

Fiona Marsh

PRINCIPAL QUALITY ENGINEER

📍 Irvine, CA

📞 (949) 555-0108

✉️ fiona.marsh@email.com

🌐 linkedin.com/in/fionamarsh

Certificates

Certified Quality Engineer (CQE)

ASQ

2015

Six Sigma Black Belt (CSSBB)

ASQ

2018

Skills

ISO 13485 • ISO 14971

Quality Management Systems

CAPA • Validation • DOE

Statistical Analysis • Six Sigma

Lean • Python

Summary

Principal quality engineer with 14 years in Class II and Class III medical devices under ISO 13485 and FDA 21 CFR 820. Sets ISO 14971 risk management for new catheter platforms, leads process validation and DOE work, and guides CAPA and quality management systems decisions across 2 sites.

Experience

Principal Quality Engineer

02/2021 - Present

Pacific Vascular Devices

Irvine, CA

Developer and manufacturer of catheters and balloon devices for vascular procedures, with 2 production sites.

- Set the ISO 14971 risk management approach for 3 catheter platforms, from hazard analysis to post-market review.
- Lead process validation (IQ/OQ/PQ) on 22 processes for a new site, finishing **6** weeks ahead of transfer.
- Design DOE studies on balloon bonding that raised yield from 81% to 94% and closed a 2-year CAPA.
- Write Python scripts that pull nonconformance data for statistical analysis, cutting monthly trend reports from 2 days to 2 hours.

Senior Quality Engineer

04/2016 - 01/2021

Saddleback Surgical

Lake Forest, CA

Orthopedic implant and instrument manufacturer with machining, cleaning and sterile packaging.

- Led **40** CAPA investigations using fishbone and 8D, with every one passing its effectiveness check.
- Directed Lean and Six Sigma projects on implant packaging that saved \$650K over 2 years.
- Hosted 4 FDA inspections and 6 notified body audits with zero Form 483 observations.

Quality Engineer

07/2012 - 03/2016

Harbor Medical Molding

Costa Mesa, CA

Contract manufacturer of molded and assembled disposable medical components.

- Validated **30** molding and sealing processes and wrote the test method validation for each.
- Managed nonconformances for 25 component suppliers, cutting incoming rejects by 35%.
- Wrote 15 inspection procedures for incoming resin and tubing lots under ISO 13485.

Education

Bachelor of Science

06/2012

University of California, Irvine

Irvine, CA

Biomedical Engineering