



Quality Assurance Quality Control Associate

ABOUT US

Liquidyne Process Technologies, Inc., founded in 1993, is a leading distributor and fabricator of innovative solutions for fluid transfer, measurement and control. Liquidyne is a dynamic, growing organization located in the beautiful Golden area of Colorado. We serve the Life Sciences, Food & Beverage, Commercial & Industrial markets with a focus on the Biopharmaceutical, Pharmaceutical, Nutraceutical, Animal Health, & Cosmetics industries.

JOB RESPONSIBILITIES:

- Review and approve completed documentation including batch records and logs to support production activities.
- Perform quality control checks as defined by internal procedures for products produced including review/ inspection of the product, associated labels, and other items as described.
- Generate and perform final approval on Certificates of Conformity (CoC) for products produced including review of testing and gamma irradiation documentation for sterile single use products.
- Participate in the review and approval for new product requests in collaboration with Operations & Engineering staff. This includes obtaining, reviewing, and maintaining the necessary validation paperwork provided by suppliers to support claims stated for the product and providing guidance to both the team and customer of applicable regulations based on the intended use.
- Participate in the creation, review, and approval of changes to products, processes, and documents to ensure internal and external regulations are met. This will include the guidance to both the team and the customer of applicable work needed to meet necessary regulations.
- Provide guidance during new product development and product changes for applicable regulatory requirements and how they apply to the company or the customer.
- Create and maintain appropriate documents for quality processes such as procedures, instructions, validation protocols / reports, site master validation plan, etc.
- Participate in investigations when quality issues are identified through internal or external methods. This will include guiding the team through root cause investigations and implementation of corrective actions to prevent recurrence.
- Support internal and external audit execution for customer, supplier, and internal audits
- Support vendor approval process to determine necessary requirements of vendors based on the product/ service provided.
- Support customer requests during client on-boarding
- Provide customer facing documents such as client surveys, evidence of quality systems, etc.
- Management of cGMP principles based upon applicable sections of FDA 21 CFR 820 and/ or ISO 13485

QUALIFICATIONS & SKILLS:

- Experience supporting audits (either internal or external)
- Experience with cleanroom environments including the controls required
- Experience with sterile / single use assemblies
- Experience with Change Request and Change Notification
- Experience a plus with sterilization validation ISO 11137 , environmental monitoring, and ISO 9001 & 1345 or other
- Demonstrated ability to analyze data and identify root causes of quality issues
- Maintain positive and professional relationships both internally and externally'
- Attention to Detail
- Ability to maintain confidentiality for customers

EDUCATION & EXPERIENCE:

- Bachelor's degree in a science related field (biology, chemistry)
- Minimum 3-5 years of Quality Assurance experience, including at least 1-2 years of Regulatory related background within cGMP manufacturing environments

COMPENSATION

\$75K-\$88K

BENEFITS PACKAGE

- Health, Dental & Vision Insurance
- 401k Plan with company contribution
- Personal Time Off bank 10 days & 5 Sick Days per calendar year.

OTHER BENEFITS

- Monthly team lunches
- Healthy Snacks & Beverages
- Quarterly team-building events
- Professional learning opportunities
- Annual holiday parties
- 9 paid company holidays
- Career planning
- Bi-annual team volunteering

Liquidyne is committed to equal employment opportunity and as such, we hire individuals based on merit and qualifications without any regard to race, creed, color, religion, national origin, sex, age, marital status, sexual orientation, disability, veteran status or any other illegal consideration.

INTERESTED CANDIDATES



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