# Laura Bennett

## Regulatory Compliance Manager

Irvine, CA (949) 555-0126 laura.bennett@email.com linkedin.com/in/laurabennett

## SUMMARY

Regulatory Compliance Manager with 10 years in medical device quality and compliance, leading FDA and ISO 13485 readiness for a manufacturer of surgical instruments sold in 30 countries. Runs internal audits and CAPA, manages EU MDR changes, and writes procedures that production and engineering teams follow.

## EDUCATION

**Bachelor of Science** 06/2016

University of California, Irvine Irvine, CA

Biomedical Engineering

## EXPERIENCE

**Regulatory Compliance Manager** 03/2022 - Present

Pacific Crest Medical Devices Irvine, CA

*Class II surgical device manufacturer with 350 employees.*

- Lead FDA inspection readiness, closing a 2024 inspection with no Form 483 observations.
- Direct 20 internal audits a year against 21 CFR Part 820 and ISO 13485 with a team of 3.
- Manage the CAPA system, cutting average CAPA closure time from 120 to **65** days.
- Coordinate EU MDR technical file updates for 14 product families, meeting every notified body deadline.

**Senior Quality Compliance Specialist** 06/2016 - 02/2022

Orange Coast Surgical Tustin, CA

*Contract manufacturer of single-use medical devices.*

- Audited 25 suppliers a year and removed 3 that failed corrective action follow-up.
- Wrote 40 quality procedures and work instructions during the 2019 ISO 13485:2016 transition.
- Investigated 150 complaints a year and documented risk management file updates for each.
- Tracked audit and complaint trends in Microsoft Excel for monthly management review.

## SKILLS

**21 CFR Part 820 • ISO 13485 • CAPA • Internal Audits • EU MDR • Risk Management FDA Inspections • Microsoft Excel • Attention to Detail • Written and Verbal Communication Skills**

## CERTIFICATES

**Regulatory Affairs Certification (RAC-Devices)**

Regulatory Affairs Professionals Society

05/2021

**ISO 13485 Lead Auditor**

Exemplar Global

11/2018