BioScreen® Testing Services, Inc.

Quality Assurance Analyst III - Validation

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 three years of experience in FDA regulated business. Knowledge of cGMP relevant to pharmaceutical testing laboratories or pharmaceutical manufacturing is a must. The primary purpose of the position is to provide technical and cGMP compliance review of documents and records generated by the ongoing equipment and instrumentation validations in various departments. Administration of OOS and OOT 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 reviewing a variety of documents and records maintained and generated by the laboratory departments.

QA Analyst III:
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. Write, schedule, plan, manage and execute installation, operation and performance qualifications of laboratory instruments, utility systems and equipment in accordance with current Good Manufacturing Practices (cGMPs), Good Engineering Practices (GEP) and the change control system. Maintain Master Validation Plan.

2. Perform timely technical and quality-based review of documents/records to ensure accuracy, completeness, and compliance with global cGMP requirements, applicable SOPs, client agreements, and industry standards. This includes ensuring adequate corrections are made to the documents and any events are escalated to the appropriate level of investigation, if not previous identified.

3. Coordinate and interface with Chemistry and Microbiology departments to assure successful validation project execution.

4. May provide quality & regulatory technical guidance Laboratory Operations and Software Departments.

5. Will review/author related validation plans, protocols and summary reports.

6. Conduct periodic validation reviews of equipment, utilities and facilities.

7. Perform follow up activities for document/protocol closure, including document requests and compilation, review of event reports, and assisting with document revisions as appropriate.

8. Perform follow up activities for document/protocol closure, including document requests and compilation, review of event reports, and assisting with document revisions as appropriate.

9. Design and implement a data collection and trending process for errors observed during document/record review and providing feedback to QA management to assist with continuous improvement initiatives.

10. Assist with Validation-related data integrity initiatives.

11. Assist with the development of SOPs associated with new and existing validated processes, systems, and the overall requirements of validation concepts and requirements, including data review and maintenance requirements.

12. Continuously audit/monitor documentation and reviewer feedback to detect undesirable trends or opportunities for improvements related to quality and/or efficiency.

13. Assist with the observation and/or execution of protocol activities, as appropriate for experience and training level. Observations may be used as part of the continuous improvement process associated with protocol and SOP development.

14. Assist in training program development related to validation activities and concepts for both QA personnel and other site departments.

15. Assist with internal audits (self-inspection) activities, as appropriate to experience and training level.

16. Development of the following documents for new equipment:

    a. User requirement specification

    b. Design qualifications

    c. Commissioning

    d. Risk assessment

Qualifications:

1. Bachelor's degree with concentration in engineering, science, or quality required.

2. Minimum of three years' experience working in a GMP environment, preferably a minimum of 1 - 2 years of validation experience.

3. Sound knowledge, understanding, and application experience of quality management systems such as Deviations, CAPAs, Change Controls, etc.

4. Validation experience within laboratory/manufacturing facilities (e.g. incubators, cold rooms, autoclaves, depyrogenation ovens)

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

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

7. Must have excellent technical writing skills, strong computer and communications skills, problem solving ability and project management skills.

Please email resumes and salary requirements to jobs@bioscreen.com

Visit our website at www.bioscreen.com

Company requires background check and drug screen prior to employment.

No phone calls.