

Title of Job: *Regulatory Compliance Associate*

Description: Responsible for all aspects of regulatory compliance and documentation, quality assurance, auditing, as well as organizational training related to GCP and SOP compliance. Reviews on-site files, folders, binders, case report forms, and source documents for completeness, accuracy, consistency, and compliance; identifies deficiencies and discrepancies, and provides remedial training and/or initiates corrective action as required. Develops, monitors, tracks, audits and reports on the Annual Clinical Quality Improvement Plan. Assists Site Managers and other staff with regulatory compliance and documentation, focused reviews, and quality improvement activities.

Educational Qualifications: Bachelor's degree required, preferably in life sciences and/or health science disciplines.

Experience/Training: 1-4 years of clinical research experience or equivalent work experience preferred. Document management and/or Regulatory experience a plus. Good interpersonal skills with effective verbal and written communication. Knowledge of GCP/ICH regulatory guidelines and clinical trial processes.

Licenses. etc: N/A

Status and Scope: Reports to the Director of Regulatory & QA

FLSA Status: Exempt

Essential Job Duties:

1. Perform record keeping.
2. Follows internal SOPs. Assists with the development of SOP's.
3. Assist with and coordinate development of clinical trial support documents.
4. Ensures maintenance of regulatory documents/binders in an organized and systematic fashion to facilitate the monitoring and auditing of research studies.
5. Ensures protocol safety reports are distributed to investigators and research team for review.
6. Ensures that all required regulatory documents are updated in the site's regulatory binder throughout the life of the study.
7. Assembles, reproduces and archives (hard and electronic copies) technical documents, as appropriate for the document type.
8. Report on status of clinical trials.
9. Facilitate communication with IRB and/or Sponsors.
10. Ensure safety of all patients treated with our products and assist with all regulatory filings in this regard.
11. Monitor clinical trial sites.
12. Represents Clinical research Advantage to sponsor representatives and regulatory agencies.

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13. Review data from clinical trials.
14. Collaborates with the research team to facilitate overall protocol operations.
15. Record and organize data.
16. Keep documents organized and ready for audit and ready for regulatory filings when required.
17. Flag problems and issues.
18. Track approvals and renewals.
19. Generates and reviews reports of regulatory data using appropriate systems.
20. Draft reports.
21. Assist in training programs.
22. Uses appropriate IT and software tools to ensure the correct format and presentation of documents.
23. Ensures all assigned tasks are conducted in accordance with federal regulation and GCP.
24. Achieves appropriate quality standards in all documentation within the timelines dictated by project plans.
25. Prioritizes personal workload in line with agreed project plans.
26. Support team activities and assume responsibility for activities, as necessary, to fulfill company needs.
27. Participates in business development activities.
28. May perform other duties not specifically listed in this job description as assigned by the Supervisor.