Panthera
Accelerating Clinical Breakthrough

Job Description

Job Title: Site Compliance Specialist

Reports to: Site Manager

Job Summary

This role will be responsible for providing oversight, mentoring and guidance to staff, ensuring compliance with all appropriate guidelines for legal, regulatory, and site compliance, as well as company policies/procedures.

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

The post holder will be required to work across local Panthera sites as required.

Personal Attributes

The post-holder should have excellent interpersonal skills, energy, pro-active drive and enthusiasm for the role, to ensure that high quality clinical research is delivered according to agreed objectives.

Key Responsibilities

Communication and Relationships

- Building key relationships with stakeholders, colleagues, clients, monitors and CRA's
- Effective communication with the Panthera site team, including management of emails, phone calls etc

Information & Data Quality

- 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
- Take personal responsibility for safeguarding and ensuring the quality of information for patients, clients and vendors
- Responding promptly to requests for information to support the Panthera team as required.

Data Compliance

- 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.
- Monitors quality and training processes to ensure appropriate timelines are met
- Liaises with monitors, client representatives, and internal and external clients.
- 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
- Professional knowledge of theory and techniques in the data and compliance field
- Comprehensive industry knowledge of quality compliance, GCP

Quality Management Systems and Processes

- The post-holder must consider and comply with all Panthera policies, procedures and initiatives including, but not limited to, quality standards, compliance and auditing requirements, confidentiality and information security.
- Reporting quality issues in accordance with Panthera SOP's.
- Adhering to policies standard operating procedures, required by the Sponsor in the conduct of clinical trials.

The post holder will always operate with integrity and professionalism, complying with regulatory requirements in accordance with the following;

- ICH-GCP
- Health and Safety regulations
- All Panthera policies and procedures and reporting of quality issues
- Data Protection Act 2018/ GDPR 2018
- Ant-bribery and Corruption Act 2010
- Health & safety at work Act 1974
- Professional codes of conduct

Training

- Attend all mandatory training applicable to this post within the required timescales.
- Seek opportunities to develop own skills.
- Adapt to any changes in the requirements of new clinical trials, or amendments to the protocol on trials that are ongoing.
- Attend any Sponsor or company training events as applicable.

Personal Development

- Actively participating in the annual Personal Development Review (PDR) process.

- Able to work on own initiative without supervision, managing own workload and working independently as well as part of the Panthera team.
- Contribute to positive working behaviours and attitude.
- Commitment and passion to the development and delivery of clinical research.
- Take responsibility for ensuring targets and deadlines are met and an exemplar service is provided.

Promoting Equality and Reducing Inequalities

- To understand and uphold organisational policies and principles on the everyday promotion of equality, diversity and inclusion.
- To create an inclusive working environment in which a variety of ideas, experiences and practice are valued, and where differences are respected and celebrated for the benefit of ourselves, Panthera and the communities we serve.

The range of duties and responsibilities outlined above are indicative only and are intended to give a broad flavour of the range and type of duties that will be allocated. They are subject to modification in the light of changing service demands and the development requirements of the post holder.

Job Review

This job description will be reviewed periodically to take into account changes and developments in service requirements. Any changes will be discussed fully with the post holder.

Post holder's Signature: _____

Site Manager Signature:_____

Date:_____

Person Specification

Description	Essential	Desirable	Assessment
Education/ Qualifications	• Degree level or equivalent experience	Health related qualification	Application/Interview
Knowledge & Experience	• Ability to take detailed and accurate notes, transposing and recording information • Processing complex information (data entry) • Knowledge and accomplishment in the processing of blood samples • Communication at different levels within an organisation • Line management experience • Strong understanding of the audit process, including audit preparation and oversight, sponsor, internal audits regulatory authority and FDA will be advantage), as well as CAPA reporting and basic root cause analyses • Experience with the preparation of and collation of regulatory documents for ethics submissions • Strong multitasking and project management skills • Strong interpersonal, leadership, and consultative skills • Good working knowledge of Business English • Appropriate MS Office Skills • Strong medical terminology knowledge • Strong time management skills • Thorough attention to detail		Application/Interview
Skills and Abilities	• Able to demonstrate attention to detail • Able to communicate effectively and politely through various means		Application/Interview

	• Face to face communication essential • Able to balance competing priorities		
Attitudes and Qualities	• Pro-active mind set • Motivated and keen to learn new skills • Flexible approach • Committed to improving quality through research • Able to demonstrate commercial awareness		Application/Interview