Quality Assurance Manager

Title

Quality Assurance Manager

Reports To

Vice President of Operations

Summary

The QA Manager is responsible for, but not limited to, working cooperatively with the President, the Chief Scientific Officer and other department heads, to ensure compliance with all aspects of GMP regulations as required by Health Canada MMPR, the US FDA, and corporate contractual obligations.

Core Competencies

- Accountability
- Adaptability
- Communication
- Critical Thinking
- Planning and Organizing
- Problem Solving
- Service Orientation
- Teamwork

Job Duties

- Ensure compliance with GMP regulations as required by Health Canada, the US FDA, orother jurisdictions in order to obtain GMP status (e.g. the Establishment License).
- Participate in internal GMP and third party Audits.
- Participate in analytical investigations of out-of-specification, examine results, change controlrequests when necessary, generate deviation reports, root cause determination, and providerecommendation for corrective actions.
- Act as authority for all interaction with Health Canada, external agencies and contracts forquality assurance and regulatory compliance related activities and documentation.
- Act as authority on validation of IQ/OQ/PQ, which include test methods, machines, operationprocess, cleaning, etc.
- Act as authority on release, rejection, customer complaint management and potential recallof all products sold by the company; ensure that customers are satisfactorily dealt with in atimely manner.
- Make decisions on release or rejection of materials based on sound judgment andcompliance to regulatory requirements, reports and specifications.

- Write, review and revise SOPs, quality policies and procedures, customer methods to ensurecontinuous compliance with GMP and regulatory compliance as well as customerrequirements.
- Review and approve method transfer and validation protocols and reports.
- Provide assistance and technical support for equipment or process optimization, validation,calibration, qualification or certification.
- Contact customers and internal departments to respond to their inquiries and resolve QAissues.
- Handle export document application such as ITC, Export Certificate, and Manufacture Declaration.
- Provide GMP and SOP training for staff.
- As required, coordinate the Safety Unit Officer and the Chief Scientific Officer for staff trainingon WHMIS.
- Participate in other tasks that may be assigned by the President & CEO.
- Assessment and validation of analytical methods for GMP applications
- Data review, approval of final reports
- Leadership in root cause analysis and investigation of out of specification results.
- Advanced knowledge of GMP and the US FDA regulations for manufacturing/packagingpharmaceutical or nutraceutical products.
- Familiarity with the regulatory requirements of foreign jurisdictions would be considered an asset.
- Able to work as a team and possess soft skills such as personnel integrity, and interpersonalskills.
- Proven ability to supervise personnel and excellent verbal/written communication skills.
- Analytical instrument calibration and preventative maintenance
- Perform all procedures accurately and according to written Work Instructions, Quality Systems and Regulatory requirements.
- Perform testing at all levels of production including raw materials, in-process components, finished products and stability testing.
- Perform visual finished product inspections.
- Performs required testing for customer complaint investigations.
- Perform failure investigations at the direction of the Quality & Regulatory Manager/designee.
- Recommend acceptance or rejection of raw material, component, finished product and other materials evaluated based upon established specifications.
- Document all paperwork according to procedures and protocols and write or revise inspection procedures as necessary.
- Update computer records/ERP and/or make calculations accurately as required,
- Maintain neat and legible manual forms. Maintain a clean, organized work area and keep supplies stocked at the bench.
- Conduct and report on the product stability testing program designed to support product stability claims.
- Perform documentation of trending data.
- Actively participate in performing validation protocols.
- Ability to interface with all levels of the organization effectively.
- Recommend and assist in the implementation of ongoing process improvements.
- Planning, organizing and supervisory responsibilities for daily lab functions
- Coaching a team of seasoned chemists performing chemical and physical analyses

- Assessment and validation of analytical methods for GMP applications
- Data review, approval of final reports
- Leadership in root cause analysis and investigation of out of specification results
- Preparation of Protocols for compendial method verification
- Analytical instrument calibration and preventative maintenance
- Preparation of method verification and validation Protocols and reports

Requirements

- You are skilled in chromatography and wet chemical analyses and have experience applying compendial methods to a wide variety of matrices.
- You have a track record of leading an effective team of analytical chemists, problem solving analytical methods, OOS investigations and assisting others with root cause analysis.
- Your degree is in chemistry or a related field, with a minimum of five years' experience in a pharmaceutical quality control laboratory. Supervisory and leadership skills would be a definite asset.A B.Sc. degree or equivalent in an applicable discipline of science (chemistry, biochemistry,medicine or related).
- Three or more years of QC/QA experience in the pharmaceutical/nutraceutical relatedindustry.
- Advanced knowledge of GMP and the US FDA regulations for manufacturing/packagingpharmaceutical or nutraceutical products.
- Familiarity with the regulatory requirements of foreign jurisdictions would be considered anasset.
- Able to work as a team and possess soft skills such as personnel integrity, and interpersonalskills.
- Proven ability to supervise personnel and excellent verbal/written communication skills.
- Knowledge in the following areas desirable but not required:
    - Chromatography
    - wet chemical analyses

Work Conditions

- Physical ability to lift up to 50 lbs.
- Safety equipment will be required, e.g. steel-toed safety boots, safety glasses/goggles, etc.
- Overtime as required
- Hazards associated with the trade
- Work both indoors and outdoors