Steven Wallace

Senior Regulatory Affairs Manager

steven.wallace@email.com • (216) 555-0158 • Cleveland, OH
linkedin.com/in/stevenwallace

Summary

Senior regulatory affairs manager with 12 years in medical device regulatory affairs, leading a 9-person team for imaging and surgical navigation systems. Interprets FDA regulations for executives, leads De Novo and 510(k) negotiation with FDA reviewers, and keeps ISO 13485 and EU MDR compliance on track across 4 sites.

Experience

03/2022 - Present
Cleveland, OH

Senior Regulatory Affairs Manager

Cuyahoga Imaging Systems
Maker of CT, X-ray and surgical navigation systems with 4 sites and 2,000 employees.

- Lead 2 managers and 7 specialists covering 60 product lines in the US, EU, Canada, Japan and Brazil.
- Secured a De Novo grant and 11 510(k) clearances, opening **$45M** in new product revenue.
- Negotiate labeling claims and testing scope with FDA in 9 pre-submission meetings.
- Direct inspection readiness at 4 sites, with no FDA Form 483 observations since 2022.

05/2018 - 02/2022
Mentor, OH

Regulatory Affairs Manager

Lakeshore Surgical Instruments
Powered surgical instrument manufacturer.

- Managed 5 specialists through 35 submissions for powered surgical instruments.
- Rebuilt the change assessment SOP, cutting unneeded 510(k) filings by 20%.
- Wrote the EU MDR transition plan for 18 product families, using problem-solving skills to rank gaps by risk.

06/2014 - 04/2018
Cleveland, OH

Regulatory Affairs Specialist

Western Reserve Medical
Patient monitoring device company.

- Prepared 10 510(k) submissions for monitoring devices, all cleared.
- Reviewed 250 labeling and promotional pieces a year.
- Maintained 40 international registrations for monitors and sensors.

Skills

- FDA Regulations
- Regulatory Affairs
- ISO 13485
- EU MDR
- De Novo
- 510(k)
- Change Assessment
- Inspection Readiness
- Negotiation
- Problem-Solving Skills

Education

05/2014
Cleveland, OH

Master of Science

Case Western Reserve University
Biomedical Engineering

Certificates

09/2017

Regulatory Affairs Certification (RAC-Devices)

Regulatory Affairs Professionals Society (RAPS)