Quality Assurance Specialist, 8-Month Contract

About Wilson Wolf Corporation

Wilson Wolf Corporation designs, manufactures and distributes innovative cell culture labware and Class I medical devices targeting the biotechnology market, with unique partnerships with biotech organizations developing novel cancer immunotherapies. The Company has an opportunity for a Quality Assurance Specialist for an approximate 8-month contract during the implementation phase of an updated Quality Management System, and seeks an experienced professional for this opportunity.

Position Summary:

The Quality Assurance Specialist is a quality focused individual with experience in the medical device industry who will manage day to day quality activities and ensure compliance to current specifications and procedures to medical device QSR and ISO 13485 requirements. Activities include Device History Record review, examination of supplier provided data, labeling and product acceptance, ensuring nonconforming product is identified, documented and segregated from acceptable product, maintain control of quarantine area. The Quality Assurance Specialist is also responsible for Document Control management activities.

Responsibilities:

Inspection & Quality Control

- Perform medical device inspections in accordance with defined procedures inspecting components, subassemblies, labels and labeling and finished products.
- Compile and complete all required quality documentation.
- Maintain segregation and ID & Traceability of all materials.
- Prepare sterilization validation and endotoxin samples and test requests and product certifications.
- Control and organization of Device History Records.
- Identify and document nonconforming product, CAPA, deviations.
- Maintain and track document change control, nonconformities, CAPAs, and deviation processes.
- Identify potential changes needed for existing documentation and processes to support continuous improvement.
- Provide support in the rapid resolution of Customer Feedback, Complaints, and Investigations.
- Provide support to warehouse personnel as needed.
- Actively participate in training programs.
- Other activities as assigned.

Document Control Management

- Perform document tracking, processing, review, distribution, release, and archiving of documents.
- Coordinate the revision (DCO's), review, approval and obsoleting of QMS documents.
- Organize and ensure accurate and reliable filing systems for paper-based GMP documents.

Required Qualifications:

Skills

- Ability to take direction and pursue goals with minimal supervision with a sense of urgency to meet project goals and customer expectations.
- Proactive with an ability to maintain attention to detail while executing multiple tasks.
- Good documentation skills to maintain neat and accurate records and files.
- Well-organized and proficient at reviewing and editing documentation.
- Self-motivated with ability to handle, organize and prioritize multiple tasks.
- Energetic with a good attitude and versatile in the areas of Quality Assurance and Manufacturing, preferably with experience in a small company.
- Good written and verbal communication skills.
- MS office applications such as Word, Excel, and Adobe Acrobat.
- Thorough and detail oriented.
- Knowledge and experience with inspection concepts, general measuring tools and test equipment, and maintenance and calibration programs.

Education and Experience

- Bachelor's degree in scientific discipline and leadership experience preferred.
- 5+ years of solid, hands on, direct quality control inspection experience and document control management in a FDA QSR and ISO 13485 regulated plastic component assembly and manufacturing environment.
- Firm understanding of quality practices and procedures, including Quality System Regulations and ISO 13485.

Hours

- 32-40 hours/week, approximately 8-month contract

For more information about the Quality Assurance Specialist opportunity or to apply, contact Sheila at: swyatt@talencio.com.