ALS provides a broad range of testing and analytical services to a wide variety of end markets and industries around the globe. We continue to remain at the forefront of the testing services industry, building an enviable reputation. BioScreen Testing Services, an ALS product-testing laboratory providing services to the Pharmaceutical/ Biotech, Medical Device and OTC/Personal Care industry, is seeking a Quality Assurance Manager.

Quality Assurance Manager – Contract Laboratory

(Job ID # 2019-7330)

About the position

ALS dba BioScreen Testing Services has an excellent opportunity for a Quality Assurance Manager. The QA Manager works within the QA department and with all other departments administering the implementation, performance and management of the Quality activities. Based at their BioScreen Torrance office, this full time position will report directly to the QA Director. The role has an overall responsibility for maintaining and administering the quality system within the company.

The successful candidate will be responsible for (but not limited to):

- Implement policy and procedures to maintain the regulatory compliance of the facilities.
- Provide Quality & Regulatory technical guidance to Process Development, Laboratory Operations, and Software Departments.
- Perform supplier and internal audits of analytical laboratory, microbiology, clinical, etc. per the audit schedules.
- Administrator and primary contact for the CAPA program.
- Recognize the need for investigations due to deviations from written procedures, review investigations into non-conformance incidents/deviations, and recommend disposition of the affected product/component.
- Facilitate and ensure timely completion of deviation/investigation reports.
- Prepare trend reports related to in-process monitoring, deviation reports, investigation reports and CAPAs. Follow-up with functional department for timely completion of corrective and preventive actions recommended.
- Manage SOP and regulated documentation systems.
- Support the preparation and or review of new, revised SOPs or test methods.
- Maintain Change Control and OOS systems.
- Develop and provide quality metrics and trending evaluation to Management.
- Perform Quality and Regulatory related training.
- Manage, coach and develop team members, as assigned.
- Review technical data for reports release.

About you

To be successful in the key role, you must demonstrate the following:

- Previous Pharmaceutical, BioTech or Medical Device industry experience, specifically in a GMP or GLP environment in Quality Assurance or regulatory compliance.
- GCP experience would be beneficial, but is not required.
- Bachelor's degree (B.S.) in a Life Science Field.
- 5 years plus industry experience and a minimum 3 years supervisory experience.
- Strong organizational and leadership skills.
- Experience in conducting FDA and ISO audits.
- Experience with regulated software design, including 21 CFR Part 11 compliance.
- Previous pharmaceutical industry experience in validation documentation preparation and execution.
- Familiarity with ICH, ISO and international regulations.
- Project management skills.

Benefits & Culture

AT ALS we believe that the people we employee are what makes ALS the company it is today.

We offer many benefits to staff, including but not limited to:

- Robust benefits package including, health, dental and vision.
- 401(k) matching.
- Opportunities to progress and develop your career within ALS including global opportunities for suitable candidates.
- ALS is proud to be an equal opportunity employer committed to achieving and maintaining a workforce which reflects and affirms the diversity of our society.

Looking for further details?

Applications covering relevant skills and experience will be treated with the strictest confident.

Please visit our website at www.bioscreen.com or apply at https://external-als.icims.com