

## Senior Manager, Quality Assurance

Astellas Pharma Canada is currently searching for a Senior Manager, Quality Assurance reporting to the Director, Product Quality Operations, Americas Region. This position located in our Canadian Head Office in Markham, Ontario.

### Description:

The Senior Manager, Quality Assurance is responsible for leading and directing all aspects of quality assurance functions for Astellas Pharma Canada, Inc. (APCA). This role is also responsible for ensuring that all activities and systems, which have direct or indirect effect on product quality, are designed and implemented to achieve compliance with current good manufacturing practices and Corporate and APCA policies. In addition, the Senior Quality Assurance Manager is responsible for directing the Quality Assurance group to execute timely approvals to support the changes to Marketed Products and maintain product supply.

### Essential Job Duties:

- Directs and supports APCA GMP activities for manufacturing, packaging, labeling and distribution including supporting supplier issue resolution, audits and regulatory authority inspections for all products marketed to ensure continuous product supply. Manages recall activities as required.
- Approves or rejects all batches of marketed drug products and ensures proper procedures are followed in determining release or rejection of a batch.
- Represents Canadian interests and actively contribute to Astellas Quality Assurance to ensure smooth implementation of planned manufacturing changes affecting product supply and stability requirements of commercial products during shelf life are met.
- Manages Health Canada GMP inspections.
- Maintains Establishment License for APCA by ensuring all foreign and local manufacturing sites comply with Canadian GMPs. Ensures filing of any updates to registered information for all manufacturing sites to maintain compliance.
- Applies quality risk management principles to develop innovative approaches to managing risk through auditing, metrics, exception management, and quality initiatives; facilitates remedial solutions across regulated functions. Manages audit data to track and trend meaningful metrics for use in systemic issue identification and resolution, summarizing compliance risks, process improvement opportunities and implementation of CAPAs.
- Ensures all necessary Quality System Documents (e.g. SOPs, WPDs, Quality Agreements and any other) required for meeting compliance requirements are in place. Authors/ revises Quality System Documents as necessary.
- Provides timely notification of trends or specific quality deviations as recognized in matters related to products, personnel or facilities and recommends corrective action to the Director, PQO AMR and or APCA Director RA & QA or API quality Assurance officers. Keeps them informed of Operational Compliance status, of failure of products to meet quality standards, and of any anticipated problems as and when required or at suitable intervals according to his/her own discretion.
- Reviews and approves all APCA product labels and ensures all trade dress and regulatory requirements are met with respect to product labels.

- Collaborates with APCA and Astellas regional and global stakeholders to ensure Quality Assurance oversight and compliance with Health Canada and corporate policies and guidelines. Participates in Astellas Regional Quality meetings and communicates with appropriate QA personnel or key stakeholders regarding project specific information.
- Keeps abreast of developments and changes in Health Canada regulations, policies and guidelines and industry practices, assesses their impact on APCA business and provides proactive guidance to management to drive continued success.
- Coaches and develops reports to serve on APCA cross-functional project teams. Supervises, interviews, hires new employees, carries out performance appraisals, objective negotiation, directs the training and development of staff and carries out disciplinary action

#### **Required Qualifications**

- B.Sc. Degree in science (chemistry or health related science).
- Minimum 7 years' experience in quality assurance with people management skills.
- Demonstrated skills in problem solving, planning, organizing, follow-up and resource management.
- Proven ability to motivate and manage a group effectively required.
- Ability to advise, direct and manage staff to resolve problems and to achieve goals on schedule.
- Excellent interpersonal skills, organizational, leadership skills, teamwork, written and verbal communication skills.
- Proficient in MS Office.

#### **Preferred**

Bilingual English and French an asset.

If your skills and experience match our needs, please email your resume to:

[employment@astellas.com](mailto:employment@astellas.com).

Astellas Pharma Canada welcomes and encourages applications from people with disabilities. Accommodations are available on request for candidates taking part in all aspects of the hiring process.

*No telephone inquiries, in-person applications, or agencies please. While we appreciate all applications, only candidates under consideration will be contacted.*