IntelGenx Corp.

Manager, Quality Assurance (Research & Development)

Job Description

The **Manager, Quality Assurance** (Research & Development) will oversee and support the overall Quality and Compliance activities during the product development life cycle processes and to ensure related practices meet Health Authority regulatory requirements.

To apply for this position, please send your resume and cover letter to quality@intelgenx.com.

Job Responsibilities:

1. Supports Product Development team in Quality & Compliance in the process of developing and technology transfer of products to commercial quality operations.
2. Responsible for lifecycle management of development products with respect to assessing and interpreting regulatory requirements related to R&D activities.
3. Review CMC and non CMC related documents, including specifications, batch documentation, process descriptions and control strategy, equipment qualification and calibration related documents, process validation protocol and reports, etc.
4. Control of documents, issuance of working copies, verification of raw data and archival of hard copy documents.
5. Perform line clearance and AQL checks, review and approve batch records, packaging records, for clinical supplies / pilot batch activities, including providing approval and release for clinical supplies and registration samples.
6. Manage QA systems such as Change Control, Deviations, Lab investigations, and CAPAs for R&D (Product Development).
7. Perform routine self-inspection visits to the R&D and manufacturing area to ensure compliance and follow up with corrective actions.
8. Authors and provides guidance in the creation, review, training and updates to standards (e.g., SOPs, Work Instructions, training program) supporting product development and continual quality improvement initiatives.
9. Develops and provides GXP training in support of compliance systems and quality improvement initiatives within the organization.
10. Partner with various internal and external groups to analyze and present monthly R&D compliance/quality issue metrics, and recommends and assists with development of appropriate solutions.

11. Ensure “Audit readiness at all times” and ability to respond to audit queries from Regulatory Agencies and business partners.
12. Support Heath Authority product specific audits and follow up on the appropriateness and completeness of corrective action plans until closure.
13. Perform other duties as required or necessary.

Job Requirements:

- Min. BA/BS in Science, Engineering, Pharmaceutical Sciences or related technical discipline in a scientific discipline from a Canadian university or equivalent.
- Min. 5 years of experience in GXP setting and/or Regulatory Affairs role (or 2 years with Master degree).
- Proficient computer skills such as MS Office applications.
- Experience with early and late-stage products including validation.
- Proficient in English.
- Strong verbal and written communication including presentation skills.
- Diplomatic in communication with internal and external stakeholders.
- Demonstrate ability to prioritize work, manage multiple projects, act and work independently and to report items as required to Project Leader.
- Demonstrated experience managing complex quality and compliance activities in a manufacturing plant.