

Department:	VALIDATION	Classification:	EXEMPT
Division:	FERNDALE LABORATORIES, INC.	Reports to:	VP, Quality Control
As Of Date:	11/12/2015		

JOB SUMMARY

Responsible for preparing, executing and finalizing equipment, system and utility IQ, OQ and PQ's. Also, required to maintain the requalification program and equipment calibration program.

ESSENTIAL FUNCTIONS

- Maintains the calibration program and performs calibration of Validation, Laboratory and Manufacturing equipment .
- Maintains compliance of Manufacturing/Quality Control/Development equipment through the requalification program.
- Writes and reviews relevant Standard Operating Procedures (SOPs).
- Updates/revises Validation master plans.
- Performs new equipment validations: assessing, vendor documentation, developing protocols for qualification and participating in factory acceptance testing.

ADDITIONAL RESPONSIBILITIES

- Performs validation studies, evaluates and analyzes validation data related to projects and writes reports
- Assists in maintaining the cleaning program and also performing cleaning validations and checks as needed.
- Supports and reviews equipment calibration, and data packages/documents of colleagues as needed.
- Write-up or assist in quality investigations pertaining to equipment calibration and cleaning failures..
- Assists in responding to audit observations from FDA, MHRA, and other regulatory agencies or third parties.
- All other duties as assigned.

KNOWLEDGE, SKILLS, & ABILITIES

Requires 1-3 years of Pharmaceutical manufacturing. Validation, QC, and QA experience preferred. Experience in the field of writing and executing validation protocols for a wide variety of manufacturing equipment. Hands on experience with calibration, routine maintenance and troubleshooting of manufacturing and/or laboratory equipment. Experience with pharmaceutical water systems. Knowledge of cGMP and FDA policies. Cleaning Validation experience a plus. Must work well within teams. Excellent written and verbal communication skills as well as computer skills including, spreadsheet capability, Microsoft Excel, Word and data base management. SOP writing skills required. Ability to handle multiple projects.

EDUCATION

Prefer a Bachelor's Degree or equivalent education/experience with pharmaceutical background.

APPLY BY:

Qualified individuals interested in applying for this position- please submit your resume to Danielle Maloney in Human Resources (x525) or send to: employment@ferndalelabs.com by Monday, November 30, 2015.

**EEO Employer Vet/Disabled
 E-verify Participant.**

NOTE: This document is a guideline and is not intended to be all inclusive of the job or work responsibilities. The employee understands that they are required to perform all work assigned by their supervisor provided it does not violate any laws or regulations, or expose the employee to any physical or health hazards.