https://www.biolink360.com/job/design-assurance-engineer-combination-devices/

Senior Quality Engineer-Medical Devices

Hiring organization
BioLink 360

Employment Type
Full-time

Beginning of employment
ASAP

Industry
Medical Device/Pharma

Job Location
Boston, MA, U.S.A.
Remote work from: USA; New Jersey, USA; D.C., USA; Pennsylvania, USA;

Date posted
December 11, 2020

Description

Our client is an industry leading Regulatory and Quality consulting company that has consistent year over year growth, and is on a major upswing with Design Assurance hiring. They work with startups to fortune 500 device companies, and there is a lot of variety with client projects.

These are full-time, permanent hire, remote based positions. This is the regular business model, and has been for many years. Typically you will be fully integrated with client teams, and work with their internal teams to meet project deliverables.

I can send you company details and links, but here are a few bullet points:
-Women owned business, 10 years established. The owners still work in the business with clients and employees.
-There's always an expert on the team, lots of room to do new things with new technologies, projects and clients.
-Our Associates love working here! Over 30% of hires this year alone were Associate referrals.
-Some travel to client sites will be required, it's minimal.
-Unlimited time off. Business closes for winter holiday. Work/Life balance is a real thing here.

*The person to fill this role will be working with a CMO with devices.

Skillsets:
Must have design assurance/design control knowledge, DHF development (have built a DHF from scratch), strong familiarity with -device products, risk management experience, V&V planning/reporting (including sampling), AND submission familiarity, sterilization, biocompatibility, paper-based DHF, design transfer.

Responsibilities

Responsibilities:
o Provide design assurance support to review/create a DHF under clients
o Design Control SOPs for products. Major deliverables will include: Design Inputs, uFMEA, dFMEA, Risk Management Plan, Hazards Analysis, Design Verification Plan, Design Verification Report (including IFU & Labeling verification), Traceability Matrix, Design and Development Plan
o Mentor and guide client team to educate on industry standard practices for product development (particularly on the device side).
o Work within constraints of clients SOPs, but also advise on QMS updates to standardize design control best practices including risk management.

Other
• International client / Eastern Time zone preferred
• ISO 13485:2016 and applicable regulatory requirements of US FDA and Europe MDR

There will be multiple hires of DA professionals with 2-15 years of experience over the next few months, to start in Jan/Feb.

Contacts
For further information, please contact:

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