Creating a Standard Operating Procedure (SOP) for Medical Device Regulatory Compliance

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1. **Overview**

    A Standard Operating Procedure (SOP) is a set of written procedures or instructions that document routine or repetitive activities within an organization. Development and implementation of SOPs helps an organization to maintain the consistency of the activities performed by its employees. Well-written SOPs are of particular importance in in the highly-regulated medical device arena to ensure that:

    1. All requisite steps are completed to assure regulatory compliance,

    2. Any and all documents for submission to testing facilities and regulatory bodies have been properly and completely prepared and

    3. The medical device manufacturer has properly documented all processes and procedures in the event of an audit.

2. **Scope**

    This document acts as a general instruction manual for developing a SOP. It lists the potential content, format, writing style, and description of text required to be included in a SOP. This document can be used as a reference to develop SOPs by different departments of an organization.

3. **Purpose/Objective**

    The purpose/objective of this document is to provide guidelines for development of a Standard Operating Procedure.

4. **Definition/Explanation of key terms**

    SOP- Standard Operating Procedure

5. **Process Owner**

    Regulatory and Compliance department is responsible for the implementation of this procedure.

6. **SOP writing procedure**

    6.1 Content of SOP

    Title
    - A title that identifies the activity or procedure.
    - SOP identification (ID) number.
    - Date of issue and/or revision.
    - The name of the applicable agency, division, and/or branch to which this SOP applies.

Change History

- This section includes the signatures and signature dates of the individuals who prepared and approved the SOP, version number and description of change. In case of electronic SOP, use electronic signature.

Table of content/index page

- Table of content is used for locating information within the SOP.

Overview and background

- Briefly describe the purpose of the work or process, including any regulatory information or standards that are appropriate to the SOP process.

Scope

- Scope should indicate what is covered in the SOP.
- Scope should identify the range of activities the SOP applies to, limitations, exceptions, and pre-conditions.

Objective/ Purpose

- In this section explain the objective this specific Standard Operating Procedure is intended to achieve.

Definition

- Include definition section, where appropriate, to define unusual or specialized terms, acronyms used in the SOP.

Responsibilities

- In this section identify the personnel, departments, and contractors responsible for performing the procedure.
- Identify the person, who is responsible for training personnel.

Equipment/Method

- Include method section, where applicable, to explain specific methods used.
- Include description of equipment that is used for the specific procedure (if applicable).

Caution/Warning

- This section is used in specific SOPs to describe the caution/warning associated with the specific procedure.

Procedure

- Under this section explain the procedure that needs to be performed. (For example, the "Procedure" section of a SOP for Project Management may contain and explain the following processes.
    – Project Initiation
    – Project Execution
    – Project Monitor and Control
    – Project Closing)
- Use flow charts to explain a process, if applicable.
- Identify any technologies or systems that are necessary to perform the steps.
- Identify the responsible personnel for each step.

References

- In this section list other related SOPs, supporting documentation and applicable regulations that need to be followed along with the specific SOP.

Version Control

- Implement version control of the SOP. Identify any changes made to the SOP, identify the type of changes, include date on which changes were made and identify the person who made changes.

Attachments/Appendices

- In this section, include any documents that refer to the SOP. For example, work instructions, other procedures, flowcharts etc.

6.2 Update requirements for SOPs

Determine a timeline to update the SOPs. There is no fixed rule for the timeline of review of the SOPs. The best approach is to find proper balance of regularly scheduled review and revision, and as-needed review and revision. The best balance depends on content factor and logistics. The timeline should be determined considering the importance of the procedure. The best practice is to review the SOP once a year. If that is not possible it should be done every two-three years instead of waiting for five years. An organization should establish a process to ensure that the current version of the SOP is in use.

7. References

1. How to write a SOP
   http://www.metabolomics.ca/News/sops/HowToWriteAStandardOperatingProcedurev1.pdf
2. Instructions for developing a business SOP
   http://www.ehow.com/how_6565819_write-business-standard-operating-procedures.html
3. http://www.epa.gov/quality/qs-docs/g6-final.pdf
4. Walsh.I., 29 Ways to write your SOP Procedure Faster, 2010, retrieved from
   http://www.standardoperatingproceduretemplates.com/procedure/getting-started-37-business-proposal-writing-tips/742/

Appendix A

Rules of Thumb

- Determine the procedures or processes for which a SOP is required.
- It should describe technical and fundamental operational elements of an organization.
- It should specify the procedures to be used, in greater details.
- Describe all appropriate QA and QC activities for the procedure described in the SOP.
- Provide a section that lists all cited or significant references.
- Ensure that the procedure is in compliance with the appropriate regulations. For example, national or local regulatory requirements.
- Once the procedure is written, test it to make sure it is ***correct***, ***concise***, ***complete***, and ***comprehensive.***
- If the SOP references other SOPs then following things should be attached with the SOP
    - Cite the referred SOP and attach a reference where and how to locate the SOP.
    - If the referenced SOP should not be followed exactly, the required modifications should be specified in the main SOP, under the section where the referenced SOP is cited.

Appendix B

Writing Style of SOPs

- SOPs should be written in a concise, step-by-step, easy-to-read format.
- Provide easily understandable instruction.
    For example, when providing instruction on version controls of a document, provide information in the following manner.
    - o Identify the new version number/ID.
    - o Provide description of changes made to the document.
    - o Indicate the person(s) made changes to the document.
    - o Indicate the person(s) reviewed and authorized the changes.
    - o Sign and date once the changes are approved and new version of the document has been created.
- The SOP should be written in third person, present tense and active voice.
    For example, when providing instruction for maintenance and implementation of SOP it should be written as "Maintain an updated SOP and ensure that the updated SOP is implemented".
- Do not use the term "you", but imply it.
    For example, maintain a version control of the Standard Operating Procedure. In this sentence the term "you" is not used, but implied.
- Do not reference to gender, unless required to clarify the instructions.
- Use flow chart to illustrate the process being described, if applicable.
- Use table for displaying information that is best suited to a tabular format.
- The style guide should be maintained for all SOPs within the organization.
- Provide separate section for each step and arrange them sequentially.

Important Tips to Remember While Writing SOPs

- Make sure that the procedure is logical and organized.
- Arrange material in order of priority to the reader.
- Number pages and sections consecutively; do not re-number each section.
- Each section title should stress the main benefits.
    - For example, the header "Writing Style of SOP" explains that the description provided under this header describes the style, which is the main benefit to the reader that should be followed when a SOP is written.
- Each section title should help readers orient themselves.
- If possible, express the key point of the section in the headline, or immediately after it.
- Highlight important points.
- The most positive points can be emphasized by using bold, underlining, different fonts, spacing, titles, bullets, and summaries.
- Write all action steps. Don't skip anything.
- Avoid banal headings and titles.
    - Example of a banal heading/title for SOP writing procedure could be "How to Write a SOP". A more applicable heading/title for this section could be "Guidelines to SOP Writing".
- Use action verbs in headers.
    - For example, "Implement the Procedure"; here implement is an action verb. Some of the other commonly used action verbs are improve, inspect, install, isolate, control , and investigate etc.
- Boiler plate texts are standard languages that are used multiple times in a document. Boilerplate text is similar to template, but a template holds style and layout information whereas boilerplate text contains text or graphics. Use boilerplate text where applicable.
- Avoid hackneyed openings and closings. The opening sentence of a paragraph/section should mention the gist of the procedure described in the paragraph/section and the closing statement should reinforce the main points that have been described in the paragraph/section.
- Use the same terms and jargon that appear in all SOPs.

Links to sample SOP

1. http://www.fao.org/docrep/W7295E/w7295e04.htm#f%20002%20%20%20administration%20of%20standard%20operating%20procedures