Alturas Analytics, Inc.
The LC-MS Experts

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www.alturasanalytics.com

This position is full time. Salary DOE with health and retirement benefits provided. Send resume, cover letter, and job application to Alturas Analytics, Inc., 1324 Alturas Drive, Moscow, ID, 83843, or email hr@alturasanalytics.com.

Job Title:
Quality Assurance Director

Position Summary:
Work with Senior Staff and TFM to set strategic direction of Quality Assurance Unit, and anticipate future QA needs. Perform analytical-based auditing activities as necessary and implement auditing systems to ensure compliance with GLP requirements. Perform a wide variety of activities to assure compliance with applicable regulatory requirements. Can apply regulatory interpretation to a wide variety of work situations of increasing difficulty to most work situations. Lead and develop training of scientific and new QA staff. Ensures a fully operational QAU and ensures QA staff competencies. Supervises activities of QAU staff members to ensure timely completion of tasks to meet deadlines. Bachelor's degree or higher in a science related field or equivalent experience. SQA RQAP-GLP or ASQ certification is preferred.

Essential Duties and Tasks:

- Oversees the QA department providing guidance and sets priorities
- Provides assistance to the QAU management and other staff members to fulfill the QAU responsibilities designated by 400 level SOPs including but not limited to study audits, facility inspections, audits of logs and records, and archived materials
- Performs inspections and audits of study-based protocols, plans, in-process activities, data (paper or electronic), test methods, and a variety of reports and issues inspection and audit reports
- Collaborates with Alturas Senior Staff to improve protocols, procedures and QAU inspection processes; ensures a culture of continuous improvement
- Reports compliance deficiencies to the QAU management and Test Facility Management and recommended actions to conform to SOP and regulatory standards
- Recommends changes to QAU management and Test Facility Management for the laboratory to conform to SOP and regulatory standards and to improve efficiency
- Works closely with Test Facility Management providing strategic planning for growth of Alturas and ensuring suitable QAU staffing
- Develops career ladders and professional growth of QAU staff member
- Performs inspections and audits of non-study-based documents and records associated with qualification and validation events and issues inspection and audit reports
- Oversees the maintenance of the QAU copy of the Master Schedule
- Works laterally with scientific staff to assure the facility and operations meets standards set by Alturas procedures and FDA regulations

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- Works laterally with and provides advisement to Test Facility Management and scientific staff to assure the laboratory continually meets SOP and regulatory standards
- Assures QAU inspections and audits of facilities, systems and processes according to SOPs (i.e., facility audits)
- Assists with development and/or reviews SOPs, Technical Procedures, Qualification Plans, and Validation Plans
- Drafting or review of Quality Assurance Statements for interim and final reports
- Sign a Quality Assurance Statement for interim and final reports
- Updates databases utilized by the QAU including those for project management
- Acts as the host for regulatory agency inspections and client audits and formulates written responses to any findings
- Conducts new employee and company-wide annual regulatory training
- Attends managerial and/or staff meetings
- Oversees periodic Status Reports to Study Directors and Test Facility Management and clinical study contacts as necessary
- Oversees off-site Study Director status and summary reports
- Carries out supervisory responsibilities in accordance with the organization's policies and applicable laws. Responsibilities include: interviewing, hiring and training employees; planning assigning and directing work; appraising performance, rewarding and disciplining employees, addressing complaints and resolving problems
- Ability to successfully operate independently with minimal guidelines
- Readily provides advice and counsel to junior level staff on complex scientific issues
- Develop, revise review and implement SOPs and Technical Procedures as applicable to the position
- Routinely interacts with client QAUs and FDA or other government inspectors

Additional Duties and Tasks:

- May attend managerial and/or staff meetings where quality and compliance topics are discussed
- May attend SQA meetings or participate in webinars or on-line training resources to further continuing education
- Leads in the development of posters or presentations related to quality assurance at conferences or on-line offerings
- Participates in the development of white papers and rapid response teams to formulate industry positions to regulatory initiatives
- Performs other duties as needed or assigned

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Education and Experience Requirements:

- Bachelor's degree or higher in a science related field or equivalent experience.
- SQA RQAP-GLP or ASQ certification is preferred
- At least 15 years of quality control or quality assurance and/or regulatory work experience or an advanced educational degree
- Working knowledge of MS Office suite (emphasis in Word and Excel)
- Knowledge of bioanalytical laboratory equipment, assays, techniques is preferred
- Knowledge of Good Documentation Practices is required
- Knowledge of FDA Good Laboratory Practices (GLPs) and other FDA regulatory guidances (e.g., Bioanalytical Guidance documents) is required
- Knowledge of MHLW, OECD, ICH and other regulatory guidances preferred
- Knowledge of ISO9001 and/or investigative methods
- 5+ years of supervisory experience. May supervise 1-6 Quality Assurance members
- An equivalent combination of education and experience or demonstrated ability may qualify the appropriate personnel for this position

Skills and Abilities Requirements:

- High level of attention to detail
- The ability to utilize appropriate mathematical concepts for interpreting scientific data
- Ability to read protocols, possess good writing and good oral communication skills
- The ability to apply reasoning skills to deal with a variety of situations and problem solving
- Skill in written and verbal communication
- Skill in organization of records
- Skill in customer service
- Ability to interpret procedures, regulations and guidelines
- Ability to travel occasionally for professional development
- Skill in evaluating or developing forms to document compliance to procedures
- Ability to function effectively in stressful situations
- Ability to interpret and apply agency regulations and guidelines
- Ability to communicate with other employees in order to develop sound procedures and policies

Physical Requirements:

- Position requires sitting over 2/3 of the time
- Position requires working in front of a computer monitor over 2/3 of the time
- Position requires walking less than 1/3 of the time between departments/offices
- Position requires standing less than 1/3 of the time
- Position requires talking or listening less than 1/3 of the time
- Position requires lifting up to 10 lbs. up to 2/3 of the time