

LAURA MENDEZ

DOCUMENT CONTROL SPECIALIST

CONTACT

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SKILLS

- Document Control
- Change Control
- ISO 13485
- FDA 21 CFR Part 820
- SharePoint
- Adobe Acrobat
- Excel
- Word
- Outlook
- PowerPoint

EDUCATION

Bachelor of Science

05/2022
San Diego State University
San Diego, CA
Business Administration

CERTIFICATES

Certified Quality Improvement Associate (CQIA)

10/2024
ASQ

SUMMARY

Document control specialist with 4 years of document control work in medical device and electronics manufacturing, managing SOPs, work instructions and engineering change orders under ISO 13485 and FDA 21 CFR Part 820. Routes 60+ change orders a month through SharePoint, formats controlled documents in Word and Adobe Acrobat, and keeps records ready for audit at any time.

EXPERIENCE

Document Control Specialist

06/2024 - Present

Coastline Medical Devices

San Diego, CA

Class II device maker with 2 production sites and 450 employees.

- Manage the document control system for 2,400 SOPs, work instructions and forms across 2 production sites.
- Process **60+** engineering change orders a month in SharePoint, cutting average change control cycle time from 12 to 7 days.
- Review new and revised documents in Word and Adobe Acrobat for template, numbering and approval errors before release.
- Support 3 FDA and ISO 13485 audits a year, pulling 150 records on request with no document control findings.

Document Control Clerk

09/2022 - 05/2024

Pacific Ridge Electronics

Carlsbad, CA

Contract electronics manufacturer for aerospace and medical customers.

- Released **800** drawing and BOM revisions a year to the shop floor, removing obsolete copies the same day.
- Built an Excel training matrix for 300 employees' SOP sign-offs, raising completion from 78% to 96%.
- Scanned 10,000 legacy device history records into the electronic archive with full metadata.
- Sent weekly open change order reports through Outlook to 6 engineering leads.

Quality Clerk (Part-Time)

01/2021 - 05/2022

Mesa Precision Machining

El Cajon, CA

- Filed **200** inspection reports and material certificates a week by part and lot number.
- Updated the calibration log in Excel for 350 gauges and flagged items due within 30 days.
- Copied approved drawings for the shop floor and pulled superseded versions from 12 workstations.