SOP: Batch Record Documentation and Review

SOP Number	[Enter SOP No.]	**Effective Date**	[Enter Date]
Department	Manufacturing/Quality Assurance	**Revision No.**	[Enter Revision]
Prepared By	[Name/Title]	**Approved By**	[Name/Title]

1. Purpose

This SOP details the process for **batch record documentation and review**, including proper recording, verification, and approval of production batch records to ensure accuracy, completeness, and compliance with regulatory requirements.

2. Scope

This procedure is applicable to all manufacturing personnel and quality assurance staff involved in the documentation, review, and approval of batch records throughout the product lifecycle.

3. Definitions

- **Batch Record:** A collection of authorized documents that record the history of the manufacturing and processing of a specific product batch.
- **Reviewer:** Authorized personnel responsible for verifying batch record entries for accuracy and completeness.
- **Discrepancy:** Any deviation or error recorded in the batch record during processing or documentation.

4. Responsibilities

- **Production Personnel:** Properly complete and record all batch data in real-time.
- **Quality Assurance (QA):** Review records for accuracy, completeness, and compliance; manage discrepancies; and approve final documentation.
- **Supervisors:** Ensure staff are trained on the SOP and monitor process adherence.

5. Procedure

1. **Batch Record Data Entry**
    - Enter all data legibly and in indelible ink immediately after performing each step.
    - Record signatures, initials, and dates where required.
    - Do not leave blank fields. If not applicable, mark as "N/A" and provide justification if required.
2. **Review Timeline**
    - Batch records must be submitted to QA within [specify time, e.g., 24 hours] of batch completion.
    - QA review must be completed within [specify time frame, e.g., 5 working days].
3. **Verification and Review**
    - QA verifies the entries for accuracy, completeness, and compliance with SOP and regulatory requirements.
    - Check for corrections made according to good documentation practices (e.g., single line strike-through, initialed, dated, with explanation if necessary).
4. **Discrepancy Management**
    - Document all discrepancies using the assigned discrepancy or deviation form.
    - Investigate discrepancies and complete corrective action as required before final record approval.
5. **Final Approval and Archiving**
    - Upon satisfactory review, QA signs off the batch record signifying approval.
    - Batch records are archived according to the company's document retention policy for traceability and regulatory inspection.

6. References

- Current Good Manufacturing Practices (cGMP) Guidelines
- Company Document Retention and Archiving Policy
- Data Integrity SOP

7. Attachments

- Batch Record Template
- Discrepancy/Deviation Report Form
- Batch Record Review Checklist