DESCRIPTION DE POSTE

Senior Specialist, Quality Assurance

Department	Global Regulatory affairs, Quality Assurance and Compliance
Direct Supervisor	Associate Director, Global Quality Assurance
Management of Team	N/A

Position Summary

The incumbent supports the Associate Director, Global Quality Assurance (QA) in order to ensure the consistency of the quality standards as per the Good Manufacturing Practices (GMP) during the documentation review, including but not limited to the specifications, master documents, change control, complaints, audits, CAPAs, SOPs, etc; to approve or reject the release of Active Pharmaceutical Ingredients (APIs),finished drug product batches, and /or injection kits. We are seeking a talented and experienced quality assurance subject matter expert who is excited to join a dynamic and growing organization and who is committed to deliver excellence in all projects under their responsibility.

Key Responsibilities

- Support in the QA activities
  - ✓ Reviews specifications and acceptance criteria
  - ✓ Ensures that the products' manufacturing, packaging and testing are defined, controlled and in conformity with GMPs
  - ✓ Reviews stability data and approves retest or expiry date
  - ✓ Evaluates the APIs and end-products' quality and determines whether to withhold the batches or release them
  - ✓ Ensures that all manufacturing steps are followed and in conformity with GMPs
  - ✓ Participates in complaints' evaluation in order to identify the causes and recommends corrective/preventive actions.
  - ✓ Evaluates incidents and provides corrective/preventive actions
  - ✓ Participates /supports regulatory audits
  - ✓ Reviews/evaluates change controls
  - ✓ Ensure timely completion of deviations, complaints, CAPAs, change controls, etc. as per established procedures
  - ✓ Contributes to the maintenance of the Quality System and the KPIs report
  - ✓ Escalates any deviation to GMPs, complaints or risk assessments that may impact the patients' security or the product's quality, integrity or purity

- ➢ Support in the compliance-related activities
  - ✓ Ensures that policies and procedures are written and revised to ensure their conformity with regulatory standards
  - ✓ Reviews all documents, packaging and labels to ensure conformity
  - ✓ Participates in the preparation and presentation of the Annual GMP training
  - ✓ Supports regulatory audits

- ➢ Key resource person for Quality Assurance matters

- ✓ Acts as the representative of the quality team in the various committees and working groups
- ✓ Evaluates and ensures the disposition of returned product

- Documentation, procedures and systems
  - ✓ Reviews/approves masters, including specifications, manufacturing and packaging master batch records, protocols, validation reports and any other GMP documents
  - ✓ Verifies temperature data during the transportation of the products and determines their status/disposition
  - ✓ Determines the disposition of a nonconforming product and proposes the necessary solutions
  - ✓ Evaluates/approves change controls, audits, out of specifications investigations and external suppliers' deviations
  - ✓ Reviews the manufacturing documentation and the investigations for customers' complaints related to product manufacturing and packaging
  - ✓ Drafts and/or approves external procedures, specifications, risk assessments, deviations, preventive/corrective measures, change controls, etc.
  - ✓ Prepares forms, memos, lists and reports as required.

- Performs any other task as requested by management

External Clients

- Quality team of external partners, manufacturers and suppliers

Required Qualifications

- Bachelor's degree in Pharmacy, Chemistry, Biology or Chemical Engineering
- Training in Quality assurance
- 5-8 years of quality assurance experience in the pharmaceutical industry, ideally with sterile products, pharmaceutical a/o biological products
- Good understanding or experience in laboratory research, pre-clinical and/or clinical research is an asset
- Experience with regulatory inspections, supplier audits and internal audits
- Experience in policies and procedures related to the pharmaceutical compliance program
- Excellent knowledge of the GMP, GLP, GDP, as well as the pharmaceutical industry's guidelines and regulations in Canada and United States
- Knowledge of the pharmaceutical industry guidelines and regulations in Europe is an asset
- Knowledge in Good Clinical Practice is an asset
- Knowledge of Word, Excel, PowerPoint and Outlook
- Previous experience working with databases
- Bilingual French and English, spoken and written
- Excellent English authoring/writing skills

Personal Qualities for all Personnel

- Ability to define objectives and meet timelines
- Ability to determine priorities
- Ability to bring ideas and find solutions

- Can work alone or in a team
- Team spirit and collaborative
- Flexibility

Personal Qualities Specific to the Position

- Leadership and accountability
- Result-oriented
- Ability to negotiate and influence others
- Multitasking
- Analytical capabilities and ability to synthesize information
- Planning and organizational skills
- Good stress management
- Attention to detail and quality
- Verbal and written proficiency
- Thoroughness in accomplishing tasks
- Available for occasional business travels