SOP Template: Quality Control Checks for Completeness and Accuracy of Forms

This SOP defines the procedures for conducting **quality control checks for completeness and accuracy of forms**, ensuring all necessary fields are properly filled and data is accurately recorded. It includes systematic verification steps, criteria for evaluating form integrity, error identification and correction processes, and documentation standards. The goal is to maintain high data quality, prevent processing delays, and support compliance with regulatory and organizational requirements.

1. Purpose

To outline the standardized process for verifying forms for completeness and accuracy, and to ensure consistency and compliance in data collection and entry.

2. Scope

This procedure applies to all staff responsible for reviewing, accepting, or processing forms across all departments handling official records.

3. Responsibilities

- **Quality Control Staff:** Conduct checks as per SOP and document findings.
- **Form Submitters:** Complete all fields according to instructions.
- **Supervisors/Managers:** Review quality control logs and implement corrective actions.

4. Procedure

1. **Receiving the Form:**
   - Ensure all forms are collected from the designated submission point.
   - Date-stamp or electronically log the received form.

2. **Completeness Check:**
   - Verify all mandatory fields are filled.
   - Check for missing signatures, dates, or attachments.
   - If incomplete, mark as "Incomplete" and follow up with the submitter.

3. **Accuracy Check:**
   - Compare data against source documents as appropriate.
   - Check for legibility, correctness of values (e.g., valid dates, numbers, identifiers), and logical consistency.
   - Highlight discrepancies for review/correction.

4. **Error Documentation & Correction:**
   - Record all errors in a quality control log.
   - Notify submitter or responsible party for correction.
   - Document corrective actions and resolution date.

5. **Final Review:**
   - Ensure all corrections have been made and documented.
   - Sign off the form as "QC Checked" with date and reviewer's initials.

6. **Archiving:**
   - Store verified forms and logs according to organizational document management policies.

5. Evaluation Criteria

Criteria	Description
Completeness	All mandatory fields are populated; no sections are left blank unless specified as optional.

Accuracy	Information matches supporting/source documents; no typos or factual errors.
Legibility	Handwritten entries are readable, or digital entries are clear and properly formatted.
Compliance	Meets regulatory and internal reporting requirements (e.g., signed, dated, proper version).

6. Documentation Standards

- All QC checks must be recorded in a **Quality Control Log** (electronic or paper).
- Corrections must be dated, initialed, and reason for correction stated.
- Retain all QC documentation in compliance with records retention policy.

7. References

- Relevant regulatory guidelines (e.g., FDA 21 CFR Part 11, GDPR)
- Internal Data Management Policy
- Form-specific Instructions/Manuals

8. Revision History

Version	Date	Description of Change	Approved by
1.0	2024-06-25	Initial template release	[Approver Name]