Example of Regulatory Coordinator Job Description

Our innovative and growing company is looking for a regulatory coordinator. Please review the list of responsibilities and qualifications. While this is our ideal list, we will consider candidates that do not necessarily have all of the qualifications, but have sufficient experience and talent.

Responsibilities for regulatory coordinator

- Manages submission of all regulatory documents to the IRB, including development of informed consent forms and protocol review for complex studies involving more than minimal risk to research subjects
- Review and preparation of site informed consent forms
- Collection and maintenance of regulatory documents
- Completion of local Institutional Review Board applications and modifications
- Tracking of IRB approvals
- Completion of continuing review reporting, and
- Preparation and assistance with internal and sponsor monitoring visits
- Develop, implement and periodically review processes and policies related to compliance with these federal and state regulations
- Participate in external compliance inspections performed by state and federal regulatory personnel and periodic testing of internal compliance procedures, issue assessment and audit findings
- Review external audit findings and prepare and submit responses to the appropriate state or federal agency

Qualifications for regulatory coordinator

- At least 1 year of clinical research work in the areas of protocol management and case report form management
- Familiarity with federal regulatory requirements

- Excellent communications and interpersonal skills for representing department positively in all communications
- Skills in organization, prioritization, and procedures, with the ability to manage priorities and duties with close attention to detail
- Strong computer skills preferably Microsoft Word and Excel