Christina Alvarez

REGULATORY AFFAIRS MANAGER

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SUMMARY

Regulatory affairs manager with 9 years in medical device regulatory affairs and 3 years leading a team of 5 for a respiratory and sleep therapy portfolio. Builds regulatory strategy, manages FDA, Health Canada and EU submissions and works directly with regulatory agencies, backed by ISO 13485 audit experience, leadership and project management.

SKILLS

- Regulatory Affairs
- Regulatory Strategy
- FDA 510(k)
- ISO 13485
- MDSAP
- Health Canada
- Regulatory Agencies
- Project Management
- Smartsheet
- Leadership

EXPERIENCE

Regulatory Affairs Manager 07/2023 - Present

Allegheny Respiratory Systems Pittsburgh, PA

Maker of CPAP, ventilator and oxygen therapy devices with 1,100 employees.

- Lead a team of 5 specialists supporting 140 products, delivering **22** submissions and approvals in 2025.
- Manage pre-submission meetings and review calls with FDA and regulators in 4 other countries.
- Run the regulatory side of ISO 13485 and MDSAP audits, closing the last 3 with zero major findings.
- Plan 30 regulatory projects a year in Smartsheet, holding 90% of filings to their target dates.

Senior Regulatory Affairs Specialist 02/2020 - 06/2023

Three Rivers Medical Devices Pittsburgh, PA

Respiratory accessories and airway management company.

- Prepared 8 FDA 510(k) submissions for ventilation accessories, all cleared within 150 days.
- Wrote the regulatory assessment SOP adopted company-wide, cutting unneeded filings by 15%.
- Reviewed 300 promotional pieces a year with marketing and legal.

Regulatory Affairs Specialist 06/2017 - 01/2020

Monongahela Diagnostics Pittsburgh, PA

In vitro diagnostics developer.

- Compiled Health Canada license applications for 25 diagnostic products.
- Maintained registration and listing records for 60 devices in Excel and the FDA database.
- Drafted 12 change assessments for reagent and software updates.

EDUCATION

Bachelor of Science 05/2017

University of Pittsburgh Pittsburgh, PA

Bioengineering

CERTIFICATES

Regulatory Affairs Certification (RAC-Devices)

Regulatory Affairs Professionals Society (RAPS)

10/2020

ISO 13485:2016 Lead Auditor

BSI

03/2022