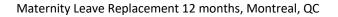


# Manager, Global Clinical Quality Assurance



# 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 preclinical 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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