**QUALITY SYSTEMS AND TRAINING SPECIALIST**

 **(CLINICAL RESEARCH)**

**Job Description**

Reporting to the President and Chief Executive Officer, the Quality Systems and Training Specialist works collaboratively to create common tools for health facilities with the aim to facilitate and optimize quality management and clinical research training in Quebec.

**Main Duties**

* Form and lead the CATALIS’ Quality and Training Advisory Committee while ensuring that committee members identify key clinical research compliance and training issues, and that simple and effective shared solutions are implemented for the benefit of health care institutions and private companies.
* Prepare and execute an action plan to facilitate and optimize the implementation of quality systems and clinical research training in Quebec. At a minimum, the action plan must include:
	+ The development, roll-out, and updating of a provincial clinical research training program for the various types of clinical research and of the tools and/or platforms to support its implementation and management
	+ The development, implementation, and updating of a qualification system for sites and their suppliers
	+ The identification and introduction of activities serving to develop an accessible and inclusive clinical research environment in Quebec by supporting the launch and operational excellence of new implementation sites for the FAST TRACK evaluation service and ensuring that these new units meet clinical research standards and requirements
	+ The identification, in collaboration with CATALIS’ Quality and Training Advisory Committee, of any other initiative that will promote clinical research quality standardization in Quebec health facilities.
* Help companies and clinician scientists to better understand the regulatory environment in Quebec and Canada.
* Contribute to panCanadian efforts while operating within the framework of the strategic activities supported by the CATALIS Network.
* Participate in assessing the quality and compliance of CATALIS’ other initiatives.
* Identify the need for hiring additional Quality Systems and Training Support resources and supervise this team (if applicable).
* Perform any other tasks related to this position.

**Requirements**

* University degree in a pharmaceutical-research related field (or equivalent experience)
* Over ten years of experience in quality systems/clinical research training management
* In-depth knowledge of quality assurance methods, PCB standards, and applicable provincial regulations
* Quality management experience in a pharmaceutical company, contract research organization or Quebec health institution is an important asset
* Experience in continuous improvement is an asset
* Extensive experience with regulatory inspections and pharmaceutical industry inspections, and being accustomed to working with these entities is also an asset

**Skills and Qualifications**

* Superior unifying leadership skills and strong ability to engage others
* Highly motivated and focused on quality and performance
* Ability to work in a rapidly changing environment and establish good relationships with colleagues, sites, and sponsors
* Excellent judgement and problem-solving skills
* Experience in project management and operations management
* Resourcefulness and ability to work independently
* Outstanding communication skills, in both French and English (spoken and written)
* Highly-developed listening skills
* Writing skills
* Political acumen, diplomacy, integrity
* Very good knowledge of Microsoft Office software (Word, Excel, Outlook, and PowerPoint), quality management systems, and learning management systems

**Working Conditions**

* Full-time position
* Flexible schedule (35hrs/week)
* Location: Montréal, telework, and on-site (as needed)
* Competitive insurance program

Please forward your CV to info@catalisquebec.com