Niamh O'Rourke

Regulatory Affairs Specialist · Devices

regulatory-affairs-specialist@example.test
Galway, Ireland

Education

BSc Biomedical Science

Alder Bay College of Science

2019

Projects

Dossier update for four device families

2025

Reconciled 63 evidence records and traced labelling revisions to the current device specifications before the regulatory lead approved the package for submission.

Summary

Regulatory affairs specialist maintaining technical documentation for reusable medical devices. Turns product changes into an evidence list, tracks responses to reviewers and checks agreement between labels, specifications and the submission record.

Experience

Regulatory Affairs Specialist

Loughmere Medical Devices

2022-03 – Present

- Prepared change assessments for new suppliers, packaging and device specifications. Recorded the rationale and sent material changes to the regulatory lead for decision.
- Reconciled verification references and review signatures before each dossier update. Sent gaps to the engineers and checked completed responses against the source record.
- Tracked regulator questions and response deadlines, and prepared concise briefs backed by controlled document references.

Regulatory Documentation Associate

Seastone Clinical Instruments

2019-06 – 2022-02

- Checked revised packaging and instructions for use against approved source text before publication.
- Maintained a history of submitted versions and their approval records, and reconciled it against the release log.

Skills

Technical documentation · Change assessment · Regulatory responses · Document control

Languages

English · Irish