

Li Fowler

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SUMMARY

Senior regulatory affairs leader with 10 years of medical device experience spanning software enabled electromechanical systems, robotic surgery, connected medical platforms, and United States market access. Leads regulatory strategy across **new product development**, submissions, approvals, and **life cycle management**. Authors **FDA Q submissions**, IDEs, **De Novo requests**, and 510(k) submissions, then prepares teams for health authority meetings and review responses. Partners closely with engineering, clinical, quality, cybersecurity, and product teams on specifications, device testing, risk management, software documentation, labeling, and technical files. Applies FDA requirements, IEC 60601 series, ISO 10993 1, software guidance, and cybersecurity expectations to practical program decisions. Brings calm judgment to complex changes, audit support, regulatory intelligence, and cross functional delivery, helping medical device teams keep evidence complete, decisions traceable, and submissions ready.

EXPERIENCE

Senior Regulatory Affairs Program Manager, Robotic Surgery Systems

January 2023 - Present

Vela Robotic Surgery Systems

San Diego, CA

Leads **regulatory strategy** and execution for software enabled robotic surgical platforms, connecting United States submissions, global documentation, product development, sustaining changes, and health authority engagement across engineering, clinical, quality, cybersecurity, and product teams.

- Aligned robotic platform strategy with engineering, clinical, quality, cybersecurity, and development milestones.
- Authored Q submissions, IDE materials, De Novo content, and 510(k) evidence packages for FDA review.
- Identified submission gaps across specifications, testing, risk files, **labeling**, software, and cybersecurity evidence.
- Converted FDA guidance updates into impact assessments and documented decisions supporting business priorities.
- Directed **change assessments**, **Letters to File**, registrations, renewals, and sustaining submission recommendations.
- Prepared FDA meeting briefs, question strategy, rehearsals, action tracking, global files, and audit evidence.

Regulatory Affairs Manager, Connected Medical Platforms

July 2020 - December 2022

Northstar Connected Medical

Irvine, CA

Managed United States regulatory programs for connected electromechanical devices with embedded software, guiding products from design development through clearance, post market change evaluation, global documentation, and quality system audit support.

- Managed connected device programs from design development through FDA clearance and post market evaluation.
- Coordinated 510(k) submissions and pre submission packages across testing, software files, risk records, and labeling.
- Applied **IEC 60601 series** and **ISO 10993 1** requirements to electrical safety and biological evaluation evidence.
- Assessed software and cybersecurity changes, documenting FDA impact and appropriate filing or internal justification.
- Prioritized concurrent product workstreams, resolved evidence needs, and maintained clear regulatory decision records.
- Supported FDA interactions, global submissions, and quality audits with traceable technical responses.

Senior Regulatory Affairs Specialist, Surgical Devices

June 2018 - June 2020

Meridian Surgical Devices

Carlsbad, CA

Executed regulatory activities for minimally invasive surgical devices and accessories, supporting United States submissions, product changes, technical documentation, labeling, regulatory intelligence, and audit readiness with clinical, quality, and engineering partners.

- Prepared 510(k) dossier sections linking testing, risk evidence, device descriptions, claims, and labeling.
- Reviewed engineering changes and documented **Letters to File** or submission recommendations using FDA requirements.
- Closed documentation gaps with clinical, quality, and engineering partners before submission milestones.
- Monitored FDA guidance and **standards** updates, then summarized project impacts for active development teams.
- Maintained design to claim traceability across **technical documentation**, risk records, and approved labeling.
- Retrieved submission records, **registrations**, **change assessments**, and correspondence during quality system audits.

Regulatory Affairs Specialist, Electromechanical Devices

June 2016 - May 2018

Pacific Biomedical Instruments

Oceanside, CA

Supported regulatory maintenance and United States submissions for electromechanical medical devices, building practical expertise in FDA requirements, product life cycle activities, registration management, change assessment, labeling review, and audit preparation.

- Compiled 510(k) sections, device records, labeling, testing summaries, and administrative forms under senior review.
- Assessed engineering and supplier changes, routing higher risk decisions for senior regulatory review.
- Maintained establishment registrations, product registrations, renewal calendars, correspondence, and submission archives.
- Reviewed product documents against approved labeling and regulatory records, resolving discrepancies with stakeholders.
- Organized traceable regulatory evidence and tracked audit requests through documented closure.

- Supported product life cycle activities while developing practical judgment across FDA submission requirements.

PROJECTS

Robotic Surgical Platform Submission Strategy 📅 2024

Connected regulatory strategy with software, cybersecurity, risk management, testing, labeling, clinical evidence, and FDA submission planning for a robotic surgical platform.

Global Medical Device Technical File Program 📅 2022

Coordinated technical documentation, change assessments, registrations, renewals, and audit evidence for connected electromechanical medical devices.

LEADERSHIP & AWARDS

- Regulatory Affairs Certification, Devices, earned 2021
- Led cross functional FDA meeting preparation recognized for clear strategy and disciplined follow through.
- Selected as regulatory subject matter expert for robotic surgery software and cybersecurity decisions.

EDUCATION

Master of Science in Regulatory Science

2018

University of Southern California GPA: 4.0

Los Angeles, CA

Coursework: FDA regulation, medical device submissions, clinical research, quality systems

Bachelor of Science in Biomedical Engineering

2016

University of California, Irvine GPA: 4.0

Irvine, CA

Coursework: Medical device design, biomechanics, systems engineering, biological materials

CERTIFICATIONS

- Regulatory Affairs Certification, Devices 📅 2021
- FDA Medical Device Regulatory Affairs Certificate 📅 2020

TECHNICAL SKILLS

- FDA Submission Pathways:** Q submissions, IDE, De Novo, 510(k)
- Medical Device Regulations:** FDA regulations, FDA guidance, United States market access
- Device Safety Standards:** IEC 60601 series, ISO 10993 1, essential performance
- Software Compliance:** FDA software requirements, software documentation, software validation
- Cybersecurity Controls:** FDA cybersecurity requirements, threat assessment, security evidence
- Risk Management:** Risk analysis, risk files, design risk assessment
- Technical Documentation:** Device descriptions, technical files, submission dossiers
- Product Life Cycle:** Change assessments, Letters to File, sustaining activities
- Market Maintenance:** Registrations, renewals, labeling control
- Health Authority Engagement:** FDA meetings, briefing packages, agency correspondence
- Quality And Audits:** Quality system audits, traceability, audit readiness
- Medical Device Systems:** Robotic surgery, vision systems, connected platforms

SKILLS

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| Regulatory strategy | De Novo | Medical devices | Regulatory writing |
| FDA submissions | Q submissions | Robotic surgery | Life cycle management |
| 510(k) | Risk management | Software systems | Cross functional leadership |
| IDE | Cybersecurity | Health authority meetings | |

PROFESSIONAL AFFILIATIONS

- Regulatory Affairs Professionals Society, medical device regulatory community
- Association for the Advancement of Medical Instrumentation, device standards community

LANGUAGES

- English (Native)
- Spanish (Intermediate)

ADDITIONAL INFORMATION

Work Status : Authorized to work in United States. No sponsorship required.

REFERENCES

AVAILABLE ON REQUEST