SCANTIBODIES Laboratory, Inc.
Harnessing the Power of God's Elegant Antibody Creation
9336 Abraham Way • Santee, CA 92071 USA • Phone (619) 258-9300 • Fax (619) 258-9366 • www.scantibodies.com

Summary:
The person in this position will establish a plan of continual improvement implementation. Responsible for all International, Federal, State and Local, etc. quality, safety, environmental, regulations and inspections. Occasional travel required.

Essential Duties:
Must be able familiar with searching engines or any other source to maintain up to date knowledge of applicable regulations for all SLI's business units
Must be able to understand and interpret regulations
Must create a plan for implementation or regulations and carry on any tasks required to finalize projects.
Must be objective in the review of internal procedures so changes are carried on in an manner that are operationally sound
Ensure design control and product development are in control and compliance.
Evaluate, expedite and improve product development.
Increase quality adherence for all current products.
Conduct, evaluate and direct changes to ensure compliance
Handle all regulatory issues for the filing of 510(k), PMA, etc.
Submits regulatory submissions to the FDA to maintain licenses.
Represent regulatory and quality during FDA inspections.
Adhere to all GMP, ISO, and international regulatory requirements.
Keep abreast of regulatory developments within and/or outside of the company as well as evolving best practices in compliance control. To include plasma collection regulations.
Review and implementation of process improvement and systems to track trends/improvements by department heads.
Establish cost containment goals for the department and plans for implementation, review and tracking.
Implement and maintain the computer system Made-2-Manage as it relates to quality issues.
Evaluate vendors and conduct vendor audits as necessary.
Direct and coordinate investigations and resolution of all complaints related to vendor quality issues.
Direct and coordinate investigations and resolution of all customer complaints related to SLI quality issues.
Meet with customers and vendors as necessary.
Interact closely with customers on new product development.
Other related duties as assigned.

Equipment Used:
Personal Computer
General Office Equipment
Laboratory Equipment

Job Specifications:
Requires a minimum of 4 years of direct experience in the field.
Familiar with a variety of concepts, practices, and procedures.
Must have 510(k), GMP, and ISO experience.
Requires BS degree or equivalent.

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Working Conditions/Physical & Mental Demands:
General Office environment

Supervision of Others:
None

Monetary Responsibilities:
None

EEO:
SLI is an equal opportunity employer and all employees are responsible for maintaining a discrimination and harassment free environment.

Ethics:
All employees are accountable for conducting their daily business responsibilities in an ethical and moral manner.

The above declarations are not intended to be an "all-inclusive" list of duties and responsibilities of the job described, nor are they intended to be such a listing of the skills and abilities required to do the job. Rather, they are intended only to describe the general nature of the job.