Angela Foster

DIRECTOR, REGULATORY AFFAIRS

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SUMMARY

Regulatory affairs director with 14 years in medical device regulatory affairs, now heading strategy for wearable cardiac monitors and software as a medical device. Leads a 12-person team, sets global submission plans for the US, EU and Japan, and advises executives, with strong problem-solving skills and written and verbal communication skills.

EXPERIENCE

Director, Regulatory Affairs

01/2022 - Present

Hill Country Cardiac Diagnostics — Austin, TX

Maker of wearable ECG monitors and arrhythmia detection software with 800 employees.

- Head a team of **12** across regulatory affairs, labeling and regulatory operations with a $3.1M budget.
- Set regulatory strategy for 5 programs, securing 6 FDA clearances, 1 De Novo grant and EU MDR certification.
- Present regulatory risk, FDA policy changes and submission timelines to the CEO and board each quarter.
- Build a predetermined change control plan that cleared 4 algorithm updates without new 510(k)s.

Senior Regulatory Affairs Manager

04/2017 - 12/2021

Balcones Medical Software — Austin, TX

Imaging and remote monitoring software company.

- Led 6 specialists through 14 510(k) submissions for imaging and monitoring software.
- Wrote IEC 62304 and cybersecurity submission templates used on every software filing.
- Managed MDSAP certification at 2 sites with zero major nonconformities.

Regulatory Affairs Manager

06/2012 - 03/2017

Lone Star Orthopedic Devices — San Antonio, TX

Orthopedic implant maker.

- Prepared 15 510(k) submissions for spinal and trauma implants.
- Advanced from specialist to manager in 3 years, then supervised 3 specialists.
- Reviewed 300 promotional pieces a year for cleared claims.

SKILLS

Regulatory Affairs | Regulatory Strategy | Software as a Medical Device | De Novo | EU MDR | IEC 62304 | Cybersecurity | MDSAP | Problem-Solving Skills | Written and Verbal Communication Skills

EDUCATION

Master of Science

05/2012

The University of Texas at Austin — Austin, TX

Biomedical Engineering

CERTIFICATES

Regulatory Affairs Certification (RAC-Devices)

06/2015

Regulatory Affairs Professionals Society (RAPS)