Job Title:	Process Validation Engineer
Reports To:	Facilities & Equipment Manager
Location:	13562 Maycrest Way, Richmond, BC, Canada V6V 2J7
Date:	

Purpose/Role

A brief description of the primary responsibilities for which the employee is accountable

The Process Validation Engineer is responsible for providing technical support to operations in terms of equipment, facility and process initial validations and re-qualifications. Will participate in equipment and facility improvement teams charged with enhancing the compliance and performance, while considering the regulatory requirements for change control.

Position Description

A listing of the deliverables to be accomplished, including specific duties/activities that make up the job

- Lead the Process Validation of a new cleanroom facility as per ISO 14644 Cleanrooms and Associated Controlled Environments.
- Analyze, investigate, troubleshoot processes that go out of specification
- Executes equipment validation studies (IQ, OQ, PQ) to include protocol preparation, scheduling, protocol execution, and final report preparation.
- Participates in developments/ improvements to validation programs as needed to remain current with industry standards.
- Participates in teams assembled to specify, install, validate, troubleshoot and maintain systems and equipment.
- Participate and collaborate with R&D, Manufacturing and Operations leaders for nonconformance's and investigations to identify root causes and define corrective and/or preventative actions (NC, PDR, INV, CAPA) related to equipment and facility.
- Provide technical guidance as subject matter expert for process validation, statistical techniques and process control.

Qualifications

Represents the desired qualifications but may not reflect the employee's existing qualifications

Education:

- Engineering degree

Experience:

- 3-5 years in medical device industry in a Quality Engineering or Process Validation Engineering position.
- Experience with process validation, statistical techniques, Quality System Requirements and problem solving/ root cause analysis.

Skills:

- Excellent attention to detail and working knowledge of ISO 13485, ISO 14644 Cleanrooms and Associated Controlled Environments, FDA Regulations/Guidance, and Good Manufacturing Practices
- Strong communication and organizational skills
- Knowledge of applicable global regulations related to the medical device industry.
- Broad statistical knowledge.
- Strong problem-solving skills and solution focused.
- Self-motivated and strong leadership skills.
- Experience with validating autoclaves, laser cutters, function testers or other similar medical device equipment an asset.

The purpose of this description is to provide a concise statement of the major responsibilities of this position in a standardized format. It is not intended to describe all the elements of the work that may be performed and should not serve as the sole criteria for personnel decisions and action.

Approvals:

_____ _____

Employee (signature) Date

_____ _____

Manager (signature) Date