



TITLE: Engineer, Instrument Process and Development

REPORTS TO: COO, Great Basin Scientific/Vela Operations

Company Overview

Great Basin, a subsidiary of Vela Diagnostics, is a molecular diagnostics company that is dedicated to the development of simple, yet powerful, sample-to-result technology and products that provide fast, multiple-pathogen diagnoses of infectious diseases. Our vision is to make molecular diagnostic testing so simple and cost-effective that every patient will be tested for every serious infection, reducing misdiagnoses and significantly limiting the spread of infectious disease.

We are looking for a dynamic team member who enjoy working in a fast-paced environment to produce high quality medical devices for our customers and their patients. If you enjoy working in a team environment and being an early contributor on a dynamic team producing high quality products please apply!

Position Summary

This position is responsible for initial manufacturing and repair and improvement of process and design for the Vela Operations US diagnostic instrument. In addition, this position will be involved in the design and prototyping of our next generation instrument.

Principal Job Duties and Responsibilities

In concert with the Vela Ops/GB team, this position writes specifications, WIDs, design documentation, test cases, validation documentation, engineering investigation reports, and other documents associated with the process development to solve a variety of complex engineering problems across functional groups and disciplines.

Interfaces with other Vela Operations/Great Basin engineers, manufacturing, personnel, quality assurance, and others in the development of manufacturing processes. Assists in departmental management and leadership. Works and communicates well with other team members and leadership to which he/she is assigned as well as company management in order to meet company goals. Reports Vela Operations US management on all tasks and timelines.

Provides support with customer issues as necessary via remote login connections to the instrument and direct customer contacts, as necessary.

Follows company policy, SOPs, WIDs, cGMP, ISO 13485, and FDA guidelines and requirements. Helps implement improvements to safety and manufacturing cost reductions

Works with the Vela Ops/GB Team to resolve/prevent instrument performance or manufacturing problems of significant scope and complexity.

Experience in the following areas is desired but not required

- Strong analytical skills
- Process design input and development
- Process validation testing



- Participate in deriving and managing product test requirements
- Participate in and conduct engineering product design reviews
- Perform root cause analysis on failures observed during testing
- Excellent testing and "hands on" development aptitude
- Experience with Risk Analysis and FMEA's
- Statistics: Knowledge and practical application of 2 sample t-test, anova analysis, proportion test, hypothesis testing, Designing, running, and analyzing full and fractional factorial DOE's, knowledge of Reliability demonstration test plans, creation of and analyzing Gage R and R's, and determining appropriate sample sizes
- FDA Regulated Industry
- Minitab

Desired Skills

- Solidworks
- GD&T
- SPC
- Process Validation
- PLC
- Electrical Schematics

Preferred additional skills

- Materials (e.g. plastics, aluminum, copper, steel, etc.)
- Pneumatics
- Heat Transfer
- Machining (esp. CNC)
- Molding Processes

Travel

Minimal travel required.

Training and Education

B.S. in Mechanical, Electrical or Engineering Physic Engineering or Equivalent combination of education and experience. M.S. preferred.

Experience

1+ years of experience in related field.

Physical Requirements

Able to safely lift 50 pounds.

Ability to perceive and distinguish colors.

If you are interested, please send your resume to gb.jobs@veladx.com and include "Instrument Engineer" in the subject line.