Mira Elise Hartwig

Pharmaceutical Quality Assurance Associate

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Basel, Switzerland

Documentation and deviation follow-up

68 packaging records — Checked reconciliation, signatures and instructions. Escalated seven incomplete records before QA review.

19 to 6 overdue actions — Documentation actions after two months of weekly follow-up.

Projects

2025 **Batch record review checklist**
Packaging quality team

Mapped recurring errors to prompts and tested them on 12 records with QA. Rewrote two prompts reviewers had interpreted differently.

Skills

GMP documentation · Batch record review · Deviation logs · Change control support · Document control

Summary

Supports documentation review, deviation follow-up and controlled instruction changes at a packaging site. Prepares the supporting records for the QA reviewer. The quality manager approves dispositions and releases.

Experience

2024-09 – Present **Quality Assurance Associate**
Lindenbarrow Pharmaceutical Packaging

- Checked reconciliation and required signatures against current instructions. Logged incomplete records with an owner and evidence reference for QA review.
- Followed up overdue documentation actions weekly. Kept original due dates in the deviation register when reviewers approved extensions.
- Prepared evidence for three change controls. Sent mismatched issued instructions to a second checker before distributing approved versions.
- Kept original files, reviewer decisions and approved replacements separate for two deviations so QA could trace changes.
- Drafted shift briefing examples from recurring errors and checked them against current procedures with QA.

2024-02 – 2024-06 **Quality Documentation Placement**
Glenweir Health Products

- Matched training records to issued instructions under supervision and flagged missing sign-offs before the coordinator checked the training matrix.
- Found approved versions for an internal walk-through and listed records that still needed review.

Education

2024 **BSc in Pharmaceutical Sciences**
Upper Rhine Applied Sciences College

Pharmaceutical quality systems, data integrity and document version control.

Languages

German · English · French