Example of Clinical Development Job Description

Our growing company is looking to fill the role of clinical development. 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 clinical development

- Clinical Operations, Biometrics, Medical Affairs, Regulatory Affairs and Commercial teams
- Responsible for managing calendar, scheduling meetings, making travel arrangements, preparing expense reports
- Development and upkeep of general Excel files, Word documents and PowerPoint presentations
- Contributes to and reviews clinical science trial related documents documents generated by other departments (Statistic, Operation, Data Management)
- Working with the team to implement the clinical protocol development process in collaboration with other members of the development team, and Safety Department
- Responsible author for clinical synopsis, outline, protocols, amendments and related documents
- Contribute to the medical/scientific input given for the development of trial-related documents and processes which reside in other line functions
- First point of contact within Halozyme for the investigational study sites with regard to questions about patient eligibility in trials, protocol waivers, safety issues, regular review of safety parameters and generation of periodic safety reports, and the receipt and processing of SAEs, including review of narratives for SAEs and participation in IND expedited safety reporting
- Will coordinate real time availability of quality clinical trial data, including safety, efficacy, pharmacokinetic, and biomarker data to provide consolidated

- Serve as the external clinical “face” of the program in interactions with development partners, and leading clinical discussions at investigator meetings

Qualifications for clinical development

- A PharmD, PhD is required
- A minimum of five to seven years progressive experience in pharmaceutical, biopharmaceutical or biotechnology drug development is required
- Working knowledge of scientific and clinical methodology, protocol design, project management and regulatory requirements for clinical studies designated for review by regulatory authorities
- A higher qualification
- Medical degree with Board Certification/Specialty background, or equivalent status, in a relevant area (Pediatrics, Neurology, Transplantation or similar)
- Regulatory/global health authority interactions, including reviewing and responding to regulatory agency queries developing medical sections of relevant regulatory documents