Kymanox
Your Life Science Solutions Partner
Bio | Pharma | Device | Combo

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APPROVED
By Stephen Perry at 10:33 am, Apr 15, 2019

# PERMANENT, FULL-TIME JOB OPENING:

## Lead/Senior Compliance Specialist/Scientist/Auditor

NOTE: Title commensurate with incoming qualifications

***Reports to Head of Compliance and Global Auditing***

**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 50 companies to small, fully-virtualized start-ups.

**Division/Region:**
Kymanox Headquarters in Research Triangle Park, North Carolina, USA
Other cities in USA may be considered, depending on candidate qualifications

**Group:**
Quality + Compliance (Main Group, led by Vice President)
Compliance and Global Auditing (Sub Group)

**Timing:**
Applications: Until June 2019
Interviews: Until June 2019
Start Date Range: Now to 22 July 2019

**Educational Background:**
Bachelor's degree in scientific, engineering, or other technical discipline from an accredited institution or equivalent. An advanced degree or industry certifications (e.g., ASQ, ISO) are preferred, but are not required.

**Experience:**
The equivalent of five (5) years of operations, quality assurance, or quality control experience in pharmaceuticals, biotechnology, and/or medical devices is required. Specific training and experience with performing or supporting internal/external audits is required. Experience with core quality management system elements is required.

**Job Description:**
The position will be engaged in supporting Kymanox's clients with compliance activities, with an emphasis on auditing, mock inspections, gap assessments, inspection remediation activities, and Quality Management System (QMS) support (e.g., managing supplier quality, internal audits). Responsibilities will be diverse and may include the following activities:

- Gap assessments against industry regulations or standards
- Auditing of raw material and component suppliers, manufacturers, laboratories, clinical sites, and distributors
- Participation in regulatory body inspection preparation, execution, and remediation efforts
- Authoring of response letters and remediation plans to regulatory bodies
- Oversight or involvement with quality management system elements, such as deviations, nonconforming products, corrective and preventive actions, complaints, change management, supplier management, and others
- Review of validation protocols or reports for equipment, methods, or processes
- Review of manufacturing records and testing/inspection records
- Due diligence assessments
- Pre-Approval Inspection (PAI) readiness support
- Training delivery related to Current Good Manufacturing Practices, Data Integrity, Good Documentation Practices, Good Clinical Practices, Good Distribution Practices, and similar topics tied to Quality Management Systems
- Project management and meeting facilitation
- Familiarity with risk management tools and applications for the life sciences
- 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 50% overnight travel domestically (primarily) and internationally is necessary to support project work; overnight travel may range from 0% to 75% in a given month. A passport is required or must be procured before start date.

**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.

**Compensation:**
Base salary is commensurate with experience, qualifications, and other intangibles evident during the interview process – as well as market conditions. Eligible for incentive program after 90 days of outstanding performance. Compensation is reviewed at least every 6 months to correspond to written performance reviews.

**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 human resources partner.

**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.*