About CooperVision
CooperVision, a unit of The Cooper Companies, Inc. (NYSE:COO), is one of the world's leading manufacturers of soft contact lenses and related products and services. The Company produces a full array of monthly, two-week and daily disposable contact lenses, all featuring advanced materials and optics. CooperVision has a strong heritage of solving the toughest vision challenges such as astigmatism and presbyopia; and offers the most complete collection of spherical, toric and multifocal products available. Through a combination of innovative products and focused practitioner support, the company brings a refreshing perspective to the marketplace, creating real advantages for customers and wearers. For more information, visit www.coopervision.com/.

JOB TITLE: Quality Engineer
DEPARTMENT: Global Supply Chain

JOB SUMMARY
Provide support for the development & management of a world-class progressive Quality System Program and ensure pro-active QSR/GMP and ISO 13485 Compliance for multinational Medical Device manufacturer in an environment that embraces teamwork, change, risk-based decision making and flexibility.

This position uses Quality Engineering principles (i.e. Lean, Six Sigma, Advance Problem Solving, and Root Cause Analysis tools and techniques) to develop and optimize systems and processes so that they are aligned with the overall Company strategy and quality system

ESSENTIAL FUNCTIONS

- Utilizes quality engineering and lean tools and techniques to establish sampling plans, develop quality plans, conduct and participate in FMEA activities, support reliability engineering activities, conduct process and systems audits and to assist in specification development.
- Investigates instances of nonconformance and facilitates the determination of root cause and corrective action/preventive action including the effectiveness of these actions.
- Analyzes routine and test data for improvement opportunities. Participates in the design experiments (DOE's) for process and product improvement and validation testing. Develops and executes

validation plans
- Supports, consults, trains and leads quality improvement projects.
- Provides statistical support for sampling plan and analysis, DOEs, Paretos, ANOVA, and SPC applications.
- Develop personal and departmental performance objectives based upon the quality objectives, reporting monthly on progress made against those goals.
- Oversees distribution validations to assure all processes comply with company specifications to include internal quality systems and ISO requirements as well as applicable laws and regulations.
- Reviews, develops and maintains all associated documentation including risk management files and quality records.
- Partners with Quality Assurance team to provide oversight regarding Quality Systems and processes.
- Partners with Quality Assurance team to deliver workshops and training as required.
- Provides process mapping and modeling, and provides guidance/ options
- CooperVision's management team is committed to the development of and implementation of the quality management system and maintaining its effectiveness by communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements.

POSITION QUALIFICATIONS
KNOWLEDGE, SKILLS AND ABILITIES

- Demonstrated project management and problem solving skills
- Demonstrated communication, facilitation and leadership skills, with the ability to work cross-functionally in a team environment.
- Applied technical knowledge of Qualitative and Quantitative data analysis, and statistical tools including DOEs. Six Sigma GB/BB or CQE preferred.
- Must possess the ability to read, analyze, and interpret general business periodicals, professional journals, technical procedures, or government regulations. Able to write reports, business correspondence, and procedure manuals. Possess the ability to effectively present information and respond to questions from groups of senior managers.
- Has a working knowledge of Quality System Regulation (21 CFR PART 820, including 21CFR806) and ISO 13485 requirements.

- Microsoft Windows, Microsoft Office
- Agile system familiarity a plus

WORK ENVIRONMENT
• Normal Office environment
• Ability to perform light to medium physical work and standing for long periods of time, if required depending on the task

EXPERIENCE
Minimum of 5 plus years applicable experience and/or training or equivalent combination of education and experience with Medical device distribution and packaging operations

EDUCATION
• Bachelor's degree (B.A.) from four -year college or university in engineering or related discipline
• Certified Quality Engineer, Green Belt training, Lean training preferred

The contact information for the role:

If interested in the role, please apply through our website at coopervision.com. If you have any questions or concerns, please contact Rebecca Kayser, Senior Recruiter, through email at RKayser@coopervision.com.