IVC Vita Health – Plant Validation Specialist – 12-month term

Job details

Job Type
Full-time
Fixed term contract
Shift & Schedule
8 hour shift
Day shift
Monday to Friday

Benefits

- Dental care
- Employee assistance program
- Life insurance
- Paid time off
- Vision care

Assists the Validation Supervisor in coordinating validation projects. Design, execute, and maintain the validation program for equipment, computerized systems, facility and utilities, cleaning, and process packaging validations to ensure compliance with GMP and regulatory requirements.

- Develop verification and validation protocols (IQ, OQ, and PQ) and other required documentation (URS, FS, TM, SR etc.) for equipment, facilities and utilities, cleaning, process packaging, and computerized systems. Assist in the procurement and "Design Qualification process" for new equipment and computerized systems, including preparation of URS and FS. Implement/execute validation and verification protocols.
- Perform validation (DQ/IQ/OQ/PQ, and Revalidation projects) of computerized systems, such as quality document management system, enterprise resource planning, computerized maintenance management system, spreadsheets, and other IVC Vita Health systems.
- Perform investigations, review calibration reports, assess equipment equivalency and/or revalidation assessment study in response to changes in raw materials, control system/computer software, equipment use and/or process steps; and assist/participate in the organization's "continuous improvement" projects.
- Proposed equipment upgrades (hardware/software), as required.
- Review and maintain Master Validation Plans (Equipment, Facilities/Utilities, Computer-Systems, and Cleaning)

- Assist in evaluation of Change Control requests, execution of engineering/feasibility studies, performing risk assessment, drafting technical reports and SOPs, and providing advice for revalidation efforts.
- Communication of specific protocol and/or general validation objectives and coordination of protocol execution (project management) skills are necessary; formation of partnership relationships and negotiation of reasonable objectives, commitments, timelines and execution schedules; communication in written or verbal form with internal customers (such as new product development, production, quality groups) or with external customers (vendors, contractors or other service providers). In all cases, expectation is for ability to clearly communicate requirements or outcomes and provide expertise in problem-solving situations where applicable.
- Participate as subject matter expert in both internal and external regulatory inspections.
- Perform periodic validation assessment of equipment, facility/utilities, computer systems, and cleaning process.
- Maintain CSV-software registry (and track validated statuses of listed GMP software-applications).
- Perform decommissioning activities of validated computer systems and equipment.
- Perform calibration on assigned equipment.
- Other duties as assigned by Plant Validation Supervisor

5+ years of relevant job experience in pharmaceutical equipment / facility qualification or similarly regulated environment is preferred; prior practical work experience and mechanical aptitude would be of value.

University Degree or Diploma in Science or Engineering (Mechanical, Electrical or Electronics).

CET (Certified Engineering Technologist) is an asset.

Expected high performance behaviors:

- Strong written /oral communication and interpersonal skills.
- Strong technical writing and communication skills
- Self-motivated; takes initiative (“self-starter”)
- Ability to work confidently, either independently or within groups/departments; ability to work proactively to meet deadlines.
- Knowledge of GMP regulations, Computer System Validation (CSV), Metrology, project management, requirements, MS-Office, MS-Projects and MS-Visio; familiarity with industry regulations/guidance, and abilities to develop (and improve): test instrument calibration procedures and test-cases for URS/FRS (user requirement specifications/functional requirement specifications) for computerized-system validation projects are definite assets.
- Knowledge in developing protocols for CSV, and IQ/OQ/PQ test-cases, is essential, to ensure system accuracy, reliability, and consistent intended performance; and the ability to suitably assess/control/maintain data integrity.

- Manual dexterity
- Prolonged sitting, walking, and standing.
- Working on a computer

Opportunity deadline: July 12, 2023.

To apply for this opportunity, please click here: https://recruiting.ultipro.ca/VIT5000VITH/JobBoard/c331edde-41fd-44ca-a09a-edc53cee1e4a/Opportunity/OpportunityDetail?opportunityId=cd7e9cad-15ec-4c81-bf7f-78424a08d5e7

Job Types: Full-time, Fixed term contract

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Schedule:

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Ability to commute/relocate:

- Winnipeg, MB R2J 3W2: reliably commute or plan to relocate before starting work (required)

Application question(s):

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Work Location: In person