9336 Abraham Way • Santee, CA 92071 USA • Phone (619) 258-9300 • Fax (619) 258-9366 • www.scantibodies.com

Summary:

The Quality Assurance Specialist is responsible for monitoring donor center processes to ensure compliance with Scantibodies Biologics, Inc. Standard Operating Procedures, as well as all applicable State, Federal, or International regulatory requirements. Reports compliance status to Operational and Regulatory Compliance management. Participates, with Center management, in the development and implementation of continuous improvement plans. Represents the Center during internal and external audits, and responds to questions. May stop operations, including shipments, to address quality concerns.

Essential Duties include:

Quality Assurance audits

Deviation Management

Release of Plasma shipments

Release of Softgoods supplies

Inspection Management of internal/external audits

CLIA and Safety Committees

Job Specifications:

· High school diploma or equivalent required. Associates degree preferred or equivalent formal Medical, Laboratory, or Manufacturing certification or license. Minimum of four years related experience, will consider experience in lieu of education requirements.

· Strong attention to detail is required, able to utilize standard office equipment and perform basic mathematical functions, and able to work independently with limited supervision. Proficient with PC in office applications software including Word and Excel programs.

· Good customer service skills is needed.

· Must maintain knowledge of state, federal and Company policies and procedures to maintain job requirements.

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The following job functions are important for success:

- Identifies/develops Quality team members' ensuring the philosophy that compliance in quality, safety, and training is constantly promoted as the way we do business.
- Performs final QA review and release for all shipments and associated documents, to ensure shipment meets customer specifications and regulatory requirements.
- Performs QA review and release for use of all softgoods and associated documents to ensure supplies meet specifications.
- Conducts daily, weekly, monthly, bi-annual and annual compliance reviews for the systematic monitoring of Center quality compliance status. Documents findings and develops and implements corrective actions.
- Performs QA review of center records to ensure thoroughness, accuracy and timeliness of required information. Initiates investigation and ensures documentation of regulatory deficiencies. Determines the need for corrective action, ensures appropriate documentation, and determines effectiveness of the action.
- Assists with any training for new Quality Assurance Specialists and Quality Assurance Designees'.
- Reviews donor center personnel training documents to ensure documents are in compliance with SBI procedures, State, Federal and CLIA regulations, and other applicable requirements.
- Conducts periodic process assessments to ensure compliance of SBI written procedures. Initiates investigation to ensure documentation of deficiencies and development of corrective action plans as necessary in partnership with management. Monitors the effectiveness of corrective and preventive action plans.
- Leads CLIA quality team in identifying and correcting problems associated with total protein testing. Conducts monthly CLIA meetings to inform, assess and identify opportunities for continuous process improvement at the center.
- Directs the review of Safety, Health and Environment policies and procedures. Assures safety training and safety practices are implemented and followed within the center.
- Assists Regulatory Compliance in conducting internal audits to monitor facility compliance with SBI procedures and policies, cGMP, OSHA, FDA and other regulations as applicable and develop center responses for deficiencies. Assists in external audits by regulatory agencies and customers.

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Working Conditions/Physical & Mental Demands:

· Environmentally controlled office and lab areas of donor center. Required to enter an environment with a temperature of -30 C for short periods of time.

· Ability to sit or stand for extended periods for up to four hours at a time.

· Occupational exposure to blood borne pathogens.

· Fast-paced.

· Strong verbal and written communication skills, communicating with various levels of employees, as well as possible presentations from time to time.