BioScreen® Testing Services, Inc.

Quality Assurance Manager - Contract Laboratory

BioScreen Testing Services, Inc. a well-established consumer product testing laboratory, providing services to the Pharmaceutical/ Biotech, Medical Device and OTC/Personal Care industry is currently seeking a Quality Assurance Laboratory Manager.

The candidate must have a minimum of a BS degree in science with at least five or more years of experience in FDA regulated business and three years in a supervisory role. Knowledge of cGMP relevant to pharmaceutical testing laboratories or pharmaceutical manufacturing is a must. Administration of Deviations, OOS Investigations and Corrective / Preventive Action (CAPA) programs. The position requires strong communication skills in a diverse and technical environment, excellent writing skills and experience with FDA and ISO audits. Experience with pharmaceutical auditing procedures as well as ICH guidelines is a must. Experience or knowledge of current ISO guidelines with respect to ISO 9001 and ISO 17025 certification is a plus. The candidate must have excellent review skills for final data packages for analytical chemistry and microbiological studies, and ANDA and NDA type reports. The candidate must have skills to manage a staff of professionals and technicians.

QA Manager:
Full Time, Exempt position

Job Summary:

This position will be responsible for working with applicable departments in the implementation, performance, and management of quality activities.

Duties:

1. Implement policy and procedures to maintain the regulatory compliance of the facilities.
2. Provide quality & regulatory technical guidance to Process Development, Laboratory Operations, and Software Departments.
3. Host vendor and regulatory agency audits, as applicable.
4. Perform supplier and internal audits of analytical laboratory, microbiology, clinical, etc. per the audit schedules.
5. Administrator and primary contact for the CAPA program. Maintain follow-up on audit issues until completion, while providing corrective action leadership.
6. 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.
7. Facilitate and ensure timely completion of deviation/investigation reports.

8. 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.

9. Manage SOP and regulated documentation systems.

    a. Support the preparation and or review of new, revised SOPs or test methods.

10. Maintain Change Control and OOS systems.

11. Interact with management personnel from the various departments to monitor QA programs and provide feedback for improved quality.

12. Develop and provide quality metrics and trending evaluation to Management.

13. Perform quality and regulatory related training.

14. Represent quality activities to current or potential customers.

15. Manage, coach and develop team members, as assigned.

16. Perform other duties as assigned.

Essential Job Functions:

1. Sitting for extended periods of time, up to ten (10) hours per business day.

2. Position requires significant time working at a computer, up to ten (10) hours per business day.

3. Position may require the lifting of items in excess of 20 lbs. in weight.

4. Position may require contact with hazardous materials within a laboratory environment.

5. Travel up to 5% may be required.

Qualifications:

1. Previous pharmaceutical industry experience, specifically in a GMP or GLP environment, in Quality Assurance or regulatory compliance.

    a. GCP experience would be beneficial, but is not required.

2. Strong organizational and leadership skills.

3. Previous supervisory experience.

4. Experience in conducting audits.

5. Experience with regulated software design, including 21 CFR Part 11 compliance.

6. Previous pharmaceutical industry experience in validation documentation preparation and execution.

7. Familiarity with ICH, ISO and international regulations.

8. Project management skills.

9. Bachelor's degree (B.S.) plus 5 years plus industry experience and a minimum 3 years supervisory experience.

Please email resumes to jobs@bioscreen.com

Visit our website at www.bioscreen.com

Company requires background check and drug screen prior to employment.

No phone calls.