Director of Regulatory and Quality (RA/QA)

GENERAL PURPOSE OF THE JOB:
This position is responsible for managing the Quality Management System and all Quality Assurance functions. This position is also responsible for development, implementation, and execution of strategies for regulatory approvals to introduce new and modified products to market, advising on regulatory requirements, preparing regulatory submissions, and negotiation of their approval.

REPORTS TO: COO

FLSA STATUS: Exempt

PRIMARY DUTIES AND RESPONSIBILITIES:

1. Quality System Management
    a. Acts as Management Representative
    b. Responsible for all design and implementation of Quality Management System (QMS)
    c. Develop, write, maintain, administer, train, and manage quality systems standard operating procedures (SOPs) that can be used effectively and meet FDA and ISO quality system requirements
    d. Responsible for planning, and coordinating responses to Internal, Regulatory and QMS audits orinvestigations
    e. Ensure schedules and performance requirements are met.
2. Regulatory Affairs Management
    a. Plan and prepare document packages for submission to global regulatory agencies (IDEs, PMAs, annual reports, and CE marking design dossiers and technical files). Prepare IDE and PMA annual reports and Justifications to File.
    b. Interact with FDA and/or other regulatory bodies for submissions and projects.
    c. Act as liaison with government officials in support of product approvals.
    d. Responsible for regulatory review of promotional material, labeling content, product and process changes, and product documentation. [detail]
    e. Exercise independent judgement in determining appropriate regulatory action and requirements for new product or product changes and preparation of regulatory documents.

SECONDARY DUTIES AND RESPONSIBILITIES:

- Represent regulatory affairs on product development and commercialization teams related to ourproducts.
- Monitor proposed and current US and EU regulations and guidance and will advise the impact of such regulations and guidance.
- Provide strategic regulatory guidance to management and interdisciplinary project teams.
- Provides input regarding regulatory aspects of clinical studies

QUALIFICATIONS: To perform this job successfully, an individual must be able to perform each essential duty satisfactorily. The requirements listed below are representative of the knowledge, skill and/or ability required. Reasonable accommodationsmay be made to enable individuals with disabilities to perform the essential functions.

- Requires a minimum of 8 years' experience in Regulatory Affairs & Quality

- A Bachelor's degree is required; Master's degree is preferred
- RAC Certification preferred
- Demonstrated experience getting FDA clearance or approvals
- Experience preparing FDA and EU product submissions required
- Experience implementing and managing FDA Quality Systems Regulation (eg., 21CFR 820, ISO 13485) required
- Experience achieving CE Mark for devices
- Strong working knowledge of all U.S. regulations that affect Class III combination drug/devices
- Strong understanding of global regulations
- Data interpretation, basic statistical analysis, and technical writing skills necessary for describing and summarizinglaboratory and/or clinical data in submissions
- Advanced experience with Microsoft Word, PowerPoint, Excel
- Relocation to Denver-metro area required
- Ability to travel 10%

ESSENTIAL BEHAVIORS, SKILLS, AND ATTITUDES REQUIRED FOR SUCCESS IN THIS POSITION:

- Willingness to be part of a fast-paced organization and possessing a hands-on, roll-up-your-sleeves mentality
- Excellent time management and communication skills; strong problem-solving and analytical ability
- Analytical thinker with demonstrated ability to perform root cause analysis, prepare and implement action plans, and lead improvement initiatives
- Commitment to HepQuant Vision and Values
- Hands-on work: ability to compile own reports, studies, data
- Proven ability to work collaboratively with colleagues, and teammates to create a results-driven, team-oriented environment
- Excellent written, verbal, and interpersonal communication skills with an acute ability to listen attentively and to communicate effectively throughout all levels of the organization
- Professional demeanor and ability to interact at executive level with persuasiveness and confidence
- Ability to function as a strong member of a highly motivated and integrated management team

WORK ENVIRONMENT & PHYSICAL DEMANDS:

The work environment characteristics described here are representative of those an employee encounters while performing the essential functions of this job. The physical demands described below are representative of those that must be met by an employee to successfully perform the essential functions of this job.

The employee must occasionally lift and/or move up to 25 pounds (lifting boxes, files, etc.). Specific vision abilities required by this job include close vision, color differentiation, distance vision, peripheral vision, depth perception and ability to adjust focus. While performing the duties of this job, the employee is required to stand; walk and talk and hear. The employee is frequently required to use hands to finger, handle, or feel and reach with hands and arms. He/she is occasionally required to sit; stoop, kneel, bend, crouch, or crawl.

Position *may* require occasional travel via airplane, car, and overnight stays in locations with business meetings.

STATUS: Full-Time

LOCATION: Denver, CO

SALARY: $130k-$180k

BENEFITS: Include Medical, Dental, Vision, Short and Long-Term Disability and AD&D, Life Insurance, 401(k) with company match, profit sharing program.

Send your resume to lisa.goggin@hepquant.com