Design Quality Engineer, Software

Job Reference: DQES Location: Carlsbad, CA

Posted: September 2024 Weekly Hours: 40

**The Role**

DNA Electronics (DNAe) is a dynamic company integrating cutting edge sequencing technologies with novel biochemical techniques to create a revolutionary sample-to-answer sequencing platform. We are seeking an experienced Design Quality Engineer to join our team of professionals who are committed to creating quality in In Vitro Diagnostic products. The Design Quality Engineer will implement, maintain and facilitate the execution of Software Development Lifecycle (SDLC) and software risk management QMS processes.

**Responsibilities:**

* Responsible for the on-going implementation of Software Development Lifecycle (SDLC) and supporting processes in conformance with applicable regulations, standards, and industry guidance documents.
* Approves content required for premarket submissions for device software functions, e.g., risk management records, system and software architecture diagrams, software design specifications, software V&V protocols / reports, vulnerability analysis, and problem resolution reports.
* Lead the execution of Hazard Analysis (HA) and Failure Modes Effect Analysis (FMEA) for risks associated with software design controls.
* Facilitate complaint agile software development practices and ensure the delivery of appropriate Design History File (DHF) deliverables at the story, increment and release layers.
* Provides guidance on follow-up actions for project teams based on development plans, coordinates activities to remove encountered project roadblocks, and escalates quality issues.
* Monitors and measures QMS processes to demonstrate the ability of the processes to achieve planned results, and as necessary, ensures appropriate corrective and preventative action is taken.
* Foster a quality culture by holding training on updated processes, clarifying QMS requirements, and promoting organizational compliance.

**Person Specification**

We are looking for people with a passion for their work - people who strive for exceptional results, but who can deliver pragmatic solutions on time. DNA Electronics’ scientists and engineers enjoy and thrive on working in an interdisciplinary team but can also work independently and use their own initiative.

# Qualifications & Experience:

Bachelor’s Degree or equivalent in Computer Science, Engineering, or related fields. Three to Five years of experience in In Vitro Diagnostics, Medical Device, or similar industries.

* Proven working experience in software quality engineering and risk management is required.
* Strong knowledge in the application of ISO 13485, IEC 62304, 21 CFR part 820, IVDR to the development of medical device software.
* Expertise in the application of software security risk management standards, such as SW:96:2023, is a plus.
* Experience implementing risk mitigations related to IT infrastructure and medical equipment safety is a plus, e.g., ISO 27001, IEC 80001 and IEC 60601 requirements.
* Ability to facilitate decision-making using quality and project management methodologies, e.g., root cause analysis, quality planning, critical path mapping, interest-based negotiation, etc.

The incumbent must be capable of accommodating 6 am to 2 pm PST working hours, as needed, to collaborate with individuals across different time zones.

# Location

DNAe Carlsbad, California

# Apply

If you believe you meet the above criteria and would relish playing a key role in developing a revolutionary technology, we would be delighted to hear from you.

We offer a competitive compensation package to successful candidates.

Please email your CV and cover letter to: HR-US@dnae.com quoting

**Your name and the** **job title** in the subject line.

For more information about DNAe, please visit our website [www.dnae.com](http://www.dnae.com)

DNAe is committed to offering staff a competitive remuneration package, alongside compelling benefits. As the primary part of the process, we conduct a rigorous market data review where each role is individually benchmarked using a vast amount of recent data. The estimated base salary range for the Software Quality Engineer role based in Carlsbad, California is: $90,000 to $110,000. Compensation decisions are dependent on several factors including, but not limited to, an individual’s qualifications, location where the role is to be performed, internal equity, and alignment with market data. Should the level or location of the role change during the hiring process, the applicable salary range may be updated accordingly.

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