Our growing company is looking for a regulatory coordinator. Thank you in advance for taking a look at the list of responsibilities and qualifications. We look forward to reviewing your resume.

Responsibilities for regulatory coordinator

- Various other duties as required to support overall regulatory functions
- Tracks new protocols through the committee system to approval, responds to committees' inquiries
- Gathers data needed to prepare and process applications for IRB review and approval
- Collaborates with the Principal Investigator (PI) in completion of application documents including all required PPHS paperwork, for approval of new clinical research trials
- Coordinates conference calls with investigators to aid in study development
- Obtains IND# for the clinical trials through correspondence with the FDA, and submission of paperwork necessary to obtain an IND#
- Collaborates with the Financial Manager on the development of the study budget (as needed)
- Updates and maintains records of protocols on clinicaltrials.gov website
- Upon protocol approval, transitions the protocol to be implemented by investigator(s), program manager(s), clinical research coordinator(s), regulatory coordinator(s), and research nurse(s)
- Organizes and conducts start-up meetings for new protocols

Qualifications for regulatory coordinator

- Organization, prioritization and procedural skills are essential, with the ability to manage priorities and duties with close attention to detail

- Uses various systems and tools
- Demonstrated ability to research, compile and/or prepare reports, responses to proposed changes in regulations, reviews of recommendations, policies, procedures, and correspondence
- Experience reading and interpreting applicable governmental regulations applicable to federally regulated intrastate and interstate pipelines and company and/or industry publications related to pipeline reporting compliance
- Experience researching, identifying, evaluating, and prioritizing problems or situations and coordinating appropriate actions or responses