DQA-Design Assurance 独占求人

募集職種

人材紹介会社
IZUMI NETWORK

求人ID
1594838

業種
ITコンサルティング

雇用形態
正社員

勤務地
東京都 23区

給与
900万円 ~ 1000万円

更新日
2026年06月01日 17:42

応募必要条件

職務経験
6年以上

キャリアレベル
中途経験者レベル

英語レベル
ビジネス会話レベル

日本語レベル
ビジネス会話レベル

最終学歴
大学卒： 学士号

現在のビザ
日本での就労許可が必要です

募集要項

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.

スキル・資格

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.

会社説明