Regulatory Affairs Specialist, Integrated Management Platform to Accelerate Clinical Trials (IMPACT)
Life Sciences Innovation Hub

The Integrated Management Plan to Accelerate Clinical Trials (IMPACT) is a program designed to facilitate the efficient conduct of high-quality clinical trials through an integrated, multi-step process.

The Life Sciences Innovation Hub (LSI Hub) at the University of Calgary is a one-of-a-kind facility located within University Research Park. The LSI Hub offers access to space (office, wet and dry labs, prototype maker space), entrepreneurial and business development programming, mentorship, and technical expertise for research-intensive startups and developing companies.

REGULATORY AFFAIRS SPECIALIST

The Regulatory Affairs Specialist will functionally report to the Executive Director of the IMPACT clinical trials accelerator program and administratively to the Director of Economic Development for the Life Sciences Innovation Hub.

The Regulatory Affairs Specialist will be the primary contact for life sciences startup companies regarding domestic and foreign regulatory documentation, requirements, and procedures relating to pre-market regulatory approvals. This position will work with the IMPACT team to assist approximately 3-5 Venture Navigators and several concurrent clinical trials.

The successful applicant must have advanced knowledge of principles, concepts, and practices related to clinical trials for new products, with specific expertise in regulatory affairs about medical devices, drugs, and digital health. They must apply their technical and functional knowledge of regulatory requirements to the design and execution of research projects. The must interpret and apply, using their discretion, any regulatory, compliance, or scientific requirements for projects and play an advisory role in assisting new companies with selecting regulatory strategies that align with their overall future commercialization goals. They must possess excellent interpersonal and communication skills, be flexible, able to multi-task, and effectively work in a fast-paced, challenging environment with frequent tight deadlines.

The successful applicant must be proficient with personal computers, have a strong working knowledge of information technology systems used to facilitate regulatory compliance, and be familiar with quality management systems.

NATURE OF POSITION

The Regulatory Specialist will play a crucial and central role within the IMPACT program, guiding, training, and advising ventures through all regulatory processes. This role will oversee the ongoing development of a customized regulatory software platform, the Tailored Regulatory, Audit, Compliance and Reporting (TRACR) system, developed to guide ventures through the regulatory submission process.

The primary responsibilities for this position include:

- Ensuring compliance with Good Clinical Practice (GCP) and relevant domestic and international guidelines;
- Advising on the proper and appropriate regulatory documentation and management for clinical trials;
- Ensuring collection and maintenance of in-date regulatory documents;
- Coordinating safety and adverse event documentation and reporting;
- Advising appropriate quality assurance and control (QA/QC) measures;
- Conducting searches/updates for domestic and international guidelines and standards and providing summaries, recommendations, and process improvements;
- Identifying and monitoring domestic and global/country regulatory and product registration requirements;
- Supporting management communication with regulatory authorities and advising on regulatory inspections/audits as needed;
- Ongoing oversight and development of the customized TRACR system.

QUALIFICATIONS/EXPERTISE:

- Minimum 5 years of experience in regulatory/medical affairs with an in-depth knowledge of clinical research;
- Must have certification in GCP guidelines and experienced in investigator-initiated or industry-sponsored clinical trials;
- Regulatory Affairs Certification (RAC) is preferred;
- Solid understanding of regulatory documentation requirements for clinical trials involving medical devices and pharmaceuticals in Canada, the US, Europe, and other countries/regions as required;
- Proficient with information technology systems and quality management systems.

KEY ACCOUNTABILITIES/TASKS AND DUTIES:

The Regulatory Affairs Specialist will provide a real knowledge of relevant regulatory processes to clinical trial planning, management, and execution. This position will require interaction with technical staff, physicians, researchers, senior healthcare administrators, and government staff. This position involves work on various projects with competing deadlines. The incumbent must have the ability to explain complex concepts while guiding ventures through structured, and often, unfamiliar regulatory processes. The incumbent must have:

- Excellent communication and writing skills;
- Ability and willingness to exercise judgement within established guidelines;
- Be a strong team player;
- Willingness to develop creative solutions to various challenges;
- And other duties as required as the position evolves.

REQUIRED SKILLS/ QUALIFICATIONS:

- MSc in a health science-related discipline or BSc in a health sciences-related discipline plus a minimum of 5 years of regulatory/medical affairs experience, specifically providing support for clinical trials involving medical devices, pharmaceuticals, or related life sciences-based products;
- Ability to facilitate and advise on the appropriate conduct of clinical trials within GCP, Health Canada, and other standardized guideline regulations;

- Proven thorough knowledge of regulatory standards in clinical trials involving medical devices and pharmaceuticals in Canada, the US, Europe, and other countries/regions;
- Documented experience coordinating regulatory aspects of successful clinical trials.

PREFERRED QUALIFICATIONS:

- Experience coordinating investigator-initiated and industry-sponsored trials;
- Regulatory Affairs Certification or Certification in the Society of Research Associates (SOCRA) preferred.

This position is a full-time position (37.5/hrs/wk), with overtime hours a possibility depending on project deadlines. Travel may be required.

Interested applicants are asked to forward their **resume and cover letter** to hr@innovatecalgary.com. Alternatively, resumes may be mailed to: HR, Innovate Calgary, 3655 36 Street NW, Calgary, AB, T2L 1Y8.

We thank all applicants for their interest; however, only those persons for whom we need further information, or are being considered for an interview will be contacted.

Application deadline: Posting will remain open until a suitable candidate is found.