



2980 Scott Street
Vista, CA 92081
(760) 477-2248 Fax: (760) 683-3314

Job Description

Title: Quality Manager

Department: Regulatory Affairs

Status: Full Time

Dept. #: 150

Classification: Salary/Exempt

Responsibilities/Duties

- Support VP RA to assure compliance with AutoGenomics quality system, FDA regulations, ISO 13485, IVDD, CMDR, and other international requirements that apply to *in vitro* devices.
- Represent Quality Assurance during product design/development, including quality planning, product requirements/specifications, risk assessment, design reviews.
- Review/approve design testing/verification/validation protocols and reports.
- Review Design History Files to ensure compliance with established design controls.
- Review/approve manufacturing process validation protocols/reports, manufacturing equipment validation protocols/reports, sampling plans/statistical rationales.
- Implement a software validation program
- Review Device History Records (manufacturing batch records) for product releases.
- Represent RA in MRB meetings
- Develop Supplier Quality Program to ensure purchased materials meet AutoGenomics requirements and specifications. Develop techniques to determine material acceptance and evaluate vendor process capabilities. Conduct supplier audits.
- Ensure product complaints are adequately documented, investigated and corrective/preventive action implemented. Evaluate effectiveness of corrective/preventive action.
- Participate in quality system training and internal quality system audits
- Other duties as needed to meet company quality goals/objectives.

Experience

- B.S. degree in science or engineering or a related technical field or equivalent.
- 4-6 years experience in quality assurance, product design/development, reliability engineering, manufacturing, working within the framework of a Quality System (i.e., FDA QSR; ISO 13485). Experience with medical device manufacturing with software/firmware and electronic and/or electromechanical products.

Benefits

Medical, Dental, Vision, Paid Vacation, Paid Sick Time, Paid Holidays, Employee ISO Plan