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Friday, 24 November 2017

FOR PUBLIC RELEASE

APPROVED

By Stephen M. Perry at 1:25 pm, Nov 24, 2017

PERMANENT, FULL-TIME JOB OPENING:

Senior / Lead / Combo Product Engineer (title commensurate with incoming qualifications)

Reports to Sr. Director of Technical Operations or Process Engineering Manager

About Kymanox and the Job:

Join Kymanox and tangibly help the world produce modern medicine more quickly, more affordably, and with the highest quality and safety standards possible in today's biotechnology, pharmaceutical, and medical device industries. With a reputation of providing unparalleled contract services, and our highly collaborative team of engineering, compliance, and project management experts, Kymanox provides an outstanding opportunity for learning and career advancement.

Kymanox is looking for a motivated individual ready to continue a career in the life sciences with an emphasis on combination products and at a higher trajectory. Kymanox provides contract engineering and compliance services to clients ranging from Fortune 100 companies to virtual start-up companies to government agencies. The company was founded in 2004 and has been growing steadily since its inception.

Region(s):

Raleigh-Durham, North Carolina (RTP) or
Boston, Massachusetts Metro Area (Newton, MA, USA) or other hub location

Primary Group(s):

Technical Operations or
Process Engineering

Timing (Subject to Revision):

Applications: Now

Interviews: Now

Start Date Range: ASAP

Required Educational Background:

Bachelors of Science in Chemical, Biomedical, or Mechanical Engineering from an accredited institution. Continuing education or certificates in project management, six-sigma, statistics, engineering, quality, or regulatory affairs is desirable but not required. Preference is Chemical Engineering degree; Mechanical Engineers with strong process aptitude are also preferred. Preference also given to advanced degrees (e.g., MEng, MS, PhD) where there is demonstrated utilization of advanced schooling.

Required Experience:

This is a mid-to-senior level position at Kymanox. A demonstrated level of medical device and biologic or drug experience is required; overall talent and ability to learn from Kymanox experts is ultimately more important for long-term success. Previous internship or co-op experience will be considered in total years of experience, as well as a strong interest in a career advancing modern medicine manufacturing. Applicants with a range of 3 to 15 years total experience are encouraged to apply if they determine the position is a good fit. Experience with pre-filled syringes and/or auto pen injectors is desired.

Job Description:

Provide a wide-range of support on a portfolio of two to six projects covering a wide range of engineering, compliance, and commercialization challenges related to complex combination products (e.g., biologic-device, drug-device). Work under the guidance of Kymanox management and with support of multiple experienced technical project managers. Projects may include any of the following focus areas:

- Medical Device Design Controls
- Combination Product Commercialization
- Design Verification and Validation
- Process and Facility Design
- Equipment Selection and Cost Estimation
- Process Improvement and Troubleshooting
- Technology Transfer and Scale-Up
- Process Validation
- Data Analysis, Including Statistical Analysis
- Regulatory Submission Authorship
- Project Management Leadership and Support
- Technical Report Authorship, Review, and Formatting
- Manufacturing Investigations
- Quality Systems Support
- Process and Product Development

Desired Aptitude and Skill Set:

- Extremely detail oriented
- Ability to work effectively with remote team members
- Highly organized
- Resourceful
- Self-directing, self-pacing
- Excellent written and oral English communication skills
- Understanding of own limitations
- Ability to solicit and utilize subject matter expert input
- Fast learner
- Ability to motivate self and others
- High energy level
- Excellent problem solving skills
- Seasoned soft skills (EQ)
- Team player
- Thrive in a fast-paced, growing, and dynamic work environment
- Technology savvy

Career Advancement:

The position will evolve over time and responsibilities will be added based on performance. Over time, opportunities to move into leadership roles will be available for the right candidates and after demonstrating a sustained performance level at Kymanox. Since Kymanox is a growing, dynamic company, there will be ample opportunities for advancement – both within the currently defined role, within the other internal groups, and roles to be defined in the future.

Estimated Travel:

Local travel within the assigned region and surrounding areas is required. Up to 30% remote travel may be required from time to time. The emphasis of this position is to stay local in the assigned region; however, project support may be required outside of the area from time to time including quarterly visits to Kymanox headquarters in RTP, North Carolina if not stationed there.

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 work.



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.