LAUREN PATEL

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SUMMARY

Senior regulatory affairs specialist with 7 years in medical device regulatory affairs, leading FDA and EU MDR submissions for Class II and III endoscopy and urology products. Writes regulatory strategy and technical documentation, applies ISO 13485 and design controls, and brings strong technical writing and project management skills to every program.

SKILLS

- Regulatory Affairs
- EU MDR
- FDA 510(k)
- ISO 13485
- Design Controls
- Technical Writing
- Regulatory Strategy
- Project Management Skills
- Excel
- PowerPoint

CERTIFICATES

Regulatory Affairs Certification (RAC-Devices)

Regulatory Affairs Professionals Society (RAPS)

04/2021

EXPERIENCE

Senior Regulatory Affairs Specialist

Assabet Medical Technologies • Marlborough, MA

02/2023 - Present

Device maker with 1,400 employees and products sold in 60 countries.

- Lead regulatory strategy for 4 product programs, securing **7** FDA clearances and 2 EU MDR certificates.
- Write EU MDR technical documentation for 20 product families and answer 150+ notified body questions on time.
- Represent regulatory affairs in design controls reviews, approving 90+ design and labeling changes a year.
- Manage regulatory readiness for 2 ISO 13485 audits with quality, closing both with zero major findings.

Regulatory Affairs Specialist

Merrimack Surgical Devices • Andover, MA

06/2019 - 01/2023

Maker of surgical staplers, trocars and energy devices.

- Prepared 9 FDA 510(k) submissions and 30 letters to file for staplers and trocars.
- Built the EU MDR transition plan for 12 legacy products, tracked in Excel and reported monthly in PowerPoint.
- Reviewed 400 promotional and labeling pieces a year for consistency with cleared indications.
- Coached 2 associates on change assessments and submission formatting.

EDUCATION

Master of Science

Northeastern University • Boston, MA • 05/2019

Regulatory Affairs