# Staff Design Quality Assurance Engineer

## Description

Hinge Health is moving people beyond pain by transforming the way it is treated and prevented. Connecting people digitally and in-person with expert clinical care, we combine advanced technology, AI and a care team of experts to guide people through personalized care directly from their phone. Our approach is proven to reduce pain by 68%, prevent 42% of new opioid prescriptions, and avoid more than half of joint replacement surgeries. Available to 18M people, Hinge Health is trusted by leading health plans and employers, including Land Oâ[?][?]Lakes, L.L. Bean, Salesforce, Self-Insured Schools of California, Southern Company, State of New Jersey, US Foods, and Verizon.Here at Hinge Health, we welcome all applicants and know a diverse team makes us better and stronger. We look for individuals who embody our leadership principles and we value varied experiences and skill sets. Beyond specific work experience, we also look for unique capabilities and skill sets that are key indicators an applicant will thrive in our fast-paced, frequently evolving environment. If this sounds like the kind of place youâ[?][?]d like to be part of, please apply – we would love to hear from you!Learn more at http://www.hingehealth.comHinge Health Hybrid Model:We believe that remote work and in-person work have their own advantages and disadvantages, and we want to be able to leverage the best of both worlds. Employees in hybrid roles are required to be in the office 3 days/week.About the RoleIn this role as a Design Quality Assurance Engineer, you will have responsibility for leading Quality Management System (QMS), Design Controls, and Risk Management initiatives that are intended to expand Hinge Healthâ[?][?]s medical device portfolio. The Design Quality Assurance Engineer is considered a subject matter expert in all aspects of product development and sustaining engineering processes while applying comprehensive knowledge of design controls and risk management to ensure the highest level of quality in new products, and their compliance to applicable regulatory standards. nWHAT YOUâ[?][?]LL ACCOMPLISHLead Design Quality Engineering on cross-functional teams, interfacing among multiple departments and teams such as Software/Hardware/Firmware Engineering, Regulatory Affairs, Operations, Supply Chain, and Project Management.Execute the product development process to design, verify and transfer high quality products to commercial launch. Ensure product compliance to regulations, standards, and quality system by driving functional excellence in Design Assurance and championing activities to implement changes and improvements.Recommend test methods and identity statistical methods for achieving required level of product quality and reliability.Proactively identify opportunities for improvements in areas of system compliance and product development.Drive compliance in all aspects of risk management and usability engineering activities throughout the product life cycle.Provide expertise and guidance, within the scope of the quality system, to ensure compliance within designated projects and product lines.Serve as quality reviewer and approver for design control changes.Ensure compliance with the quality system and may own corrective actions (CAPA).BASIC QUALIFICATIONS6+ years of leading QMS initiatives and Design Controls with Risk Management within a medical device organizationExperience with creating processes, from scratch or significantly updated, compliant with 21 CFR 820, ISO 13485, ISO 14971Experience in the design and development of software as medical device (SaMD) to IEC 62304 and medical electrical devices to IEC 60601Experience in leading product initiatives from project team formation to project planning, execution and to product launch ready.Ability to engage, coach, and teach cross-functional team members regarding Quality System and medical device requirementsTravel 5-15%PREFERRED QUALIFICATIONSFamiliarity with international regulations and new market entryBachelorâ[?][?]s or masterâ[?][?]s

**Hiring organization**
Hinge Health

**Job Location**
San Francisco

**Base Salary**
$ 95000 - $ 125000

**Date posted**
May 17, 2024

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degree in an engineering or other STEM disciplineWHAT YOU'LL LOVE ABOUT USInclusive healthcare and benefits: On top of comprehensive medical, dental, and vision coverage, we offer employees and their family members help with gender-affirming care, tools for family and fertility planning, and travel reimbursements if healthcare isnâ[?][?]t available where you live. Planning for the future: Start saving for the future with our traditional or Roth 401k retirement plan options which include a 2% company match. Modern life stipends: Manage your own learning and developmentn$144,000 – $216,000 a yearConsider the range above plus equity, and benefits.  Please note that the base salary range is a guideline, and individual total compensation will vary based on factors such as qualifications, skill level, competencies and work location.nPlease mention the word **STUNNING** and tag RMTA3LjE3OC4yMzkuMjA5 when applying to show you read the job post completely (#RMTA3LjE3OC4yMzkuMjA5). This is a beta feature to avoid spam applicants. Companies can search these words to find applicants that read this and see they're human.

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