Example of Clinical Affairs Job Description

Our innovative and growing company is hiring for a clinical affairs. If you are looking for an exciting place to work, please take a look at the list of qualifications below.

Responsibilities for clinical affairs

- Monitors the progress of the project and updates clinical project leader on an ongoing basis
- Prepares, oversees, and reviews the preparation of clinical documents, , Protocols, Investigator Brochure, Annual Report updates, Case Report Forms and Clinical Study Reports
- Lead clinical risk assessment for adverse events, participate in decision on field corrective actions
- Develop, implement and collaborate on training for company operating procedures, GCPs, protocols, database, compliance, device accountability, adverse event reporting, study investigation protocols, amendments, regulatory documentation requirements, process improvement training and proctoring new employees on trial and study related activities
- Collaborates with Lead CRAs to collect feedback and information related to monitoring visit reports, site report cards and dashboards for ongoing management of site issues
- Management and oversight of the Clinical Project Associate team's activities, ensuring compliance with applicable regulations and SCRI SOPs
- Manage the performance of direct report personnel, including role expectations and performance reviews
- Ensure adequate support, trouble shoot performance issues, and identify and develop training opportunities for department and individuals
- Supervise, educate, direct and support the Clinical Project Associate Team
- Develop and define career development pathways for the Clinical Project

Qualifications for clinical affairs

- Familiarity with dental CAD/CAM technologies
- Must be able to set priorities adapt to changing priorities
- MD, DO or PhD from an accredited institution in a Medical/Scientific discipline
- MD or DO with eight plus (8+) years OR PhD with ten plus (10+) years industry experience in US medical affairs, understanding of the US clinical practice environment and clinical drug development
- Clear record of successfully planning and executing Medical Affairs and/or Clinical Development strategy, clinical trials, regulatory submissions and a demonstrated ability to function at a program level
- Comprehensive and authoritative knowledge in the therapeutic area