NORTHEAST LABORATORY SERVICES

JOB DESCRIPTION

Job Title:	**QA/QC Manager**
Department:	Media Manufacturing
Reports to:	General Manager
Schedule:	Monday – Friday (or to be determined by General Manager)
FLSA Status:	Exempt

Summary of Duties & Responsibilities:
Responsible for the Quality Management System as well as guiding the Quality Control group. Ensures quality management system adheres to regulatory requirements and is effective in producing quality, safe and reliable products. Works with operations and production to ensure procedures and guidelines are in compliance. Understands and identifies customer requirements in order to assist with technical inquiries and formulate custom products. Audits internal documentation to support release of products and implements specific training programs for enhancing Quality Awareness and regulation knowledge.

Essential Duties & Responsibilities:

- Assist with calibration and validation efforts of equipment and processes.
- Perform Root Cause Analysis, corrective action, and preventative actions as necessary to ensure high quality finished product.
- Reviews and develops Standard Operating Procedures in an effort for continuous improvement.
- Has working knowledge of 21CFR 820, as well as ISO 9001:2015; understanding of 21CFR 211, USP, ISO13485:2016, and USDA regulations.
- Establishes quality and reliability standards by studying product and consumer requirements with other members of management and with production operators, technicians, and engineers.
- Establishes in-process product inspection standards and final disposition criteria by studying manufacturing methods, devising testing methods and procedures.
- Prepares product and process quality reports by collecting, analyzing, and summarizing information and trends.
- Achieves financial objectives by preparing the quality assurance budget; scheduling expenditures; analyzing variances; initiating corrective actions.
- Establishes product quality documentation system by writing and updating quality assurance procedures.
- Maintains product quality by enforcing quality assurance policies and procedures and regulatory requirements; collaborating with other members of management to develop new product and engineering designs and manufacturing and training methods.
- Completes quality assurance operational requirements by scheduling and assigning employees, following up on work results.
- Manages quality assurance employees to include hiring, training, evaluations, terminations, coaching, counseling, disciplining employees, planning, monitoring, and appraising job results.
- Manages Certification/Accreditations for NEL Manufacturing division.
- Performs Method and Quality Audits with assistance from Supervisors and QA/QC Officers/Technicians
- Manages a program for reports to Management and Management Review
- Manages a program for calibration of support equipment throughout the Manufacturing division
- Addresses/manages the discrepancies/corrective actions program with the aid of the database (track trends, produce reports, etc.)

Physical Demands:
Must be able to lift 30 lbs. to chest height.

Supervisory Responsibilities:
Manages QA/QC employees.

Minimum Qualifications:

Education:	BS in Science, Microbiology, Biology or Engineering or relative experience
Experience:	>5 years' experience in medical device manufacturing and/ or Medical Device Quality Systems
Other:	Must have basic computer skills and have the ability to document work with accuracy. Must be detail oriented and possess good statistical, communication, organizational and multi-tasking skills.

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