

DQA-Design Assurance 👍 Exclusive job

Job Information

Recruiter

Izumi Network Yugen Kaisha

Job ID

1594838

Industry

IT Consulting

Job Type

Permanent Full-time

Location

Tokyo - 23 Wards

Salary

9 million yen ~ 10 million yen

Refreshed

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General Requirements

Minimum Experience Level

Over 6 years

Career Level

Mid Career

Minimum English Level

Business Level

Minimum Japanese Level

Business Level

Minimum Education Level

Bachelor's Degree

Visa Status

Permission to work in Japan required

Job Description

Job Title: **Design Assurance Lead**

Location: Hachioji, Tokyo

Role Summary

The Design Assurance Engineer provides technical leadership and expertise in sustaining engineering activities for medical devices, ensuring compliance with EU MDR, FDA, and international regulatory standards. This role is responsible for maintaining design control documentation, driving risk management processes, and supporting cross-functional teams to deliver high-quality, cost-effective, and compliant products throughout their lifecycle.

Key Responsibilities

Design Control & Documentation

- Maintain and update Design History Files (DHF) and Technical Files.
- Ensure product documentation integrity and linkage across requirements, risk management, and verification protocols.
- Drive DHF remediation efforts and CAPA projects as needed.

Risk Management

- Apply ISO14971 principles to manage product risks.
- Trace requirements from product specifications through FMEA to design verification protocols.
- Develop and maintain risk management documentation.

Sustaining Engineering

- Lead sustaining activities including technical planning, feasibility studies, device development, investigations, corrective actions, cost reductions, and validation activities.
- Provide technical solutions and support for product improvements and compliance updates.

Regulatory & Compliance

- Ensure adherence to FDA 21 CFR 820, EU MDR, IEC60601, GMP, and other applicable standards.
- Support compilation of documents for regulatory submissions.

Technical Leadership

- Mentor junior engineers and provide guidance on best practices for engineering tools and methods.
- Collaborate with cross-functional teams including Sales, Marketing, RA, and suppliers.
- Serve as a core or extended team member on projects.

Required Skills**Design Analysis & Verification**

- Perform tolerance stack-ups, strength of materials analysis, and statistical evaluations.
- Develop robust verification and validation strategies, including sampling plans.

Required Skills & Competencies

- Medical Device Expertise: Strong knowledge of design control, DHF, Tech Files, and EU MDR compliance.
- Regulatory Knowledge: FDA, ISO14971, IEC60601, GMP standards.
- Technical Skills: SolidWorks proficiency, GD&T, tolerance analysis, xFMEA, statistical tools (Minitab preferred).
- Manufacturing Knowledge: Injection molding, common medical device materials, and manufacturing processes.
- Problem-Solving: Ability to resolve complex issues using logical and systematic thinking.
- Communication: Strong verbal and written communication skills; ability to influence and present effectively.
- Leadership: Experience mentoring engineers and leading cross-functional teams.
- Proficiency in Japanese is must.

Qualifications

- Bachelor's or master's degree in mechanical engineering, Electrical Engineering, or related field.
- Bilingual Japanese is mandatory.

- Minimum 8+ years of experience in medical device design, development, and sustaining engineering.
- Proven track record of managing projects in compliance with EU MDR and FDA regulations.

Company Description