HOW TO WRITE A

Standard Operating Procedure

Tips and tricks for your Quality Management System

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A Standard Operating Procedure (SOP) is an integral part of the Quality Management System. It is a documented set of instructions that allows the user to achieve a specific purpose in an effective and efficient manner. It might seem as going back to basics, however, our experience with numerous audits on both sides, as auditors and auditees when providing audit support to clients, show that many SOPs are poorly written. An inadequate procedure is not only inefficient from the user`s perspective but can also lead to lack of ownership and compliance issues. Having properly documented and enforced standard operating procedures in place that comply with the regulatory requirements is of paramount importance for medical device companies and is one of the prerequisites of a positive audit outcome. Obviously, it is much more advantageous to medical device companies to have adequately written procedures from the start rather than initiating and conducting corrective actions later. So what are the auditors looking for and how can you 'audit-proof' your SOPs? I have put together the basic SOP writing instructions as well as some hints on how to avoid deficiencies.

Preparation

1. Gather relevant information.
2. Identify regulatory requirements.
3. Define the purpose and intended outcome of the procedure.
4. Interview those who perform the relevant tasks on a daily basis to gain a thorough understanding of the current procedure and to get an insight of what has proven to be effective in practice and what has not.
5. Identify the logical sequence of the tasks.
6. Create a process flowchart based on the feedback you have received.
7. Review the process with the team to identify and remove redundant steps.
8. Brainstorm with the users of the procedure and the management on possibilities to make the process leaner and more efficient.

Structure of the Document

- Identify the document title, identification number, version and the effective date.
- Identify Process Owner and Responsible Person.
- Insert page number and total number of pages.
- Identify author, reviewer and approver of the document, including dates and signatures.
- Insert a table of contents.
- Define the purpose of the procedure (keep it short and to the point).
- Define the scope of the procedure.
- Insert a Glossary to describe the terms and definitions. Explain the abbreviations.
- Describe the roles and responsibilities.
- Identify competence and training requirements, including safety issues or any other precautions to be considered, if there are any.
- List the applicable references (both internal & external).
- Reference applicable Common Specifications and Harmonized Standards, if available
- Reference applicable templates, checklists, equipment or supplies etc. needed for the procedure.
- Describe the interface of the current process with other processes in the organization highlighting the Inputs & Outputs.
- Describe each step of the process (each step can be broken into smaller steps).
- Try to keep the procedure as high level as possible and include specific requirements in the templates whenever possible.
- Cross reference and avoid duplication of the information.
- Draw a flowchart, where appropriate.
- Provide illustrations and tables, where appropriate.
- Include appendices, where necessary.
- Define where this procedure will be stored.
- Define a review cycle (to evaluate whether the procedure is adequate for the purpose and is producing expected performance).

Practical Tips

- Keep the SOP short not more than 20 pages.
- The description of the tasks should be concise and complete.
- Only reference the regulations that your procedure fully complies with.
- It is best to follow e.g. guidelines but not list them in the applicable reference section as the auditors will expect full compliance to each listed reference.
- Describe the tasks in a way that is understandable to the reader and remember that the user of the SOP is not always a regulatory or quality expert.
- Break down the major tasks into smaller sections to make it easier to follow.
- Use the verb in imperative for clear guidance (e.g. 'use', 'review', 'evaluate', 'define' etc.).
- Try to avoid vague expressions and long sentences to rule out ambiguity, which may leave the reader guessing and lead to deviation.
- Avoid making your requirements in the SOP stricter than the external regulatory requirements.
- If the Regulation requires an annual update of a report, don't restrict yourself by defining your internal requirement to be a monthly update. You can still do a monthly update as a best practice but define in your procedure that the report shall be updated at least once per year. This will give you more flexibility in an audit.
- Add notes and explanations, where necessary.
- Make sure that the flowchart corresponds to the process description.
- If there is a decision point in the flowchart, both positive and negative scenarios should be described (i.e. Yes/No).
- Perform a dry run to test the procedure if it is complete and understandable to the reader
- Define key performance indicators (KPIs) to monitor the effectiveness of the procedure.
- Always check the formatting before publishing.
- Train all employees for whom the procedure is relevant and keep the records of the training.

QUNIQUE can help!

If you need support in writing or updating your procedures according to ISO 13485: 2016, MDR (EU) 2017/745 and other applicable requirements or reviewing the efficiency of your Quality Management System , our subject matter experts can assist you to reach your specific goal in the most efficient manner. QUNIQUE is focused on offering tailored solutions that fit the specific context and resource framework.

You can get in touch with us through e-mail: info@quniquegroup.com or book a consultation directly on the QUNIQUE website www.quniquegroup.com.