SOP Template: Batch Record Completion and Review Guidelines

This SOP details the **batch record completion and review guidelines**, outlining the procedures for accurately completing, verifying, and reviewing batch records. It includes instructions on documentation standards, required approvals, error correction protocols, and timelines for record submission to ensure compliance with regulatory requirements and maintain product quality and traceability throughout the manufacturing process.

1. Purpose

To define the standard procedures for completing and reviewing batch records, ensuring compliance with regulatory and internal requirements and maintaining batch traceability and data integrity.

2. Scope

This SOP applies to all staff involved in the preparation, completion, verification, review, and approval of batch records in the manufacturing facility.

3. Responsibilities

- **Operators:** Accurately complete all relevant batch record entries during processing.
- **Supervisors/Team Leaders:** Verify accuracy and completeness of batch records prior to submission for review.
- **Quality Assurance (QA):** Conduct thorough review, ensure compliance, approve or reject records, and monitor timely submission.

4. Definitions

Term	Definition
Batch Record	Official documentation containing the complete production and control history of a batch.
SOP	Standard Operating Procedure.
QA	Quality Assurance.

5. Procedure

5.1 Batch Record Completion

1. Enter all required information in black or blue permanent ink (if physical record).
2. Record data at the time each manufacturing step is performed (contemporaneous recording).
3. Complete every required field. Mark non-applicable fields as "N/A" and provide justification if needed.
4. Use full signatures, initials, and dates where indicated.
5. Maintain legibility at all times; avoid overwriting or use of correction fluids.

5.2 Documentation Standards

- Record all entries in English or as otherwise required by site-specific SOPs.
- Use only approved abbreviations and symbols.
- Ensure that original documents are protected from loss or damage.

5.3 Error Correction Protocol

1. Draw a single line through the error so that the original entry remains legible.
2. Enter correct information above or next to the strikethrough.
3. Sign and date the correction; include a brief explanation if required.

5.4 Batch Record Review & Approval

1. Submit completed batch records to the supervisor/team leader within **<specify timeframe, e.g., 24 hours>** after batch completion.
2. Supervisors/team leaders review for completeness, accuracy, and compliance before forwarding to QA.
3. QA reviews all entries, supporting attachments, and compliance with SOPs and regulatory guidelines.
4. Any identified discrepancies or incomplete sections must be resolved prior to final approval.
5. All approved batch records are filed and stored per record retention policy.

6. Timelines

1. Batch records should be completed in real-time and submitted for review within **<specify timeframe, e.g., 24 hours>** of batch completion.
2. QA review and approval must be completed within **<specify timeframe, e.g., 5 working days>** of receipt.

7. References

- Current Good Manufacturing Practices (cGMP)
- Site-Specific Manufacturing and QA SOPs
- WHO, FDA, or other relevant regulatory guidelines

8. Revision History

Version	Date	Changes	Approved By
1.0	YYYY-MM-DD	Initial Issue	Name/Title