Emily Nguyen

Regulatory Affairs Associate

Minneapolis, MN • (612) 555-0138 • emily.nguyen@email.com
linkedin.com/in/emilynguyen

SUMMARY

Regulatory affairs associate with 2 years supporting 510(k) submissions and product changes for Class II cardiovascular devices. Compiles submission sections, handles labeling review and tracks registrations in Excel, bringing attention to detail and strong written and verbal communication skills to a fast-paced regulatory team.

SKILLS

- **510(k) Submissions**
- **Labeling Review**
- **Regulatory Assessments**
- **GUDID**
- **21 CFR 820**
- **ISO 13485**
- **Microsoft Word**
- **Excel**
- **Attention to Detail**
- **Written and Verbal Communication Skills**

EXPERIENCE

Regulatory Affairs Associate 08/2024 - Present

North Loop Cardiovascular Minneapolis, MN

Developer of Class II catheters and vascular closure devices with 450 employees.

- Compile device description, labeling and bench testing sections for **6** 510(k) submissions, 4 cleared without extra questions.
- Review 150+ labels, IFUs and marketing pieces a year against cleared indications and FDA labeling rules.
- Draft regulatory assessments in Microsoft Word for 40 design and supplier changes, recording each filing decision.
- Maintain FDA registration and listing and GUDID records for 220 catalog numbers.

Quality Associate 06/2023 - 07/2024

Mill City Medical Plastics Plymouth, MN

Contract molder of single-use device components.

- Reviewed 300+ device history records a month for completeness under 21 CFR 820.
- Logged 45 nonconformance reports in the eQMS and tracked each one to closure.
- Updated 20 work instructions and SOPs after line and process changes.
- Collected training records for 90 operators ahead of an ISO 13485 surveillance audit.

EDUCATION

Bachelor of Science 05/2023

University of Minnesota Minneapolis, MN

Biomedical Engineering

CERTIFICATES

ISO 13485:2016 Internal Auditor

BSI

03/2024