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Regulatory and Quality Compliance-Diagnostics/Medical Devices

Hiring organization
BioLink 360

Employment Type
Full-time, Contractor, Temporary

Industry
Pharma/Biotech

Job Location
Grayslake, IL

Base Salary
$ 55 - $ 75

Date posted
December 2, 2024

Description

Job Title: Quality Engineer
Reports to: Site Leader
Location: Northern IL

Position Overview:
We are currently seeking an experienced Medical Device Engineer to join our team. The successful candidate will be responsible for remediating design history files (DHF) to ensure compliance with In Vitro Diagnostic Regulation (IVDR), and U.S. Food and Drug Administration (FDA) regulations. This role involves a thorough understanding of medical device development processes, regulatory requirements, and quality management systems.

Responsibilities

- Review and assess existing design history files for compliance with applicable regulatory requirements including IVDR, and FDA CFR Part 820.
- Identify gaps in compliance and develop remediation plans to address deficiencies in the DHFs.
- Collaborate with cross-functional teams such as R&D, Quality Assurance, Regulatory Affairs, and Clinical Affairs to gather necessary documentation and information and drive continuous improvement specific to DHF remediation processes, ensuring alignment with regulatory standards and best practices.- Fostering productive collaborations with suppliers and external partners, ensuring seamless integration of external resources into DHF remediation processes
- Revise and update design control documents including design input requirements, risk management files, verification and validation protocols and reports, and design review records to ensure accurate representation of the design process.
- Execute change control processes to uphold DHF compliance when design or documentation changes are implemented. Ensure alignment with regulatory standards and maintain transparent and compliant DHFs throughout product development.
- Ensure traceability throughout the DHF to demonstrate that design outputs meet design inputs and that all requirements are tested appropriately.
- Demonstrate readiness for regulatory audits and inspections. Maintain a state of preparedness by ensuring that all DHF documentation and processes meet regulatory standards, facilitating smooth and successful audits and inspections.
- Implement and maintain processes to ensure continuous compliance and effectiveness of the design control system.
- Prepare and present regular progress reports to management and other stakeholders about the status of remediation activities.
- Stay up to date with regulatory guidance’s, industry standards, and best

practices for medical device design and development.
- Lead DHF remediation projects, overseeing project timelines, budgets, and quality objectives to ensure successful completion and compliance with regulatory standards.

Qualifications

– Bachelor's degree in Chemical Engineering, Systems Engineering, Mechanical Engineering, or a related field.

– A minimum of 5 years of experience in medical device industry with a focus on design controls and regulatory compliance.

– Proven knowledge of MDR, IVDR, FDA regulations, including 21 CFR Part 820, and ISO 13485 quality management system requirements for medical devices.

– Demonstrated experience in remediating design history files and aligning medical device documentation with regulatory standards.

– Familiarity with configuration management and DHF architecture.

– Strong analytical and problem-solving skills to identify non-compliance issues and develop appropriate solutions.

– Excellent organizational and project management abilities to manage multiple tasks with strict deadlines.

– Proficient communication skills to effectively interact with all levels of management, cross-functional teams, and regulatory bodies.

– Detail-oriented with a high degree of accuracy and precision in work.

– Certified Quality Engineer (CQE), Regulatory Affairs Certification (RAC), or similar professional certifications are a plus.

– Prior experience in leading DHF architecture and remediation projects is a plus.

Education:

- Bachelor's, Master's, or Ph.D. in Life Sciences, Biotechnology, or a related field with a focus on gene therapy.