

Quality Assurance Associate

Astellas Pharma Canada is currently searching for a Quality Assurance Associate reporting to Senior Manager, Quality Assurance. This position is located at the office of Astellas Pharma Canada., Inc. in Markham, Ontario.

Description:

The Quality Assurance Associate is responsible for reviewing laboratory test results and manufacturing batch document and release of finished product. In addition, this position is responsible for the maintenance of SOPs, Product Masters, Stability and Validation Binders along with handling the product complaints in the Quality Assurance system. This role is also responsible for maintaining the change control system in the Quality Assurance system as well as assisting in external and self-audits.

Essential Job Duties:

- Reviews laboratory test results (raw data) against approved Astellas specifications and methods. Reviews manufacturing batch documents against the current Master Batch Records.
- Facilitates the QA SOP revisions and updates the SOP Binders. Updates the Product Masters, Stability and Validation Binders.
- Documents product complaints and updates the files as new information is received.
- Manages Change Controls for assigned products.
- Assists QA audit process as required.
- Prepares/reviews deviations that impact quality of products.
- Co-ordinates laboratory testing as required.
- Prepares batch documents files from manufacturing facilities, approves and releases products.
- Performs other duties as assigned.

Required Qualifications

- B.Sc. Degree in Chemistry, Microbiology or Life Sciences.
- Minimum of 2 years relevant work experience in the ethical pharmaceutical industry.

- Thorough knowledge of GMP regulations and testing technology in chemistry and microbiology.
- Excellent written and verbal communication skills are required, including French as asset.
- Meticulous attention to detail.
- Proficient in Microsoft

Preferred Qualifications

- Bilingual (English/French) preferred

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