CREATION AND IMPLEMENTATION OF EFFECTIVE STANDARD OPERATING PROCEDURES IN THE PHARMACEUTICAL INDUSTRY

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Introduction

Standard Operating Procedures (SOPs) are an integral part of the day-to-day operations in the pharmaceutical industry, and every relevant organizational unit within the industry must have its own SOPs. SOPs are also a regulatory requirement, and represent a proof of compliance with the Good Manufacturing Practice. They are regularly reviewed by the inspectors/auditors during the audits/inspections performed on the site of the manufacturer. The SOPs in the pharmaceutical industry are tested, verified, approved and documented way of performing activities/operations in the industry. The key points in the SOPs are answers to these questions:

- Why this document is required?
- Who will be responsible for the performing of activities/controlling of performed activities?
- What is the scope of the document?
- What is the expected outcome/results of this activity?

Materials and methods

This paper reviews the available literature data and analyzes a Quality Management System of a pharmaceutical industry in a way of creating and implementation of effective standard operating procedures.

Discussion

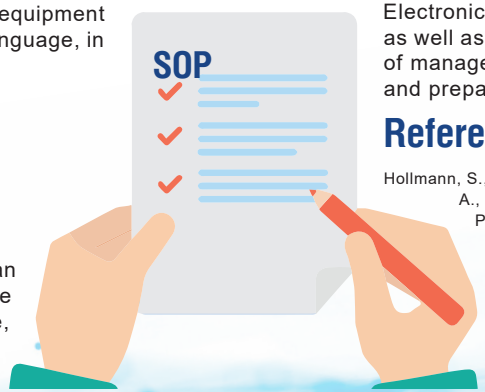
Standard Operating Procedures are documents that formalize the tasks in the company, by stating the positions of employees who are responsible for the process/s, as well as the resources used in the process/s. In this way, identification of the data about who, what and when is performed during each stage of the process is done.

This type of documents describes the activities "step by step" and contains more details about the execution of the tasks, including the method and time of execution. Most often, these documents are created based on the user manual from the equipment manufacturer, they contain uncomplicated instructions using simple language, in order to ensure consistency of the process/procedure.

These documents have a workflow that covers several stages:

- initiating/creating a new SOP/new version of a SOP,
- writing of the SOP (working/draft version),
- checking and approval,
- obtaining the status of an approved SOP,
- obtaining the status of a valid SOP,
- archiving of invalid version/invalid SOP.

Every workflow starts with a need for a new SOP or a new version of an existing SOP. First, the responsible person submits a request for the assignment of a new code or a new version of an existing code, respectively. During this procedure, there should be information about all persons who will appear as authors/verifiers or approvers of the relevant document, as well as for whom it is intended.



In the draft phase, the designated author(s) of the SOP writes/drafts the document, which represents a draft or working version of the document. After the completion of this phase, the document is handed over to the reviewer(s) for document review.

Electronic management of standard operating procedures (SOPs) in the pharmaceutical industry implies to the utilization of software or computerized systems to create, approve, control, and distribute SOPs that document routine or repetitive activities in various departments such as production, quality control, quality assurance, and other relevant organizational units.

Numerous benefits of electronic SOP management range from:

- Ensuring compliance to regulatory requirements like as GMP, GCP, GLP, and others;
- Enhancing the consistency and quality of operations and products;
- Reducing errors, delays, and costs associated with paper-based or manual SOPs;
- Facilitating employees training and evaluation simpler to do.

An electronic document management system (eDMS) is a computerized system that assists in the administration, storage, and distribution of electronic documents connected to regulatory affairs, quality assurance, and other pharmaceutical industry tasks. It can assist to shorten the submission process, assure standard and regulatory compliance, and promote cooperation and efficiency.

An eDMS system is important for the pharmaceutical industry because of its main features:

- Managing and storing documents related to research and development, regulatory submissions, quality assurance, and other activities;
- Ensuring compliance with standards and regulations, such as Good Manufacturing Practice (GMP), and other relevant documents;
- Minimizing the costs and risks of noncompliance, errors, delays, and data loss;
- Supporting innovation, collaboration, and overall success.

Electronic management of SOPs requires a centralized and secure document repository that allows users to easily search for and retrieve SOPs, as well as a workflow system that supports electronic signatures, revision control, and audit trails.

Conclusion

Standard Operating Procedures play an important role to ensuring pharmaceutical product and process quality, safety, and efficacy, as well as compliance with regulatory requirements and industry standards. SOPs should be crated and implemented with involvement of the employees who perform the tasks, with a support of the management. Their content should be consisted of clear, simple and consistent language that follows a logical and intuitive format.

Electronic management of SOPs is a way of improving the efficiency, quality, and consistency as well as ensuring compliance with regulatory requirements and industry standards. This type of management of SOPs can organize and standardize the processes, reduce errors or costs, and prepare the manufacturer for inspections and audits.

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