

# United States Jobs Expertini®

## Senior Design Assurance Engineer

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Company: JUUL

Location: United States

Category: architecture-and-engineering

### THE COMPANY

Juul Labs' mission is to impact the lives of the world's one billion adult smokers by eliminating combustible cigarettes. We have the opportunity to address one of the world's most intractable challenges through a commitment to exceptional quality, research, design, and innovation. Backed by leading technology investors, we are committed to the same excellence when it comes to hiring great talent.

We are a diverse team that is united by this common purpose and we are hiring the world's best engineers, scientists, designers, product managers, operations experts, and customer service and business professionals. If the opportunity to build your career at one of the fastest growing companies is compelling, read on for more details.

### ROLE AND RESPONSIBILITIES:

We are seeking a Senior Design Assurance Engineer to independently support both new product development and design changes. The ideal individual will ensure product quality, reliability, speed to market, reduction of risk to users, and regulatory compliance.

### KEY RESPONSIBILITIES:

Responsible for Risk Management, design control documentation, and assurance that Design and Manufacturing process changes are assessed for potential risks to customers or regulatory compliance

Assist the Design Assurance function to build a comprehensive Design Assurance system compliant to FDA requirements, by reviewing Design Control procedures and policies, and

assisting in document writing

Provides mentorship to JUUL Engineering to implement an improved and robust Design Control system

Reviews product change notices and change documentation to ensure thorough review of quality documents submitted for technical changes, design changes or manufacturing changes in order to ensure all regulatory requirements related to these changes are completely followed and conform to the Design Control regulations

Application of Reliability requirements, Design Control and Risk Management and knowledge and familiarity with the concepts of FDA CFR 820, ISO 13485, IEC 62304, IEC 60601 and ISO 14971 Risk Management

Reviews and approves Verification and Validation methods including performance, biocompatibility, and manufacturing processes to ensure requirements are met

Assists in the determination of sample size, confidence levels, and associated statistics pertaining to Verification and Validation activities

Support Post Market in the analysis of Complaint data/ Adverse Events and develop corrective and preventive actions for quality incidents

Lead and participate in internal and external audits to ensure compliance with quality standards and regulations

Support the development and review of process validation test plans, protocols, and reports (MVPs, IQ/OQ/PQ, TMVs)

**PERSONAL AND PROFESSIONAL QUALIFICATIONS:**

Minimum of 5 years of design control/testing experience in consumer electronics and/or electro mechanical medical devices within an FDA QSR or ISO 13485 regulated environment

Exceptional cross-functional workplace collaboration

Possesses robust technical skills to facilitate critical, open and data driven thinking

Demonstrates excellent attention to detail with respect to Quality and Regulations

Medical Device Experience is required

### **EDUCATION:**

Bachelor's Degree in Engineering (Electrical, Mechanical) or similar technical field required at a minimum

Preferred Master's degree

### **JUUL LABS PERKS & BENEFITS:**

A place to grow your career. We'll help you set big goals - and exceed them

People. Work with talented, committed and supportive teammates

Equity and performance bonuses. Every employee is a stakeholder in our success

Cell phone subsidy, commuter benefits and discounts on JUUL products

Excellent medical, dental and vision benefits

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