NoNO Inc.

Position: **Project Leader, Quality Assurance and Training**
Reports to: **Director, Quality Assurance and Training**
Status: **Permanent**

NoNO Inc. is accepting applications for the position of **Project Leader, Quality Assurance and Training** to be based in our office in Toronto. The successful applicant will assist the Director, Quality Assurance and Training to develop and oversee all aspects of the company's quality management and regulatory compliance activities. He/she will be responsible for ensuring that all processes and systems comply with applicable industry standards and applicable regulatory agency regulations. The successful candidate will provide strategic and tactical development, implementation and execution as well as execution of the Training Programs. He/she will develop and coordinate GCP compliance training activities for Company staff to ensure adherence to applicable GCP regulations and guidance. The Project Leader, Quality Assurance and Training will also assist in the development, maintenance and delivery of training curricula in connection with GCP compliance requirements and will assist with any preparation, coordination and follow up of potential inspections by Regulatory Authorities.

RESPONSIBILITIES INCLUDE BUT ARE NOT LIMITED TO THE FOLLOWING:

- Assist in activities related to domestic and international GxP audits and inspections of clinical study sites, clinical laboratories, Contract Research Organizations (CROs), NoNO's clinical study documentation and data to ensure compliance, among other things, with applicable regulations, guidelines, study protocols and amendments, and SOPs.
- Assist in the preparation of audit reports. Review and evaluate audit responses to ensure that all non-conformance issues have been satisfactorily addressed. Communicate audit outcomes and QA recommendations to NoNO stakeholders.
- Assist in the preparation, revision and maintenance of Master Audit plans and, when applicable, associated Gantt charts for various projects involving QA.
- Manage the maintenance and update of the QA audit spreadsheet to track the status of compliance audits and audit findings.
- Follow up on deviations and investigations stemming from non-compliance issues.
- Coordinate with various NoNO Departments, including Clinical Development, Regulatory Affairs and Drug Safety in the development of compliance surveillance programs to assure internal and external compliance with regulations, guidelines, directives and applicable SOPs.
- Coordinate SOPs development, revision, withdrawal, maturity, approval and publishing for applicable internal Departments.
- Create and review Standard Operating Documents (SODs) that encompass Policies, SOP's, and Work Instructions and ensure internal compliance with these.
- Assist in the creation, revision and review of Quality Agreements.
- Provide recommendations on continuous process improvements to ensure ongoing compliance.
- Represent NoNO QA on cross functional project teams.
- Problem-solve and troubleshoot quality and compliance matters. Actively participate in and contribute to the achievement of NoNO objectives.
- Keep abreast of local and international GxP regulations, guidelines and directives.
- Performs all work in accordance with all established regulatory and compliance and safety requirements.
- Perform additional duties, as assigned.
- Work collaboratively with other Company employees, communicate effectively, and deliver work products in a timely manner.

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QUALIFICATIONS

- Minimum of 5 years relevant experience in a pharmaceutical or regulated setting or M.Sc. /B. Sc. with 4 years relevant experience.
- Robust knowledge of ICH GCP, Knowledge of EU and FDA pharmacovigilance regulations would be an asset.
- Must be able to deal with ambiguous and sometimes complex compliance issues in a knowledgeable and firm, but professional manner.
- Applied experience in the pharmaceutical industry.
- Knowledge of risk-based quality systems approaches consistent with ICH E6 for GCP.
- Understanding of study design and research best practices in the pharmaceutical industry.
- Excellent oral and written communication skills.
- Familiarity with Microsoft Office package.
- Availability and willingness to travel internationally (10-20%)
- International / global experience is an asset
- Fluent in verbal and written English
- Able to legally work in Canada
- Salary commensurate with experience

Please send Cover Letter and Resume in PDF format to qajobs@nonoinc.ca

Subject line: Job Application - QA Project Leader