



**MLKC CONSULTING, LLC**

*Life Science Quality and Regulatory Experts*

## **SOP Writing Best Practices Checklist**

This checklist provides best practices for writing effective Standard Operating Procedures (SOPs) that ensure regulatory compliance and operational efficiency. Use this guide to develop, review, and maintain SOPs that meet FDA, GMP, and industry standards.

### **Use this checklist to:**

- Develop clear and compliant SOPs for regulatory requirements
- Ensure consistency and accuracy in procedure documentation
- Train employees on SOP execution and compliance expectations
- Maintain a structured review and update process for all SOPs
- Prepare for FDA inspections by aligning SOPs with current regulations

### **1. Define SOP Purpose & Scope**

- Clearly state the objective of the SOP.
- Ensure alignment with FDA, GMP, and ISO regulatory requirements.
- Identify key processes that require SOPs (e.g., Manufacturing, Quality Control, CAPA).

### **2. Use a Standardized SOP Format**

- Include SOP title, document number, revision history, and effective date.
- Use a structured format with clear headings for each section.
- Keep instructions concise, step-by-step, and easy to follow.

### **3. Ensure Regulatory Compliance**

- Reference applicable FDA regulations (e.g., 21 CFR Parts 210, 211, 820, 1271).
- Incorporate industry best practices such as ICH, ISO, or GAMP 5.
- Include change control and document approval procedures.

### **4. Write in Clear, Simple Language**

- Use active voice and direct instructions (e.g., 'Record temperature' instead of 'Temperature should be recorded').

- Avoid excessive jargon and complex sentence structures.
- Use bullet points, tables, and flowcharts where applicable.

## **5. Implement a Training & Compliance Program**

- Conduct regular employee training on SOP implementation.
- Maintain training records and employee acknowledgment logs.
- Test employee comprehension through assessments or practical demonstrations.

## **6. Establish an SOP Review & Approval Process**

- Ensure SOPs are reviewed by department heads and QA teams.
- Document all revisions with a version history.
- Implement a controlled document management system to track updates.

## **7. Schedule Routine SOP Audits & Updates**

- Review and update SOPs at least annually or after process changes.
- Perform internal audits to verify SOP adherence in daily operations.
- Ensure obsolete SOPs are archived and no longer in use.

### **Pro Tip: How to Maintain SOP Effectiveness**

- \* Conduct annual SOP reviews to ensure they align with the latest regulations.
- \* Train employees on SOP execution and compliance expectations.
- \* Implement an electronic document management system (eQMS) for controlled SOP tracking.
- \* Use mock FDA audits to evaluate the effectiveness of SOP adherence in daily operations.

### **Need Expert Support for SOP Development?**

MLKC Consulting, LLC specializes in SOP writing, compliance training, FDA audit readiness, and regulatory documentation. Contact us for expert guidance!

### **Contact us today for a Consultation!**

Email: [Meredith@mlkcconsulting.com](mailto:Meredith@mlkcconsulting.com)

Website: [www.mlkconsulting.com](http://www.mlkconsulting.com)

Phone: 937-503-4265