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

Regulatory Affairs/Regulatory Compliance Specialist
Job Description

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.

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- Meet with customers and vendors as necessary.
- Interact closely with customers on new product development.
- Regular, reliable and predictable attendance.
- Other related duties as assigned.

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.
- Valid driver's license, current proof of insurance and clean driving record.

Equal Employment Opportunity (EEO):

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