Director, Quality Assurance and Regulatory Affairs

TRIO (Translational Research in Oncology) is a not-for-profit clinical research organization that is dedicated to advancing translational cancer research by pursuing forward innovative and targeted therapeutic concepts in the clinical trial setting. We are committed to providing treatments of the future to the world of today.

TRIO is looking for a Director of Quality Assurance and Regulatory Affairs (QARA) to join our TRIO Leadership team. We are seeking a Director who can manage high-level strategic initiatives and the day to day requirements of the QARA department. The preferable location for this role will be in Paris, France or TRIO's head office in Edmonton, Alberta, Canada.

Reporting to the Chief Executive Officer, this role is responsible for the following:

- Complement TRIO's global strategy by setting the strategic direction of the QARA department;
- Lead the QARA team on various projects/ initiatives as determined by the strategic plan;
- Manage the team of 5 direct reports, 2 in-direct reports, in Paris, France and home-based in Canada.
- Oversee the Clinical Quality Assurance (CQA), Regulatory Affairs (RA), and Computerized System Validation (CSV) units, including the review of the applicable metrics for their activities;
- Design and maintain an appropriate Quality Management System (QMS);
- Oversee and occasionally conduct audits;
- Manage the annual review of TRIO's Standard Operating Procedures and Standard Guidelines;
- Host external audits and inspections;
- Review study documents from a QA and RA perspective;
- Oversee Regulatory Intelligence;
- Act as one of the Data Privacy Officers as well as a Department Disaster Recovery Leader;
- System Owner for the CAPA Management System.

The successful candidate will have the following qualifications:

- Minimum Bachelor of Science degree
- 10 years of progressive clinical development experience in monitoring/project management/quality assurance/regulatory affairs, ideally in an international setting
- Minimum 7 years of experience in a Clinical QA Department with demonstrated knowledge in international clinical audits and SOP management
- Effective supervisory skills and team management
- Internal and external audit experience (investigator sites, contractors, etc.)
- Fluent written and oral English is required; French would be an asset
- Strong organization and communication skills

- Knowledge in oncology would be an asset

If this sounds like the opportunity you have been seeking please forward a cover letter and resume, by email to: human.resources@trioncology.org

Please quote requisition number **19-11** in the subject line when applying.

We thank all candidates for their interest; only those selected for an interview will be contacted.