Aleafia Health

Validation Specialist

Paris, ON | Full-time

Aleafia Health is committed to being Canada's leading patient-focused healthcare enterprise offering medical cannabis care. Our mission is to build a global cannabis brand. Through education, research, and development, we will advance the cultivation and science of medically authorized cannabis.

Reporting to the Sr. Quality Assurance Manager. The primary purpose is to provide expertise for the generation, execution, modification and summation of Validation documents of equipment (manufacturing and laboratory), processes, cleaning, sanitizing and facilities aspects of Paris' manufacturing site that may affect the quality of the product produced or tested. This is accomplished through interaction and co-ordination of activities with all relevant departments within the organization.

ESSENTIAL FUNCTIONS

- Write Validation Protocols addressing all critical functionality and limits for equipment and processes required to be validated (IQ/OQ/PQ/Process).
- Ensure protocols provide:
- a high degree of assurance that a specific equipment or process will consistently produce a product meeting predetermined specifications and attributes,
- assurance of the establishment of controls required by current Good Manufacturing Practices (cGMP).
- Responsible and accountable for the execution of Validation Protocols including:
- observation and documentation of the equipment or process,
- collection of samples,
- coordination of testing and
- coordination of third party services.
- Perform change control assessment and determine impact to validation equipment and processes.
- Write reports that summarize and assess impact of the results generated through the Validation Protocols. Where required, recommend corrective measure(s) with the objective of attaining validated status.
- Evaluate new equipment from a validation perspective through participation on the equipment selection team with engineering to ensure that new purchases will be capable of meeting validation requirements.
- Apply statistical methods (as required) in process validations and equipment qualifications
- Maintain Validation documentation archive ensuring prompt document retrieval when required.
- Write Validation related SOP's or Policies as required.
- Collaborate with internal stakeholders to ensure equipment is qualified/re-qualified and processes are validated/re-validated as required and according to schedule.
- Identify deviations from established process or equipment standards and provides recommendations for resolving deviations.

- Manage effectively all assigned Validation projects.
- Provide training specific to validation protocol requirements for sampling, to the production department
- Train Aleafia personnel on validation related SOP's as required.
- Establish strong relationships inter- and intra-departmentally and provide leadership and guidance.
- Participate in and/or lead Non Conformance Investigations
- Complete Corrective and Preventive Actions (CAPA's)
- Initiate, and follow through with actions required to close Change Controls
- Participate in Internal, Customer and Regulatory Audits.
- Participate in internal or external training programs to maintain knowledge of validation and qualification principles, industry trends, or novel technologies.

ROLE REQUIREMENTS/ABILITIES

Experience / Education

- Degree in a relevant field, such as: Pharmaceuticals, Biotechnology, Engineering, Manufacturing, Quality Assurance, Quality Control, Laboratory Sciences Certification as a Quality Engineer, Process Analysis, Continuous Process Improvement, LEAN or Six Sigma considered an asset.
- 3 to 5 years of experience in Validation, with experience in equipment qualification, process and cleaning validation.
- 2 to 5 years of experience of working in Production/Quality department in pharmaceutical manufacturing environment
- Familiarity with regulatory requirements with respect to validation and qualification activities in pharmaceutical industry.
- Certification in Project Management, while not required is considered a plus.
- Knowledge of GMP, Health Canada and ISO.

Skills & Abilities

- Systems and process thinker who understands the importance of continuous improvement and how it fits within the Quality Management System and Risk Management.
- Previous experience in process design, flow mapping, writing and conducting process validations and equipment qualifications.
- Demonstrated ability in project management and project management tools.
- Strong computer skills (Word, Excel, PowerPoint, Visio, etc).
- Must be well organized.
- Exceptional listening, communication, analytical and problem-solving skills.
- Ability to handle multiple priorities and a dynamic changing environment.
- Able to bring innovative solutions to process and equipment design and flow mapping.
- Flexible, adaptable and previous experience in a fast-paced environment.
- Strong relationship-building capabilities.
- Collaborative, team-oriented and versatile.
- Other duties as assigned

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Note: The chosen applicant will be required to successfully complete reference checks and a criminal background check.

We appreciate the interest by all candidates however we will be contacting those that best fit the requirements. Aleafia Health welcomes and encourages applications from people with disabilities. Accommodations are available on request for candidates taking part in all aspects of the selection process. If you are selected to participate in the recruitment process, please inform Human Resources of any accommodations you may require. Aleafia Health will work with you in an effort to ensure that you are able to fully participate in the process.

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