Qualified Person In Charge

Title

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Summary

The Qualified Person in Charge 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/GPP regulations as required by Health Canada Cannabis Act, the US FDA, and corporate contractual obligations. This position requires Health Canada security clearance.

The QPIC is responsible for supervising activities with respect to narcotics specified in the licence, and for ensuring, on behalf of the standard processor, that those activities comply with these Regulations and the Cannabis Act.

Core Competencies

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

Job Duties

- Ensure compliance with GMP/GPP regulations as required by Health Canada, the US FDA, or other jurisdictions in order to obtain GMP/GPP status (e.g. the Establishment Licence)
- Conduct assessment and validation of analytical methods for GMP/GPP applications
- Participate in internal GMP/GPP and third party Audits
- Ensure compliance with all QA/QC related regulations
- Provide leadership in root cause analysis and investigation of out of specification results
- Conduct results examination and analytical investigations of out-of-specification occurrences
- Generate deviation reports, conduct root cause analyses and provide recommendations for corrective actions as well as respond to change control requests when necessary

- Act as the authority for all interactions with Health Canada, external agencies and contracts for quality assurance and regulatory compliance related activities and documentation
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- Make decisions on the release or rejection of materials/products based on sound judgment, regulatory requirements, reports and specifications
- Write, review and revise SOPs, quality policies and procedures and methods to ensure continuous compliance with GMP/GPP
- Review and approve method transfer, validation protocols and reports
- Act as the authority on validation of equipment as per IQ/OQ/PQ Protocol providing assistance and technical support for equipment or process optimization, validation, calibration, qualification and/or certification
- Contact customers and internal departments to respond to their inquiries associated with the resolution of QA/QC issues
- Handle export document applications such as ITC, Export Certificate and Manufacturer's Declaration
- Provide GMP/GPP and SOP training for staff
- As required, coordinate with the Safety Unit Officer and the Chief Scientific Officer for staff training on WHMIS
- Participate in other tasks that may be assigned by the President & CEO
- Conduct and/or oversee analytical instrument calibration and preventative maintenance
- Perform precision work with instruments to conduct laboratory studies to test, evaluate and screen products
- Perform assessment and validation of analytical methods for GMP/GPP applications
- Conduct programs of sample data collection and analysis
- Prepare protocols for compendial method verification
- Prepare method verification and validation protocols and reports
- Review data and provide approval of final reports
- 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
- Conduct and report on the product stability testing program designed to support product stability claims
- Actively participate in performing validation protocols -Perform visual finished product inspections
- Recommend acceptance or rejection of raw material, component, finished product and other materials evaluated based upon established specifications
- Perform required testing for customer complaint investigations
- Document all paperwork and prepared reports according to procedures and protocols
- Write or revise inspection procedures as necessary

- Perform documentation of trending data
- Recommend and assist in the implementation of ongoing process improvements.
- Update computer records/ERP Quality Assurance Manager
- Perform mathematical calculations accurately as required and to understand and apply advanced mathematics for research purposes
- Maintain neat and legible manual forms
- Ensure maintenance of a clean, organized work area and that supplies are supplies stocked
- Supervise personnel in an effective manner
- Conduct planning, organizing and supervisory responsibilities for daily lab functions
- Coach and oversee a team of chemists and/or laboratory technicians performing chemical, biological and physical analyses

Requirements

- Familiar with the provisions of the Act and the regulations that apply to the licence of the standard processor
- Advanced knowledge of chemistry and pharmacology
- Advanced knowledge of GMP/GPP and the US FDA regulations for manufacturing/packaging pharmaceutical and/or nutraceutical products
- Demonstrated ability to supervise personnel and effectively lead a team of analytical chemists and/or laboratory technicians
- Demonstrated ability to problem solve, perform analytical methods, conduct OOS investigations and assist others with root cause analyses
- Demonstrated ability to perform compendial methods to a wide variety of matrices
- Ability to interface with all levels of the organization effectively
- Ability to work as a team member exhibiting integrity, respect and commitment
- Possess excellent interpersonal, communication and verbal/written skills
- Attention to detail and precision in all aspects of work -Experience in the following areas desirable but not required:
- Chromatography
- Wet chemical analyses
- Familiarity with the regulatory requirements of foreign jurisdictions would be considered an asset

Qualifications

- Experience as a pharmacist or a practitioner of medicine, dentistry or veterinary medicine, registered with a provincial professional licensing authority
- Possess a Graduate degree in an applicable science (PhD preferred), such as pharmacy, medicine, dentistry, veterinary medicine, pharmacology, organic chemistry or chemical engineering or related, with a minimum of 3-5 years QC/QA experience in a pharmaceutical/nutraceutical related industry and/or pharmaceutical quality control laboratory

Work Conditions

- Light strength demands; 5-10 kg (11-22 lbs)
- Sitting, Standing, Walking
- Safety equipment will be provided as needed
- Overtime as required
- Hazards associated with the profession (e.g. use of chemical substances, odours, equipment)

Job Type : **Full-time**