



Corporate Headquarters

1009 Slater Road, Suite 450
Durham, NC 27703 USA

info@kymanox.com

General +1 919.246.4896

Thursday, 15 February 2018

FOR PUBLIC RELEASE

PERMANENT, FULL-TIME JOB OPENING:

APPROVED

By Stephen Perry at 2:22 pm, Feb 15, 2018

Quality Engineer (exact title based on incoming qualifications) **Reports to Manager, Quality Engineering**

About Kymanox:

Kymanox is a diversified organization that helps its clients in the biotechnology, pharmaceutical, and medical device industries. Besides providing contract services, we also develop and maintain products for use in the same industries. Kymanox was founded in 2004 and has been growing steadily since its inception. Our clients range from large Fortune 500 companies to small, fully-virtualized start-ups.

Division/Region:

Kymanox Headquarters, Durham, North Carolina, USA
Chicago, Illinois, USA
Philadelphia, Pennsylvania, USA

Group:

Quality + Compliance

Timing:

Applications: February to April 2018
Interviews: February to April 2018
Start Date Range: February to May 2018

Educational Background:

Bachelor's degree in engineering or related technical discipline from an accredited institution or equivalent. Advanced degree or industry certifications preferred, but not required.

Experience:

Ideally 2 to 5 years of Quality Engineering, or similar quality and technical experience, is expected in pharmaceuticals, biotechnology, and/or medical devices. In some circumstances, new graduates with special qualifications may consider applying for this position. A strong preference for combination product experience or understanding will be given. Candidates with more than 5 years of experience are also welcome to apply.

Job Description:

The position will be engaged in supporting Kymanox's clients with Quality Engineering activities in a project-based or temporary staff augmentation role, depending on the client. Relevant experience may include any of the following activities:

- Product design and engineering documentation creation, review, or oversight to meet regulatory or client internal requirements
- Oversight or involvement with Quality Management System elements, such as deviations, nonconforming products, corrective and preventive actions, complaint management, change management, design controls, risk management, and others
- Test protocol development, review, or oversight to meet USP/EP/JP, ASTM, ISO, or other consensus standards
- Creation or maintenance of Design History Files, Technical Files, or related documentation for medical devices and combination products
- Manufacturing and process improvement initiatives
- Raw material, component, or partner selection for complex product development programs
- Quality review of validation protocols or reports for equipment, methods, computerized systems, and manufacturing processes
- Training delivery related to Quality Engineering Tools and Methods, Design Controls for Medical Devices, Statistical Process Control, and others
- Project management and meeting facilitation
- Familiarity with risk management tools and applications
- Others, as applicable

Desired Aptitude and Skill Set:

- Highly organized and excellent attention to detail
- Ability to follow-up on assignments without reminders
- Good understanding of own limitations
- Fast learner and accepting of change
- High energy level
- Pleasant and positive communication style
- Strong customer-service aptitude
- Computer-savvy
- Ability and desire to follow procedures when they exist
- Appreciation for variety
- Technical writing skills (content and format)
- Adept at Microsoft Office suite of products
- Natural ability to exercise confidentiality and discretion with sensitive information

**Travel:**

Up to 25% travel domestically and internationally may be necessary to support client work. A passport is required.

Career Development:

The position will evolve over time and more responsibilities may be added. Since Kymanox is a growing company, there are opportunities for advancement both within the currently defined role and in other groups within the organization.

Starting Annual Salary:

Commensurate with qualifications and experience.

Benefits:

Full medical healthcare including dental and vision, short- and long-term disability, life insurance, matching 401(k) retirement plan with eligibility in first 60 days, continuing education assistance, and other benefits from our world-class human resources partner, TriNet (www.trinet.com).

Application:

Send your resume to careers@kymanox.com. At some point in the application and interview process, you will also need to complete the application that can be found on www.kymanox.com under "Careers." Any missing application information, if applicable, must be explained. All applications are processed to ensure candidate confidentiality and data security.

Kymanox is an equal-opportunity employer and works diligently to protect the rights of job seekers by following all local, state, and federal laws as well as best Human Resource (HR) practices in the Life Science industry.