Our company is looking for an external auditor. To join our growing team, please review the list of responsibilities and qualifications.

## **Responsibilities for external auditor**

- Assists in identifying updates to law/rules/regulations as they impact the agency & the monitoring process
- Provides technical assistance to AAAs/PAAs during the monitoring process
- Participates in meetings with agency & representatives of the audited entity to review audit findings & recommendations
- Prepare, coordinate, participate, and administer external regulatory audits and inspections
- Train all inspection support personnel in assigned Site Regulatory Inspection team roles in addition to the inspection support structure and process
- Leads Site Management in formalizing a response, corrective and preventive actions, and related commitments to any external regulatory agency citation/observation/finding
- Perform key compliance projects including gap assessments to ensure compliance with regulatory requirements, including FDA, Health Canada, and other international audits as assigned
- Coordinate, execute, and perform lead audit functions during internal cGMP audits to assure compliance with applicable regulations and international laws and standards, guidelines, and procedures
- Manage and support compliance projects to achieve plant quality objectives and initiatives including benchmarking with other sites and participating on committees/teams that support cGMP compliance programs
- Edit, write, review and approve standard operating procedure change controls

- 5 years of work experience interfacing with and auditing external suppliers or subcontractors in healthcare and /or medical device regulated environments
- 7 years of work experience in a Healthcare or medical device company
- Healthcare industry certifications
- Healthcare industry training
- MBA or Masters in Accounting preferred
- Requires a Bachelor's in Accounting or a related field