Jonathan Keller

SENIOR DEVICE ENGINEER

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Summary

Senior Device Engineer with 10 years in catheter design for vascular and neurovascular devices, taking products from concept through design transfer, including 2 FDA 510(k) clearances. Leads design controls, DFMEA and process validation for Class II and III devices and mentors engineers across R&D and manufacturing.

Skills

- Catheter Design
- Design Controls
- DFMEA
- Design Verification
- Process Validation
- Design Transfer
- SolidWorks
- GD&T
- Minitab
- ISO 14971

Experience

Senior Device Engineer 02/2021 - Present

Pacific Coast Vascular Irvine, CA

Peripheral vascular device company with 450 employees.

- Lead a team of 6 engineers designing a peripheral thrombectomy catheter from concept to design freeze.
- Manage the DFMEA, ISO 14971 risk file and design verification plan for 32 requirements, finishing verification **6 weeks** early.
- Validate the catheter process through IQ/OQ/PQ during design transfer, reaching 94% first-pass yield at launch.
- Specify GD&T on 40 component drawings in SolidWorks and qualify 3 extrusion and braiding suppliers.

Device Engineer 07/2016 - 01/2021

Saddleback Medical Technologies Lake Forest, CA

Neurovascular device maker with 200 employees.

- Designed delivery systems for 2 neurovascular stents that received FDA 510(k) clearance in 2019 and 2020.
- Ran Minitab DOE studies on bonding and tipping processes, reducing tip failures by 45%.
- Wrote 25 test protocols and reports for the design history file and notified body audits.
- Supported design transfer of 3 products to a contract manufacturer in Tijuana, Mexico.

Education

Master of Science 06/2016

University of California, Irvine Irvine, CA

Biomedical Engineering

Certificates

Certified Quality Engineer (CQE)

ASQ

2020