ENCISION

AEM SAFETY - PERFORMANCE - VALUE

JOB DESCRIPTION

Position Title:	Director/VP of Regulatory Affairs and Quality Assurance
Department:	RA/QA
Reports To:	President
FLSA Status:	Exempt
Prepared By:	Mala Ray
Date:	17Oct2018
Approved By:	Greg Trudel
Date:	17Oct2018

SUMMARY:

Manage the Regulatory and Quality activities of the company. The Dir/VP of RA/QA is responsible for ensuring domestic and international market clearance for Encision's current and developing product lines, and for development and implementation of a quality system in compliance with FDA Quality System Regulations, and with quality system requirements in target international markets. In fulfilling that responsibility, the Dir/VP of RA/QA is responsible for ensuring that robust systems are maintained which are effective at evaluating, measuring, and improving Encision's processes, and for reporting on the performance of the quality system to management with executive responsibility for review.

All successful candidates will work within 21CFR820, ISO13485 (including applicable regional and sub-ISO standards), and Sarbanes Oxley compliant systems. Additional regulations and standards may apply.

DUTIES AND RESPONSIBILITIES:

- Develop and maintain the company's quality system and related documentation.
- Serve as official correspondent/representative with regulatory bodies.
- Remain current and proficient with US and international medical device regulations and provide interpretation and expertise to guide to the company on those regulations.
- Supervise the activities of outside agencies providing consulting services in the field of regulatory compliance and quality matters.
- Represent the Company in regulatory compliance and quality audits, and coordinate responses to audit findings.
- Work collaboratively with department heads to develop appropriate and meaningful measurement, evaluation, and presentation of results of Encision processes for executive review.
- Develop, maintain, perform, and/or supervise implementation of procedures for key quality system activities including: tracking, prompt investigation and resolution of product complaints.
- Investigation, evaluation, and reporting of adverse incidents or device malfunctions as required by FDA and international regulatory authorities.
- Internal audit process for review and evaluation of compliance of Encision's systems with internal and external requirements.
- Corrective and preventive action activities addressing deficiencies in quality systems and products.
- Maintenance of regulatory, international, and industry standards related to Encision's products.
- Quality system training for new employees and for employees affected by changes to the system.

- Document control, including release and changes, for all DMR and quality system related documentation.
- Lead Quality Control functions and manage QC personnel
- Planning, budgeting, and administration of expenditures required for execution of departmental activities.
- Recruitment, supervision, training, and development of qualified staff required for execution of departmental activities.

QUALIFICATIONS:

- Requires a bachelor's degree, relevant technical training, plus at least 5 years operating experience in regulatory and/or quality assurance function in a medical device company.
- Regulatory affairs and or quality certification or equivalent.
- Expertise in relevant medical device legal and regulatory requirements, as defined in the Encision Quality Manual, is required.
- Ability to read and comprehend instructions, short correspondence, and memos. Ability to write simple correspondence. Ability to effectively present information in one-on-one and small group situations, all in English.
- Ability to read and interpret documents such as safety rules, operating and maintenance instructions, and procedure manuals. Ability to write routine reports and correspondence. Ability to speak effectively before groups of customers or employees of the organization (as appropriate) in English.
- Demonstrated business acumen and the ability to lead and manage teams.

COMPETENCIES:

- Must communicate effectively with company management, including those who may not be well-grounded in regulatory requirements or quality system requirements. Must be able to communicate effectively with customers.
- Must be completely proficient in all basic mathematics skills
- Must be proficient in Microsoft Office
- Must be an effective manager, able to hire, train, develop and manage regulatory and/or quality professionals
- Commitment to following documented processes and procedures
- Ability to work effectively and professionally in collaborative team settings.
- Familiarity with email-usage
- Ability to work within internet-based and internally-based software.
- Must lead by example and be results oriented.

PHYSICAL DEMANDS:

The employee is regularly required to sit, stand, walk, and reach with hands and arms, use hands to finger, handle, feel, and be able to talk, and hear. Specific vision abilities required by this job include close vision, color vision, and ability to adjust focus. The employee is frequently required to lift and/or move up to 30 pounds. Employee will be required to travel on company business from time to time for vendor audits and customer visits. Reasonable accommodations may be made to enable individuals with disabilities to perform the essential functions.

Please send Resume and contact information to Mala Ray, Human Resources Director at mray@encision.com.