Kymanox
Engineering + Compliance Solutions for Modern Medicine Manufacturing

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By Stephen Perry at 4:46 pm, Mar 12, 2018

# PERMANENT, FULL-TIME JOB OPENING:

**Validation Engineer** *(Staff/Senior/Principal, title commensurate with incoming qualifications)*
***Reports to Head of Validation in Technical Operations Group***

**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 Fortune 500 companies to virtual start-ups to government agencies.

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

**Department:**
Commissioning, Qualification, and Validation (CQV)

**Timing:**
Applications and Interviews: Now
Start Date Range: ASAP

**Required Educational Background:**
Bachelors of Science in a STEM degree (Science, Math, or Engineering) from an accredited institution – engineering degree preferred. Continuing education or certificates in project management, engineering, quality, Six-Sigma, and statistics are a plus.

**Experience:**
The ideal candidate will have 3 to 7 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 ideally should have specific experience with Computer System Validation (CSV), Part 11, and will want get that experience for the 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.

**Desired Aptitude and Skill Set:**

- Proven ability to develop validation strategy independently
- Detail-oriented
- Highly organized
- 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
- Team player
- IT and technology savvy
- Strong understanding of FDA's CGMPs (i.e., Quality Systems)
- Ability to manage resources, either directly or indirectly via project management
- LEAN Six-Sigma exposure

**Job Description:**

Provide technical project leadership and contributions to validation projects, including managing schedules, budgets, and project execution.

Provide review and input on areas of subject matter expertise. Define, develop, and execute the validation lifecycle following GAMP® 5 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. Help identify and implement new internal systems to support growth initiatives.

Help 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.

**Estimated 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.

**Starting Base Salary:**
Commensurate with incoming qualifications.

**Bonus:**
Eligible for incentive program after 3 months of outstanding work.

**Career Advancement:**
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 Assurance/Regulatory Compliance).

**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.*