Quality Assurance Auditor II

Location: Horsham, PA

For nearly 70 years, Charles River employees have worked together to assist in the discovery, development and safe manufacture of new drug therapies. When you join our family, you will have a significant impact on the health and well-being of people across the globe. Whether your background is in life sciences, finance, IT, sales or another area, your skills will play an important role in the work we perform. In return, we'll help you build a career that you can feel passionate about.

BASIC SUMMARY:

Independently perform audits of a broad range of records and reports and inspections of a variety of processes to assure compliance with applicable regulatory requirements, international standards, and corporate policies and procedures. In the GMP facilities, also responsible for approval and release of the finished product for distribution to clients.

ESSENTIAL DUTIES AND RESPONSIBILITIES:

- Assure Charles River's compliance with applicable federal, state, and local regulations as well as corporate policies to avoid any business interruptions. Communicate all identified compliance and quality risks to supervisor.
- Perform data audits to assess that records are attributable, legible, contemporaneous, original, accurate, and in compliance with regulations, international standards, SOPs, protocols/batch records, and corporate policies and procedures.
- Review SOPs, protocols/batch records, reports, and other quality and regulated records involving technically complex issues and processes for accuracy and compliance with all applicable regulations and internal policies.
- Maintain written and signed records of all audits and inspections as required and may sign records documenting the performance of audits and inspections and reporting to management.
- Participate in the preparation and review of study and QA files in preparation for sponsor site visits and regulatory inspections; assure that QA audit files are retained.
- Host client site visits and participate in regulatory inspections.
- Coordinate the development of corrective and preventative actions to respond to client visit and regulatory inspection findings.
- Provide recommendations to Regulatory Affairs and Compliance management for improvements in auditing of Quality Systems based on extensive knowledge and understanding of regulations and quality principles.
- Identify, document, and report deviations from regulations, protocols/batch records, SOPs, and specifications.
- Review protocols and batch records and reports to assure accuracy, completeness, and compliance with all regulations, international standards, and company policies and procedures.
- Independently perform inspections and audits to monitor processes, facilities, equipment, personnel, materials, methods, practices, records, and controls to assure compliance with regulations and international standards.

- Participate in inspections and audits of subcontractors, vendors, and suppliers of products and services.
- Assure the suitability of materials and supplies for compliance with specifications.
- Assist with providing basic regulatory training to QA and operations personnel.
- Assist in scheduling and tracking QA audits, inspections and procedures as requested.
- Assist with review and revision of QA SOPs to reflect current practice.
- In GMP facilities, review and approve all procedures related to production and maintenance, approving or rejecting incoming materials, in-process materials and finished product.
- Participate in collecting and reporting of quality metrics.
- Perform all other related duties as assigned.

Qualifications

- *Education:* Bachelor's degree (B.A./B.S.) or equivalent, preferably in a life science or related discipline.
- *Experience:* 2-4 years experience in a QA role.
- An equivalent combination of education and experience may be accepted as a satisfactory substitute for the specific education and experience listed above.
- *Certification/Licensure:* None.
- *Other:* Good working knowledge of Microsoft Office applications (e.g. Word, Access, Excel). Good knowledge of applicable regulations and guidance documents; able to apply critical thinking skills to evaluate requirements. Must be detail oriented and able to effectively communicate findings verbally and in writing.

Equal Employment Opportunity

Charles River Laboratories, Inc. is an Equal Opportunity Employer M/F/Disabled/Vet

To apply, please send resume and any questions to Branden Cornell at branden.cornell@crl.com