JOB DESCRIPTION

Senior Specialist, Quality Assurance

Service	Regulatory Affairs, Quality and Conformity
Supérieur immédiat	Associate Director, Quality Assurance
Gestion d'équipe	N/A

The incumbent supports the Associate Director, 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 quality agreements, products' annual reviews, specifications, change control, complaints, audits, CAPAs, SOPs, etc.; to approve or reject the release of Active Pharmaceutical Ingredients (APIs) or end-product batches. The incumbent will also support the Director of Regulatory Affairs, Quality and Compliance in compliance-related tasks.

Key Responsibilities

- Support in the QA activities
  - Reviews acceptance specifications and criteria
  - Ensures that the products' manufacturing, packaging and analysis are defined, controlled and in conformity with the GMP
  - Reviews the stability data and approves the new testing or expiry date
  - Negotiates quality agreements with the various external partners
  - 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 the GMP
  - Participates in the complaints' evaluation in order to identify the causes and recommends corrective/preventive actions.
  - Evaluates the incidents and provides corrective/preventive actions
  - Participates as QA expert to the regulatory audits
  - Reviews/evaluates change control
  - Ensure timely completion of deviations, complaints, CAPAs, change control, etc. as per the established procedures
  - Contributes to the maintenance of the Quality System and the KPI's report
  - Escalates any deviation to the GMP, complaints or risk assessment 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 the standards
  - Reviews all documents, packages and labels to ensure proper conformity
  - Conducts internal audits to ensure the conformity with internal procedures and GMP rules
  - Supports regulatory audits

- Key resource person for Quality Assurance Matters
  - Acts as the representative of the quality and compliance team in the various committees and work groups
  - Evaluates and ensures the disposal of returned product

- Documentation, procedures and systems
  - Reviews/approves the master, including specifications, manufacturing and packaging master batch records, protocols, validation reports and any other GMP document
  - 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, below average results' investigations and external suppliers' deviations
  - Reviews the production 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 requests, etc.
  - Drafts the annual quality review of the products
  - Produces forms, memos, lists and reports for required documentation.

- Performs any other task as requested by management

External Clients

- Quality team of external partners, manufacturers and external suppliers

Required Qualifications

- Bachelor's degree in Pharmacy, Chemistry, Biology or Chemical Engineering
- Quality assurance background
- 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 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
- Knowledge of Word, Excel, PowerPoint and Outlook
- Previous experience working with databases
- Bilingual French and English, spoken and written

Personal Qualities for all Staff

- Ability to set goals and objectives and meet deadlines
- Ability to prioritize

- Ability to generate ideas and find solutions
- Ability to work independently and in a team environment
- Team spirit and willingness to assist team members
- Versatility and 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