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

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FOR PUBLIC RELEASE
APPROVED
By Stephen Perry at 3:14 pm, May 16, 2019

PERMANENT, FULL-TIME JOB OPENING:

Sr. Validation Engineer (Exact Title Based on Incoming Qualifications)
Reports to Director of CQV Engineering

About Kymanox:
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 professional services from our highly collaborative team of 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 at a higher trajectory. Kymanox provides professional services related to science, engineering, compliance, and project management; we service clients ranging from Fortune 100 companies to virtual start-ups. The company was founded in 2004 and has been growing steadily since its inception.

Division/Region:
RTP Headquarters (Durham, North Carolina USA)

Group:
Commissioning, Qualification, and Validation (CQV)

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

Required Educational Background:
Bachelors of Science in a STEM degree (Science, Math, or Engineering) from an accredited institution. Continuing education or certificates in project management, engineering, quality, and regulatory affairs a plus.

Experience:
The ideal candidate will have 4 to 10 years of experience in the Biotechnology, Pharmaceutical, and/or Medical Device industries working in two (2) or more of the following departments:

- Validation
- Manufacturing
- Process Engineering or Technical Services or Manufacturing Sciences
- Quality Control or Quality Assurance or Regulatory Affairs
- Project Management or Program Management
- Process Development

This candidate will have specific experience with Computer System Validation (CSV), Part 11, and will either have direct experience managing staff members, or be ready for that next step in their career.

Additional experience ideally includes the following:

- Leading and executing a variety of technical projects and/or programs.
- Collaborating with highly skilled professionals with advanced degrees.
- Supporting process development, design, scale-up, technology transfer, and start-up of CGMP manufacturing.
- Construction, commissioning, start-up, and validation of a CGMP facility, utility, or equipment.
- Working with quality and regulatory professionals and/or regulatory authorities, including associated documentation.

Job Description:
Provide technical project leadership and contributions to validation projects, including managing schedules, budgets, support staff, and project execution.

Provide review and input on areas of subject matter expertise. Define, develop, and execute the validation lifecycle following GAMP5® principles – including requirement specifications and qualification protocols (e.g., URS, FRS, DDS, DR, IQ, OQ, PQ, TMX) in support of Commissioning & Qualification (C&Q) activities. Review and summarize data for presentation to quality and regulatory professionals. Provide support and execution for the following types of validation:

- Computer System (CSV/Part 11) (REQUIRED)
- Facility and Cleanroom (REQUIRED)
- Utility (REQUIRED)
- Equipment (REQUIRED)
- Process (DESIRED)

- Cleaning (a type of process validation) (DESIRED)
- Analytical Method (A PLUS)

Maintain a high-level of customer service and satisfaction to facilitate follow-on business. Motivate, direct, and manage employees and contractors effectively and efficiently. Identify and implement new internal systems to support growth initiatives.

Employ cost saving measures to minimize overhead and project-related costs. Utilize new but proven technologies to improve efficiencies, communication, quality, timelines, costs, and performance. Evaluate and address opportunities for improvement at customer facilities.

As needed, support other regions with remote or on-site support. Perform additional responsibilities as requested or assigned.

The degree to which these job description requirements can be fulfilled will be based on the individual and his/her level of experience.

Desired Aptitude and Skill Set:

- Proven ability to develop validation strategy independently
- Ability to manage resources
- Detail-oriented
- Highly organized
- Managerial (i.e., “do things right”) or leadership (i.e., “do the right thing”) skills
- Excellent written and oral English communication skills
- Understanding of own limitations
- Fast learner
- Ability to motivate self and others
- High energy level
- Excellent problem solving skills
- Seasoned soft skills
- Team player
- IT and technology savvy
- Understanding of FDA’s CGMPs (i.e., Quality Systems)
- Lean Six-Sigma Exposure

Travel:

Local travel within RTP, Raleigh, and Durham areas is required – as well as other areas in North Carolina from time to time. Up to 30% remote travel is possible and will fluctuate based on active projects. The emphasis of this position is to stay local and work primarily in the RTP area; however, national travel should be expected. A

passport is required for this job to support projects in Europe and similar locations from time to time.

Career Development:
The position will evolve over time and responsibilities will be added continuously as this is a fast-growing part of Kymanox's business. At least a 1-year assignment in this vertical (i.e., CQV) is expected so that the person can learn, optimize, and perform in the role before transitioning to something else, if so desired. Since Kymanox is a rapidly growing company, there will be many opportunities for advancement – both within the currently defined role and with the other verticals (e.g., Technical Project Management, Process Operations, Quality/Regulatory Compliance).

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:
Medical healthcare including dental and vision, short- and long-term disability, life insurance, matching 401(k) retirement plan, continuing education assistance, and other benefits from our world-class human resources partner, ADP TotalSource.

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. All applicant resumes are kept on file for one year.

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.