Manager, Global Clinical Quality Assurance

Maternity Leave Replacement 12 months, Montreal, QC

Job Summary

The incumbent supports the Director, Global Quality Assurance (QA) to ensure of the consistency of the quality standards for Theratechnologies' pre-clinical and clinical studies in Canada, US and Europe according to Good Clinical Practices (GCP) and Good Laboratory Practices (GLP). We are seeking a talented and experienced clinical quality assurance subject matter expert who is excited to join a dynamic and growing organization and who is committed to deliver excellence in all projects under their responsibility.

Key Responsibilities

Compliance of Clinical activities

- Act as a Subject Matter Expert in Clinical Quality Assurance for Theratechnologies pre-clinical and phase I-IV clinical studies in Canada, US and Europe
- Develop and maintain GCP/ICH compliant processes for the management and execution of pre-clinical and clinical studies

- Audit activities to ensure that Theratechnologies pre-clinical and clinical studies are conducted according to protocols and that any deviation is documented and assessed
- Ensure CAPAs are developed and executed in a timely manner
- Provide quality oversight to Clinical Research Organizations (CROs), sites and vendors as required
- Conduct GCP and/or GLP audits of contracted vendors (CROs, laboratories, central imaging vendors, central pathology vendors, central Institutional Review Boards (IRBs etc.), prepare reports and escalate to management audit findings
- Conduct internal audits to ensure compliance to internal processes and regulations
- Support regulatory authorities' inspections
- Facilitate quality improvements by using a risk-based methodology
- Partner with Clinical Development stakeholders, including Regulatory Affairs, Clinical Operations and Pharmacovigilance/Safety, regarding compliance issues and provide compliance guidance

Review clinical documentation

- Review Protocol / Protocol Amendments for clarity and compliance
- Prepare audit plans and audit clinical sites according to the audit plan
- Review/audit Clinical Study Reports including Table, Figures and Listings
- Audit the Trial Master File as required
- Initiate or review/approve deviations to procedures
- Review protocol deviations and provide approval
- Ensure site initiation requirements are met to authorize investigational drug shipments
- Assess investigational drug temperature excursions
- Review vendor agreements
- Review and approve Risk Management Plans
- Ensure requirements for site closures are met
- Liaise with the QA team for lot availability/release
- Participates in complaints' evaluation or approval in order to identify the causes and recommends corrective/preventative actions
- Reviews/evaluates change controls related to clinical activities
- Evaluates and ensures the disposition of transferred/returned/recalled product
- Prepares forms, memos, lists and reports as required
- Performance any other task as requested by management

External Clients

- Medical Affairs, Clinical Operations, Regulatory Affairs, and Pharmacovigilance/Safety
- Quality team of external partners, CROs and suppliers

Qualifications Required

- Bachelor's degree in Nursing, Pharmacy, Chemistry, Biology or Sciences or equivalent
- Three to five (3-5) years of quality assurance experience in the pharmaceutical industry in pre-clinical and clinical research
- Experience with Medical Devices is an asset
- Experience with regulatory inspections, supplier audits and internal audits
- Experience in policies and procedures related to the pharmaceutical compliance program
- Excellent knowledge of the FDA, EU and Canadian regulations, GCP, GLP, as well as ICH guidelines
- Good knowledge of GMPs
- Knowledge of Word, Excel, PowerPoint and Outlook
- English, spoken and written, fluency in French is an asset
- Excellent English authoring/writing skills

Personal Qualities Specific To Position

- Leadership and accountability
- Result-oriented
- Ability to negotiate and influence others
- Multitasking
- Analytical capabilities and ability to synthesize information
- Planning and organizational skills
- Good stress management
- Attention to detail and quality
- Verbal and written proficiency
- Thoroughness in accomplishing tasks
- Available for occasional business travels

Personal Qualities For All Staff

- Ability to define objectives and meet timelines
- Ability to determine priorities
- Ability to bring ideas and find solutions
- Can work alone or in a team
- Team spirit and collaborative
- Flexibility

What Thera offers -

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Referral Program	Care Days	Spot Award Program	Stock Option Plan