

Design Assurance Quality Engineer II

at Access Vascular
Billerica, MA

Job Description

Provide Quality Engineering support for Product Development Projects throughout all phases of Design Controls (Concept to Launch), with additional responsibility for post-market surveillance activities. This is a collaborative position working closely with R&D, Manufacturing, Sales & Marketing, and others to ensure compliance with AVI's QMS, and FDA QSR requirements, with a particular focus on Design Controls.

Duties & Responsibilities

- Fulfill a Design Assurance (DA) role on Product Development projects
- Lead cross-functional teams to implement risk assessment (FMEAs) and risk management processes (RMP / RMR / RMF)
- Support development, implementation, and maintenance of Design Verification & Validation (V&V) methodologies and best practices to impact product quality and launch timeliness
- Interface with manufacturing, NPI Engineering, Research and Development, and other Quality team members to ensure effective design transfer to manufacturing

Qualifications

- BS in related technical field, preferably Engineering
- 3-5 years of design assurance experience in the Life Science or Medical Device Industries
- Working knowledge of 21 CFR 820 and ISO 14971:2019 are a must
- Working knowledge of data analysis methods, including basic statistics, preferably using Minitab or other similar data analysis software
- Teamwork, flexibility and adaptability to change
- Critical reasoning and excellent data presentation skills
- Excellent written and verbal communication and skills
- Self-initiator with strong organization skills
- Ability to lead through influence

Conditions of Employment:

Candidates will be required to show proof that they are fully vaccinated against COVID-19 prior to commencing employment. For purposes of this requirement, "fully vaccinated" shall have the then-current meaning ascribed by the US Center for Disease Control and Prevention (CDC). Exemptions from this requirement as a reasonable accommodation will be considered on a case-by-case basis in accordance with applicable law.



Access Vascular, Inc is a proud Equal Opportunity/Affirmative Action Employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, age, protected veteran status or disability status.

About Access Vascular

[Access Vascular](#) was founded in 2015 to address the most common and costly complications of intravenous therapy: infection, thrombosis and phlebitis. The company is developing a suite of venous access devices made from patented biomaterials which are highly biocompatible and are capable of long-term thrombus resistance and infection protection.