Assists in the development of quality plans to support new product development, including inspection plans, test and measurement methods, and process auditing, assisting with identification of needed inspection & testing, lead creation and maintenance of FMEAs and the support of process validations.
- Support Risk Management activities (Hazard Analysis/FMEA) in the development and maintenance of the Risk Management File. Utilize risk management tools and aids in accordance with documented procedures, including but not limited to DFMEA, Fault Tree Analysis, Failure Mode Analysis, etc.
- Supports design mitigation efforts. Develops process mitigation plans and strategies that are designed to mitigate the risks identified through the Risk Management process.
- Support design verification and validation activities per appropriate regulatory standards

- Support test method development and validations as needed. Coordinate the execution of validations and creation of written protocols including change control activities.
- Create Engineering Change Orders as needed.
- Review and approve documentation related to quality/regulatory procedures, test plans, test reports, design documents, and specifications.
- Support creation and maintenance of Design History Files (DHF) in accordance with Design Controls.
- Leads the review, disposition, and risk assessment of corrective/preventive action activities associated with discrepant components, materials, sub-assemblies, finished products, and process
- Develops and provides Quality Metrics and trend reports pertaining to the Development Process and related projects.
- Supports concurrent engineering efforts by participating in design development projects representing quality assurance
- Contribute to our culture of being collaborative, respectful, transparent, ethical, efficient, high-achieving, and fun!

DESIRED QUALIFICATIONS

- Quality Engineering related experience, preferably in medical device, pharmaceutical, and/or combination device industry.
- Experience in Product Development related activities and expertise in the New Product Development process and associated deliverables.
- Strong verification & validation experience writing, approving, and executing protocols, IQ, OQ, PQ.
- Thorough experience with statistics and inspection/sampling plans.
- Experienced in the implementation of Quality Engineering Tools including DOE, Root Cause Analysis and use of 6sigma/Lean tools.
- Thorough knowledge and experience in applicable Quality System Regulations and industry standards, FDA 21 CFR 820 and ISO 13485, with an emphasis in Design Controls and Product Realization.
- Experience with multiple product launches
- Medical Device, preferably FDA regulated environment
- Excellent technical writing abilities
- Ability to be part of a team and adept in building and leading teams.
- Experience with planning and executing process validations and managing process risk assessment
- Diagnostic experience is a plus
- Regulatory experience is a plus

MINIMUM QUALIFICATIONS

- Bachelor's degree in Mechanical, Electrical, Biomedical or related Engineering field with at least 3-5 years' Quality Engineering experience.
- Good verbal and written communication skills, and the ability to effectively interface with Research and Development, Operations, Marketing, Quality Assurance, and other functional groups in the organization
- Knowledge of Good Manufacturing Practices (GMP)

COMPENSATION & BENEFITS

COMPENSATION

- Salary is competitive with the market rate, and based on the successful candidate's specific experience and skillset.

- We offer stock compensation and performance-based raises.

BENEFITS

- Full health, dental, and vision insurance packages
- Unlimited time off as long as you're getting the job done
- Access to a full kitchen, bottomless coffee, and unsupervised play time with 3d printers
- The chance to work alongside a committed team of people who plan on saving lives and changing the world

TO APPLY

Does this job description sound like you? If so, we can't wait to meet you. Please send us an email to rhinton@theneolight.com that includes the following:

- A resume detailing your professional experience
- A cover letter (with specifics about your interest in this specific role, specifically with Neolight),
- A list of no more than 3 professional references (including their name, relationship to you, email address, and phone number)

DISCLAIMER

Neolight participates in the federal E-Verify program to confirm the identity and employment authorization of all newly hired employees. For further information about the E-Verify program, please click here: http://www.uscis.gov/e-verify/employees**.**