

Job Description

Position: Quality Control Specialist

Location: Atlanta, GA

Mission:

To be a trusted partner who drives better business results for our healthcare customers. Together we grow.

Position Summary:

The Quality Control Specialist oversees the day to day operations of Quality Control of GlobalMed Logistix, a leader in medical device distribution. Daily tasks would include but are not limited to QMS oversight, record review, SOP implementation, assistance in internal audits. Works closely with Operation Managers and Quality Director to ensure day-to-day operations are performed to all FDA / Federal regulations and internal standards. Maintains rigorous quality mindset and advocates strict adherence to compliance practices within the facility. Possesses skills in the medical device industry and current Good Manufacturing Practice (cGMP) compliance requirements for storage, initial importations, CBP process, international shipping, and domestic shipping etc.

Scope of Role Responsibilities:

- Ensures the QMS system is updated, implemented, and adhered to by all employees of GMLx
- Develops and performs to Operational and Performance Metrics
- Implements, collaborates, and reviews QMS systems
- Scheduling tasks with new startups to maintain internal and regulatory standards
- Interacts with managers to discuss project planning cross functional QMS procedures
- Interacts with internal staff to identify SOPs and regulatory documents requiring further improvement or development
- Responsible for appropriately conducting internal audits in accordance with FDA, cGMPs, ISO 9001, and ISO 13485
- Assures company personnel are following all company SOPs and safety rules in compliance with all Federal Agencies
- Prepares and revises technical documents to ISO standards
- Assures that records and other paperwork are completed according to QMS system, cGMPs, and company SOPs
- Engage, interact and respond in a prompt, accurate, courteous and poised manner to encourage positive business relationships
- Consistently demonstrate a positive, constructive, and cooperative attitude in the business environment

Critical Experience & Skills:

- Bachelor's Degree
- 1-2 Years Quality Control Experience
- Experience in working in a matrix environment in which collaboration in all directions is necessary
- Proficient level with Microsoft Office (Outlook, Excel, PowerPoint)
- Experience working in a fast-paced rapidly growing environment
- Writes and speaks clearly in a variety of communication platforms (E-mail, telephone, in-person)

Desired Experience & Skills:

- Bio-medical degree
- Six Sigma
- 1-3 years' experience with ISO 9001 and 13485
- 1-2 years' in a Quality Control position

Competencies:

Accuracy/Quality– Is attentive to detail and accuracy. Committed to excellence, looks for improvements continuously, monitors quality levels, finds root cause of quality problems and own/acts on them.

Adaptability/Flexibility – Adapts to change, is open to new ideas, takes on new responsibilities, handles pressure and adjusts to meet changing needs.

Dealing with Ambiguity - Effectively copes with rapid change. Comfortably handles risk and uncertainty, is not easily rattled.

Dependability – Meets commitments, works independently, accepts accountability, handles change, sets personal standards, stays focused under pressure and meets attendance/punctuality requirements.

Innovation - Finds creative solutions to problems/needs that lead to positive outcomes, translates creative ideas into tangible action items.

Integrity/Ethics – Deals with others in a straightforward and honest manner, is accountable for actions, maintain confidentiality, supports company values and conveys good news and bad.

Organization – Manages multiple, simultaneous client activities and projects. Organizes resources to accomplish tasks in an efficient and effective way, coordinates multiple people and functions to accomplish a single goal, prioritizes multiple activities and capitalizes on all available resources.

Problem Solving – Interprets data and gives recommendations, solves unique and challenging problems, undertakes task and breaks them down into manageable parts in systematic way and thinks of all possible alternatives for a situation.

Sense of Urgency – Makes and executes decisions in swift and timely manner. Pursues everything with drive and preservice, often goes “above and beyond” to complete the task at hand.

Teamwork - Meets all team deadlines and responsibility, listens to other and values opinions, help team leader to meet goals, welcomes new comers and promotes a team atmosphere.

Physical Demands

- Light to moderate physical activity. Lifting of at least 50 pounds
- Standing, sitting or moving for extended amounts of time
- Occasional overnight travel