Panthera
Accelerating Clinical Breakthrough

Site Compliance Specialist - Enfield

We have an exciting opportunity for a Site Compliance Specialist to join our expanding research site in Enfield.

Panthera is an independent Site Management Organisation helping pharmaceutical and contract research organisations find the right patient, for the right trial, at the right time. The Panthera team is run by a world-class team of experts with more than a hundred years of clinical research experience.

Our mission is to improve patient access to clinical trials across the United Kingdom but also to promote awareness on the importance of clinical research in healthcare.

Job Summary

The Site Compliance Specialist will be responsible for providing oversight, mentoring and guidance to staff and ensuring compliance with all appropriate guidelines for legal, regulatory, and site compliance, as well as company policies and procedures.

They will also provide support to the site regarding Quality Management System (QMS), follow-up on CAPAs, preparation for internal and external audits, operational compliance checks, identification and/or support in reporting of QI and communication of any issues with site.

Key Responsibilities

- Building key relationships with stakeholders, colleagues, clients, monitors and CRA's
- Responsible for complex data collection, transcribing information into case report forms in accordance with Good Clinical Practice
- Ensuring accuracy and high quality of data input in to Panthera systems
- Ensuring patient notes are always complete and up to date
- Responsibility for safeguarding and ensuring the quality of information for patients, clients and vendors
- Prepares individual/site operational compliance plans and performs quarterly operational compliance check activities.
- Prepares associated reports and follows up on quality issues from all sources and related CAPAs.
- Performs regular quality control and oversees that quality of data is accurate, on time and adheres to latest approved SOPs, COP's standards, GCPs, Local Regulatory and protocol.
- Validates and checks quality of essential documents, participant files and site study data, ensuring accuracy of data entered and source documents and reports discrepancies.
- Develops, maintains and produces a dashboard for tracking patients, flow of CRFs, and queries, ensuring that this is provided in a timely manner.
- Conducts, hosts, and produces meeting minutes and actions for departmental and other relevant meetings, ensuring that issues impacting on business are highlighted to senior leaders as needed.
- Monitor's quality and training processes to ensure appropriate timelines are met
- Completes the preparation for monitoring visit duties and audits and clarifies concerns related to CRF completions; resolves queries as well as CAPA reporting and basic root cause analyses.
- Identifies trends in data queries and escalates appropriately.
- Supports QA regarding notifications, preparations and facilitation of client audit and regulatory inspections, investigations of quality issues and tracking and follow up of local CAPA status.
- Ensures that quality and patient safety are at the forefront of all activities through review and interpretations of audit reports, quality statistics and operating procedure robustness, and follows up on quality issues.
- Ensures robust application and compliance with Good Clinical Practice and Data Protection Act or SOPs, QA and applicable regulatory guidelines

Ideal Candidate

- Degree level or equivalent experience
- Strong interpersonal, leadership and consultative skills
- Experience with the preparation of and collation of regulatory documents for ethics submissions
- Ability to take detailed and accurate notes, transposing and recording information
- Proactive mind set, motivated and keen to learn new skills
- Committed to improving quality through research
- Able to demonstrate commercial awareness
- Comprehensive industry knowledge of quality compliance, GCP

Salary & Benefits Package

- £27,000-32,000 per annum, negotiable depending on experience
- 25 days annual leave plus bank holidays
- Life insurance, 3x annual salary
- Employee healthcare cash plan programme + Employee Assistant Programme
- Enhanced sickness and family friendly policies