Chiara Bellandi

Validation Engineer · Medical Device Packaging

validation-engineer@example.test · Bologna, Italy

Summary

Validation engineer for medical device packaging lines. Prepares qualification protocols for sealers, reviews production trial data and traces deviations to objective evidence before quality approval.

Skills

Process qualification · Protocol authoring · Seal integrity testing · Deviation investigation · Requalification

Projects

Sealer qualification across three lines

2024

Qualified three sealers using approved acceptance criteria for two pouch materials. Linked each seal-strength result to its equipment ID, material lot and test condition.

Experience

Validation Engineer

Asterline Medical Packaging | 2022-02 – Present

- Drafted equipment and process qualification protocols for three sealers. Agreed the operating ranges, sampling plan and approved acceptance criteria with Quality and Manufacturing.
- Reconciled seal-strength results against the instrument record and packaging lot. Identified a mislabelled low-setting run and documented the retest conditions before repeating it.
- Investigated nine protocol deviations and indexed each result to its original record. Quality accepted the disposition before any affected run counted toward qualification.
- Maintained the requalification register and compared proposed changes with the validated ranges. Escalated a new pouch material for assessment instead of treating it as a routine substitution.

Qualification Technician

Juniper Curve Devices | 2018-09 – 2022-01

- Ran approved equipment checks and collected pre-run evidence for gauges and fixtures. Reported discrepancies before proceeding to process trials.
- Collated operator training records and instrument certificates into the protocol file. Flagged missing signatures while the responsible staff could still verify the original record.

Languages

Italian · English

Education

BEng Biomedical Engineering

Brenta Institute of Applied Engineering | 2018