Competition Number: J0519-0648
Position Title: Regulatory Affairs Team Leader
Employee Group: Research, Grant & Contract
Job Category: Research
Department or Area: Canadian Cancer Trials Group
Location: Kingston, Ontario, Canada
Salary: $63,709.00/Year
Grade: 09
Hours per Week: 35
Job Type: Permanent (Continuing)
Shift: 7 Monday - Friday
Number Of Positions: 1
Date Posted: October 7, 2019
Closing Date: October 20, 2019

About Queen's University

Queen’s University is the Canadian research intensive university with a transformative student learning experience. Here the employment experience is as diverse as it is interesting. We have opportunities in multiple areas of globally recognized research, faculty administration, engineering & construction, athletics & recreation, power generation, corporate shared services, and many more.

We are committed to employment equity and diversity in the workplace and welcome applications from individuals from equity seeking groups such as women, racialized/visible minorities, Indigenous/Aboriginal peoples, persons with a disability, persons who identify in the LGBTQ+ community and others who reflect the diversity of Canadian society.

Come work with us!

Job Summary

Reporting to the Manager, Office of Compliance and Oversight (OCO), the Regulatory Affairs Team Leader will lead the Regulatory Team for the Canadian Cancer Trials Group (CCTG) within the OCO. The core responsibilities include leadership to ensure compliance with national and international regulations essential to the compliant conduct of clinical trials, development and implementation of Standard Operating Procedures at the Operations and Statistics Centre and in support of partnering organizations, and providing guidance in alignment with CCTG strategic directions. The Regulatory Affairs Team Leader will lead and supervise staff to coordinate and facilitate the regulatory processes essential to the successful oversight clinical trials.

Job Description

KEY RESPONSIBILITIES:

• Lead the regulatory area for CCTG. Provide expert knowledge and application of national and international clinical trial regulations to support compliant filing of clinical trials with relevant Health Authorities. Provide leadership to ensure Group is proactive and current with relevant regulations and expectations of filing processes (e.g. Health Canada, FDA, EMA, others as applicable). Develop and establish Group standard for national and international processes including filing IND's outside of Canada.

• Develop regulatory strategies to help guide the clinical trial and regulatory submission pathways, nationally and internationally.

o Work with cross-functional team to prepare and submit regulatory submissions to Health Authorities.

o Evaluate trial protocols, in consultation with the Manager, OCO and Senior Investigator(s), regarding the need for Health Authority filing. Consideration for when Health Authority filings are required (e.g. Initiative to Streamline Clinical Trials).

o Lead consultation with the Manager, OCO and Senior Investigator(s), regarding regulatory responses including screening and other clarifax requests.

o Define and oversee expectations with respect to regulatory documentation reviews and appropriate levels of review when questions from regulatory team arise.

o Oversee records retention process from a regulatory perspective.

o Ensure compliance with expectations around Investigational Medicinal Product labeling and importation including any biologic/fax back expectations.

o Provide overall guidance for regulatory processes, documentation, and review expectations.

• Participate in national and international initiatives on behalf of CCTG (e.g. Modernization of Clinical Trial Legislation).

• Develop and implement key Standard Operating Procedures (SOP's) and Work Instructions to deliver quality and ensure consistency across all team members within the regulatory team.

• Develop training materials and evaluations for new quality initiatives and oversee the training and education of regulatory team and the CCTG network, as applicable.

• Develop and implement tools to increase quality and efficiency within the ethics team. Manage quality and efficiency by effectively motivating, monitoring, and managing team performance with regards to efficiency and quality.

• Leadership and supervision of team members to ensure Group goals are met in compliance with applicable national and international regulations and guidelines.

o Lead regulatory team in review, processing, tracking, monitoring of regulatory documents to ensure compliance with CCTG standard operating procedures.

o Provide support, expert advice, and facilitate process development including implementation and training.

o Delegate work of the team, ensure quality control and quality assurance activities are conducted, and manage metrics/timelines required in line with the Group's strategic agenda, projects, and trials.

o Provide day-to-day supervision to staff in the unit. Review assignments and provides feedback on work to employees. Provide coaching and feedback on work quality issues. Escalate unresolved performance and/or disciplinary matters to OCO Manager.

• Perform other duties as assigned. Supports the regulatory operational function as required.

REQUIRED QUALIFICATIONS:

• Master’s degree in Health Sciences or equivalent field.
• Minimum of 5-7 years relevant experience in one or more of the following: clinical research, health sciences, health policy, ethics or regulatory affairs field.
• Expert understanding and experience interpreting and implementing regulations pertaining to national/international clinical trials.
• Proven experience supervising and leading employees.
• Consideration may be given to an equivalent combination of education and experience.

SPECIAL SKILLS:
• Respects diversity and promotes inclusion in the workplace.
• Expertise in regulations and guidelines governing clinical trials.
• Leadership and supervisory skills.
• Ability to work collaboratively within a team and across functional groups, as well as have the ability to work independently.
• Proven problem solving and analytical skills.
• Excellent attention to detail.
• Must be highly organized with the ability to prioritize workload.
• Ability to work well under pressure and multi-task in a changing environment.
• Strong communication and interpersonal skills
• Ability to critically and accurately review and interpret medical information.
• Ability to make formal presentations and represent the Group at professional meetings.
• Computer skills including Word, Excel, PowerPoint, knowledge of database structures (i.e. Oracle, Web Based Systems, Electronic Data Capture systems, Clinical Trial Management Systems).
• Ability to work with confidential information.
• Working knowledge of French is considered an asset.

DECISION MAKING:
• Determine effective communication processes (across teams, departments, centres, etc.).
• Delegate work to team members and ensure its accuracy.
• Determine priorities and make decisions about staff utilization and the assignment of work to achieve optimum efficiencies and productivity.
• Monitor and assess output and the quality of employees’ work, and recommend need for formal training or development plans to management and identifies possible staff performance and/or disciplinary issues.
• Review variations in regulatory processes and documentation to determine whether the Group and national/international requirements have been met.
• Review trial initial/amended documents to ensure compliance with CCTG SOPs and applicable regulations and guidelines. Determine if processes are appropriate and if required elements are sufficiently addressed.
• In collaboration with senior leadership, determine appropriate policies and procedures with respect to functions of the Regulatory Affairs Team and decide how modifications should be proposed and implemented.

Closing Statement

The University invites applications from all qualified individuals. Queen’s is committed to employment equity and diversity in the workplace and welcomes applications from women, racialized/visible minorities, Indigenous/Aboriginal Peoples, persons with disabilities and LGBTQ+ persons.

The University provides support in its recruitment processes to applicants with disabilities, including accommodation that takes into account an applicant's accessibility needs. Candidates requiring accommodation during the recruitment process are asked to contact Human Resources at hradmin@queensu.ca.