SEVEN STEPS TO IMPLEMENT AN AFFECTIVE AND INTEGRATED SOP AND TRAINING SYSTEM

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ABSTRACT

Regulated industries such as Pharmaceutical, Biotechnology and Medical Devices, among others, require the use of Standard Operating Procedures (SOPs), to perform in the workplace, consistently. For several years the Food and Drug Administration has observed that some of these industries do not have the ability to create specific and easy to follow SOPs. It results in process deviations, ineffective trainings and non-compliance. A research was performed to identify best practices and tools recommended by different experts from the Industry. As a result of this research, a model was developed and used to enhance SOPs used in a Packaging Operation. Two methodologies were integrated in this project: DMAIC (Define, Measure, Analyze, Improve, and Control) and HPT (Human Performance Technology). The model consists of seven steps and the associated tools required to implement effective SOPs and effective trainings. The model is available for future implementation in any industry to reduce errors and improve performance.

INTRODUCTION

Standard Operating Procedures are used in regulated industries to describe, step by step, how to perform an operational process consistently. Depending on how effective these documents are created, transferred and followed, they may impact the operational results and regulatory compliance.

It is a concern how we can improve the documents that are used to standardize the performance and the knowledge transfer. After evaluating different sources and pharmaceutical practices we can conclude that the SOPs' creation and validation are critical steps to have effective and adequate documents. If the SOPs are prepared appropriately, the knowledge transfer through training and practice will improve the execution, impacting the organizations' results.

The SOPs from a Packaging Operations were used to apply the model developed. Current SOPs uses the traditional format and are not supporting the training process and the organizational results. As a result, deviations to the process due to human error and failure following the SOPs have occurred.

The model presented below provides the steps to be followed to gather and validate the information that is going to be included in an SOP, a non-traditional format to present the information more illustrative, and a performance based training approach to transfer the knowledge.

REGULATORY BACKGROUND

The SOPs are required by the Food and Drug Administration (FDA) in, at least, twenty five separate citations in the Code of Federal Regulations (CFR) Title 21 – Current Good Manufacturing Practice for Finished Pharmaceutical.

Although industries have formal SOP and Training Systems, the FDA continues observing deficiencies in the SOP System. In the year 2007, the SOPs were included among the top seven FDA observations in the San Juan, PR District [12].

Some of the observations from FDA inspections have been [11]:

- Lack of clarity.
- Lack of assigned responsibilities.

- Lack of proper trainings.
- Failure following SOPs.

As a result, operators omit steps or perform incorrectly impacting the products' manufacturing: the costs, the safety, and the quality. A common cause assigned to these deviations is human error because the operator could not follow an SOP or because the training was inadequate. The most common corrective action is to re-train or to add information to the SOPs. Although these measures are implemented, the deviations and the FDA observations continue.

FDA wants to ensure that the employees understand the procedures and can execute in the workplace in accordance with the written documents. A documented evidence of SOP readings is not enough. To satisfy FDA's expectations it is required to have an effective SOP system and an effective training program.

FDA is implementing in the Agency a renovated training system. This system is implemented by levels: for apprentices and for fully performers, using discussion, practical exercises, on the job trainings, and field audits. The focus is more on situations and applications rather than on the basics. They classified the on the job training as essential and the audits as "the real test" [13].

RESEARCH

Several articles from technical magazines, pharmaceutical industry associations' publications, books on documentation practices, SOPs, and training were used in this research to evaluate pharmaceutical best practices and current models used to implement effective SOPs and training systems.

The following is a summary of the research results.

STANDARD OPERATING PROCEDURES – SOPS

Lavian et al. [11] describe the SOPs as "the document that details the tasks that must be performed at each step in the manufacturing process", "the first line of defense during an inspection"

According to DeSain [3], "SOPs are documents that describe how to perform various routine operations in a GMP manufacturing facility". SOPs are documents that describe the performance of routine tasks and support commitments to FDA. They are used during FDA inspections to evaluate [3] "how well these written commitments are fulfilled". Also, SOPs are consulted by personnel in Quality Control, Production, Maintenance and Material areas, among others, on a daily basis, in order to perform their assigned tasks in a consistent manner.

Although SOPs play an important role in fulfilling regulatory requirements and are the best tool for product quality, consistency, personnel training and operational efficiency, they are not written for the FDA. They do not contain policy statements or specifications.

De Sein [3] recommends that SOPs are written when the process has been defined and when it is clear how the task will be performed (how), who is responsible (who), why and its applicability (scope). When the process has not been defined prior to developing the SOP, the results can be pre-determined: the SOPs do not represent the current operation and the employees do not follow them.

Effective SOPs are written using a clear and direct language; in a logical order, with step by step instructions, using directive, active verbs in third person; written by or with the subject matter experts who perform the operation, specific and self explanatory. SOPs should be reviewed by the personnel who will be using them.

SOPs should be controlled by using SOP's and edition's number and should be approved by the Quality Assurance Department. Lavian et al. [11] recommend "to minimize the number of signatures required and to maximize the ability of signatories to effectively review the SOP".

The standard sections of a procedure used in most of the Pharmaceutical Industries are as follows:

- ***Title*** - Identifies the SOP purpose. Should be brief and direct.
- ***Table of Content*** - Used for easy retrieval of information within the SOP.
- ***Purpose*** - Describes the reason for writing the SOP.
- ***Scope*** - Describes what the SOP does apply to.
- ***References*** - This is an optional section, used to reference other SOPs or documents that are related or that are required to be used with the SOP.
- ***Safety Considerations*** - It includes physical safety issues, protection and contamination issues, among others.
- ***Procedure Step*** - Step by step instructions that tell how a task is going to be performed, by whom, with a duration or quantity, if applicable. It can include diagrams or flowcharts.
- ***Standardize Header / Footer*** - It is expected to have a standard header or footer that includes the SOP Number, Edition and Pagination, among others.
- ***Approval / Dates*** - It should include two minimum approvals from: Originator's and QA areas. Also, an effective and revision dates.

When SOPs are used as a quality tool, written in a clear and simple manner, they support training activities.

The SOPs Support the Training System

A Training Program should specify who needs to be trained, on what equipment or process. Trainings should be performed by qualified trainers and documented for evidence.

FDA requires, in the CFR Title 21 Section 211.25 [5] that "each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, and experience, or any combination thereof, to enable that person to perform the assigned functions. Training shall be in the particular operations that the employee performs". Also, it applies to "each person responsible for supervising the manufacture, processing, packing, or holding of a drug product" and "there shall be an adequate number of qualified personnel to perform and supervise the manufacture, processing, packing, or holding of each drug product" [5].

The technical trainings used to transfer SOPs information have three attributes that need to be considered [10].

- Require learning exact skills, following certain procedures, and performing accurately.
- Require trainers to be proficient at the relevant technical skill, able to transfer their expertise to learners, and able to deal with feelings of learners.
- Covers a wide range of learning needs from basic reading, speaking, computational skills, critical thinking skills, to job performance skills.

Today, a blended instructional design is recommended because it includes a combination of classroom sessions, use of case studies, games, role plays, simulations, and hands on activities, among others. Through the developed model, we pretend to demonstrate that enhanced SOPs may be used as the main source for the training material development. The integration of both systems: the SOPs and the training systems may result in the improvement of the knowledge transfer and the execution.

SOP & Training Models

The following models that are based on similar strategies to improve the SOPs have been recommended by the researched references:

Model 1 - Roadmap to Create SOPS

Chaneski [2] recommends the use of the SOPs as a "roadmap" to ensure performance and results, consistently. "Standardized work procedures", as Chaneski [2] called them, "make continuous improvement possible". The standardization allows the improvement of the processes in a dynamic environment. Also, "the standards allow to measuring performance fairly". "Standardize work procedures" are essential for training purpose,

specially, for new employees because common techniques are shown.

Chaneski [2] recommends observing the process, working with the people doing the job and asking questions to understand why people do things the way they do. This process supports the identification of those activities that do not add value to the operation to try to eliminate them. Once the best process is defined, then it is time to create the standard work procedure.

Figure 1 shows a roadmap with the steps to be followed to create an SOP.

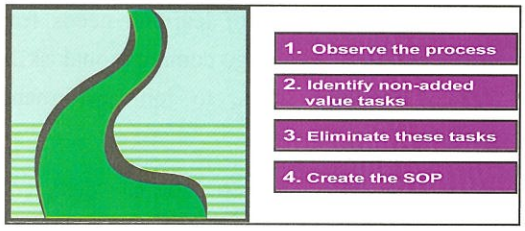


Figure 1: *SOP's Roadmap*

Model 2 - Four Steps Process Design

DeSain et al. [4] recommend a four (4) steps "Process Design Approach" to create SOPs:

1. To know the process purpose and what is intended to achieve (the goal).
2. To measure the goal once it has been met.
3. To determine what processing steps (procedure) are required to meet the goal.
4. To verify that the processing step was effective to meet the goal.

Model 3 – Operational Excellence Cycle

Bigelow [1] recommends an operational excellence cycle (see Figure 2). This cycle describes how to establish, communicate and assess the requirements from the organization. It includes but is not limited to:

1. Establish clear and accurate requirements, using pictures, diagrams or flowcharts to facilitate users understanding. This can be accomplished through the development of policies or SOPs, among others.
2. Communicate the requirements effectively through trainings, orientations and subject matter expert talks.
3. Assess requirements continuously conducting audits: internal or externals.

Figure 2: *Operational Excellence Cycle*

According to Bigelow [1] "if management takes the time to do training right the first time, it will have fewer errors, deviations, reworks, rejects, returns, back orders, recalls and complaints, not to mention the significant long-term operational cost reductions it will achieve".

The recommendations made by Bigelow [1] to implement an effective SOP and on-the-job training process are as follows:

- Pre-test the worker.
- Provide the worker with sufficient time to read the SOP or job requirement prior to training.
- Tell, show, and illustrate one SOP at a time.
- Let the worker perform the job, correct errors and repeat the task until it is performed correctly.
- Measure the understanding of the job using Post-tests.
- Follow-up the worker performance.
- Measure the training effectiveness by using tests, workshops, debates, performance checklists.
- Trend, analyze training performance and effectiveness results, report and follow up any action plan identified to improve training improvement opportunities.

Model 4 – Information Mapping®

Another method used to create effective SOPs was developed by the company Information Mapping® [7]. This method is used to have an

easier communication of the information when it is presented visually and used for analyzing the information.

The Information Mapping® Method was a research initiated and designed in 1965 by Robert Horn.

This model "arranges the words and illustrations to reveal something about the structure and relationships in the information" [7]. These arrangements are known as maps. When this method is compared to conventional instructional method where a student reads and answers questions about what he/she read, the following advantages were observed:

- Reading speed improvement.
- Comprehension and learning improvement.
- Reduction in learning time.
- Reduction in information retrieval time.
- Improvement in performance for writing tasks – writing documents and training material can take less time due to the reduction in the number of words written using the method.

These mapped documents are preferred because they are simpler, easier to read, better organized, presented a better sequence of information, easier to study, and more interesting.

Information Mapping® has a system of principles that arrange the information as maps to communicate quickly to users.

The Principles are:

- ***Chunking/Relevance:*** group information into small and manageable units that relates to one main point.
- ***Labeling:*** a label (title) is provided for each unit to describe the content of each unit or identify the purpose.
- ***Consistency:*** use of similar words, labels, formats, sequence, and organizations.
- ***Integrated Graphics:*** graphics are used as an integral part of the presentation.
- ***Accessible Detail:*** communicate at a level of detail considering audience needs.

Figure 3 is an example of the Principle System.

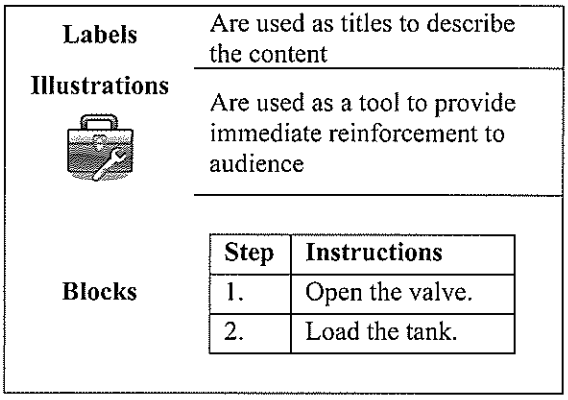


Figure 3: The Principle System

MODEL 5 – REDUCTION OF HUMAN ERRORS

Talsico® [14] shows that 96% of workplace errors are attributed to "human errors" that may be prevented. Human errors are classified in six (6) categories:

- Learning gap (do not know).
- Memory gap (know but do not remember).
- Inconsistency (know but the performance and results are inconsistent).
- Application (know but applied wrong action).
- Omission (know but missed a step or action).
- Decision (wrong decision or behavior).

In Talsico® [14] it has been demonstrated that in some cases, errors classified as "human errors" are associated to the design of the documentation or the systems and that re-training is not the solution to reduce errors. Changing the documents based on the way the human brain processes the events let to achieve a 74% of error reduction in two (2) weeks in some cases.

After several studies, Talsico® [14] found support to their methodology in MRI studies. These studies demonstrated that habits and routine tasks are handled sequentially by a different part of the brain, paying attention to the start and decision points but being in auto mode in between.

Talsico® [14] describes the use of the SOPs for four primary purposes:

- To help people learn how to perform a routinely task.
- To set a performance standard.

- To serve as a quality and audit tool.
- To be used as a job aid tool (a training tool).

It has been proved that effective SOPs improve the individual and organizational performance. Studies performed demonstrated that the following characteristics can be found in non-effective SOPs:

- Have an excessive length.
- The number of reading repetitions or access rate is not enough to improve the performance.
- The reading effectiveness is impacted by the lengths and the format of the document and the colors, symbols and flowcharts used. People skip parts on lengthy documents impacting the reading effectiveness.
- Poor Access – When an operator needs to stop the performance of a task to retrieve and read a document, it is not a good access.

Talsico® [14] uses a methodology that simplifies the documents using symbols, flowcharts and photos, reducing the length, providing investigative interviewing tools to capture current and correct practices and providing the tools to improve reading effectiveness and implementations.

RESEARCH SUMMARY

The models evaluated have similarities specially that all recommend to validate with the experts the process information before writing the SOP, to include pictures and flowcharts in the procedure, and to simplify the information that will be communicated to the performers. Based on the studies performed by the company Talsico® these best practices have been validated and proved in clinical studies.

METHODOLOGY AND RESULTS

To develop the model that will support the enhancement of the SOPs and obtain better results during the execution, two similar methodologies were used: DMAIC and HPT.

DMAIC

The DMAIC methodology is "a quality strategy for improving processes" [9]. It consists of five steps. For this project only four steps were followed. The remaining activities were identified and are described for a future implementation.

1. *Define* – The customers, their requirements, expectations, critical issues, process involved, project boundaries, and process to be improved are defined.
2. *Measure* – The performance of the process involved is measured. During this step, a data collection plan is developed, data from different sources is collected and customer surveys are performed.
3. *Analyze* – The data collected is analyzed and process maps are developed to determine improvement opportunities.
4. *Improve* – Design and develop creative solutions to fix and prevent problems on the process or system identified. The implementation plan is developed and deployed.
5. *Control* – It is established by developing, documenting and implementing a monitoring plan.

HPT-HUMAN PERFORMANCE TECHNOLOGY

The International Society for Performance Improvement – ISPI – is an international association founded in 1962, dedicated to improve productivity and performance in the workplace. This association believes that competitiveness can be achieved by having "an outstanding learning system" focused on performance, in addition to training and education [8].

ISPI uses a systematic approach that consists of a set of methods, procedures and a strategy for solving problems, improving productivity and competencies. This approach is called Human Performance Technology – HPT. It combines three fundamental processes: performance analysis, cause

analysis, and intervention selection with the following steps similar to DMAIC: selection, analysis, design, development, implementation and evaluation of programs that "influence human behavior and accomplishment" [8].

The combination of these two methodologies is described in the Table below.

Table 1: DMAIC & HPT Methodologies

PROCESS STEPS		ACTION	TOOLS USED
DMAIC	HPT		
1. Define	Selection	▪ Process Definition ▪ Problem Statement	▪ Meetings ▪ Interviews ▪ Questionnaires ▪ Project Charter ▪ Project Timeline
2. Measure		Data Collection ▪ Regulatory Observations ▪ Process Deviations ▪ Root Cause and CAPAs	▪ Quality Reports
3. Analyze	Analysis	▪ Operational Process ▪ SOP System ▪ Training System ▪ Causes for Human Errors	▪ SOPs ▪ Process Mapping ▪ Gap Analysis (SWOT) ▪ Histograms
4. Improve	Design	▪ Design the Model and Tools	▪ Model ▪ Tools: Templates and Checklists
	Development	▪ Revision of SOPs based on proposed model	▪ Revised SOPs
	Implementation	The model could not be implemented and evaluated as part of this project. The activities recommended for a future implementation are: ▪ Development of training material (including OJTs) using the enhanced SOP. ▪ Development of pre-tests For the Evaluation process, the development of questionnaires, metrics and tests are recommended.	

The following steps were performed during the project definition, design and development:

1. Define the problem and the current process (As Is) – Current SOPs in the Packaging Area are not supporting the training process and as a result, there have occurred deviations to the process due to human error and failure following the SOPs. The SOPs use a traditional format as the example in Figure 4.

Mecánico de Empaque

6.37 Realice la verificación de sensores durante el "Set-Up" (Ajustes), cada cambio de turno, cada hora (1 hora) durante el proceso de empaque y luego de una intervención mecánica. Documente la verificación de los sensores en los anejos para la verificación de sensores del Registro de Empaque. El Anejo 2 del Registro de Empaque se utiliza para documentar los resultados de verificación de sensores durante el "Set-Up". El Anejo 7 del Registro de Empaque se utiliza para documentar los resultados de verificación de sensores realizados cada cambio de turno, luego de intervenciones mecánicas y cada hora. La verificación de sensores realizada cada hora tendrá una variación permitida de más o menos 20 minutos (1 hora ± 20 minutos).

***Figure 4:** Example of SOP with Traditional Format*

The example shows several deficiencies that were described in the literature researched. Some of them are:

- Complex sentences.
- More than one instruction per step.
- Few visual tools.
- Lack of flowchart.
- Ambiguous instructions.
- Some pre-requisites instructions not included.
- Topics not broken into sections or chunks.

Other findings from the SOP are:

- Responsibilities not clear.
- Use of language or terminology not aligned to operational terms or native language.
- Incorrect use of verbs.
- Paragraphs with regulatory or operational information not easy to retrieve.
- Complex processes in a single document.
- Small fonts.
- Current process not reflected in the document.
- Redundant information.

2. Quality trends and metrics were analyzed to identify deficiencies and to establish a comparative measure between the As Is process and the proposed model. Also, the CAPAs-Corrective Actions-Preventive Actions assigned to the process deviations were

analyzed to identify the assigned cause and corrective actions. The following results were obtained:

- From sixteen (16) deviations in the Packaging Area, thirteen (13) were assigned to human error.
- From thirteen (13) deviations due to human error, ten (10) were classified as SOP not followed. Figures 5 and 6 show this information.

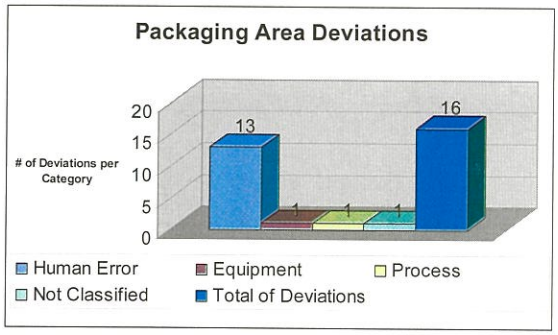


Figure 5: *Packaging Area Deviations*

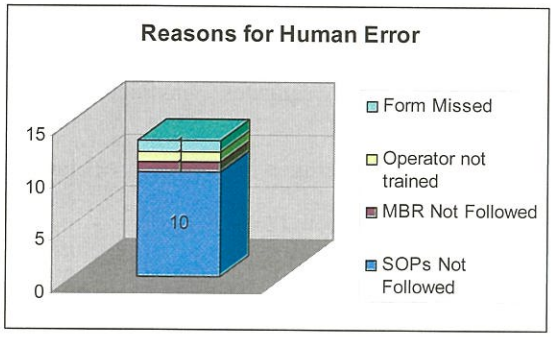


Figure 6: *Reasons for Human Error*

- The Corrective Actions determined were to re-train the operators.
- These findings validate the information presented in this article and in the literature review.

3. After completing these steps the Model was developed and the following steps were performed using the Model sequence. The model developed consists of seven (7) steps to gather information, create the SOP, validate it, transfer the knowledge, and measure effectiveness. Figure 7 shows the developed model.

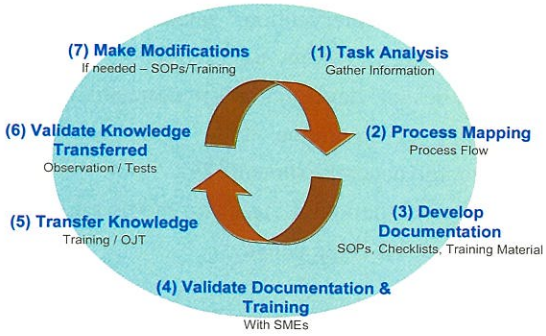


Figure 7: *Seven Steps Model*

The following steps are the description and the results obtained during the execution of these steps:

- ***Step 1- Task Analysis*** – During the task analysis the Analyst uses templates and questionnaires to gather the current process tasks performed in the workplace. In case of SOPs that are being revised, the non-added value tasks are identified to eliminate them. During this step the following tools were used:
  - *Questionnaires* – The questionnaires gathered information from the operators such as: education, years of experience, their feedback on SOP's format, information retrieval and on the relation between the SOPs and the deviations. A sample of five operators was used. All of them had over twenty years of experience in the industry and in the packaging operation. All of them did not have post-secondary education.
  - *Interviews* – The operators, group leader, and supervisor were interviewed after reading the SOPs to clarify the packaging operation process and compare their feedback to the information contained in the SOPs. This information was used to develop the process mapping.
- ***Step 2- Process Mapping*** – Using the task analysis tools as reference, a process map is developed to diagram the process flow, identifying the inter dependencies, and the process sequence. The Process Map was used to validate the information gathered and the

process sequence. Current SOPs were challenged against the Process Map. The results obtained demonstrated that some steps were omitted from the SOP and some responsibilities were not clearly defined.

- ***Step 3- Develop Documentation*** - Once the process is defined and the tasks are identified, the information is transferred to the SOP. In the next Section the recommended SOP format is described. The SOP is used either to develop the training material or as the training material itself.
- ***Step 4- Validate Documentation and Training*** – This is a critical step recommended by the Subject Matter Experts: to validate the information written in the SOP and the training material. Any modification should be made in this step prior to the approval of the documents.
- ***Step 5- Transfer Knowledge and Step 6- Validate Knowledge Transfer*** – To transfer the information already validated in the SOP and measure the transfer effectiveness, the following steps are recommended:
  - The qualified instructor should identify the knowledge and skills required to execute the task that will be taught. If there is a deficiency identified prior to the training, a remedial activity or training to improve this deficiency, should be taken.
  - The performer reads the SOP individually.
  - A Pre-Test is completed before the Training.
  - Training on the SOP content is performed by a qualified instructor.
  - The performer clarifies doubts.
  - Demonstrations or Simulations are used to illustrate the procedure.
  - A Post Test on the knowledge is completed.
  - An On the Job Training is performed to demonstrate the operation in the field area.
  - A final On the Job Assessment is completed to validate that the operator can perform independently.
  - In these steps several documents are used as tools: tests, checklists, job aids, or computer presentations, among others.
- ***Step 7- Make Modifications*** – Because it is a dynamic process it should be evaluated and modified on a continuous basis. An Evaluation form should be used to evaluate the program effectiveness.

SOP FORMAT

The SOP's format depends on the objective of the document. An SOP may be a System SOP or an Operational SOP.

A System SOP is used to describe a quality system or a documentation system such as the Process Validation SOP, the Training SOP, the SOP on How to Develop SOPs, or the Calibration Program SOP.

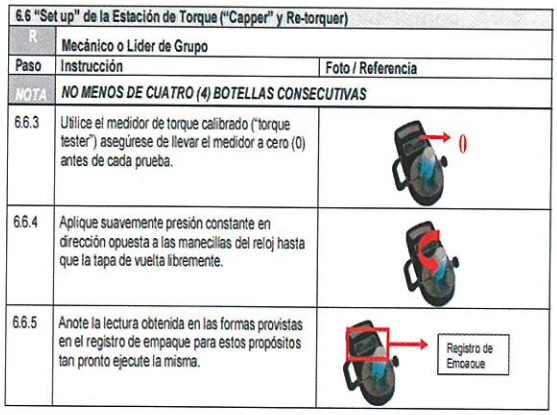
An Operational SOP is an SOP written for the operators or performers who should follow the steps described in the SOP in a predetermined sequential order.

One of the errors associated to the SOP format is to use the System SOP format for Operational SOPs.

After analyzing these deficiencies, the recommended format consists of:

- Sections to divide the content per topic.
- Complex operations separated in several SOPs.
- Use of labels and content separately.
- Illustrate with pictures, photos, flowcharts or diagrams
- Use of tables ("blocks") to list the sequential steps and the responsible person.

Figure 8 shows an SOP using the proposed format that consists of labels, pictures, and clear and specific instructions. Figure 9 shows how the training can be prepared easily using the same information included in the SOPs.



6.6 "Set up" de la Estación de Torque ("Capper" y Re-torquer)		
R	Mecánico o Líder de Grupo	
Paso	Instrucción	Foto / Referencia
NOTA	NO MENOS DE CUATRO (4) BOTELLAS CONSECUTIVAS	
6.6.3	Utilice el medidor de torque calibrado ("torque tester") asegúrese de llevar el medidor a cero (0) antes de cada prueba.	0
6.6.4	Aplique suavemente presión constante en dirección opuesta a las manecillas del reloj hasta que la tapa de vuelta libremente.	
6.6.5	Anote la lectura obtenida en las formas provistas en el registro de empaque para estos propósitos tan pronto ejecute la misma.	Registro de Empaque

Figure 8: *Recommended SOP Format*

Figure 9*: Example of Training Material*

CONCLUSION

This model is based on a complete cycle that goes from the identification and validation of the tasks of a particular process to the implementation of better SOPs and better trainings. As a result, the possibility of performing errors during the execution due to the SOP documentation or the training is minimized. Although the revised SOPs with the associated training and tests were not implemented, the studies performed by the companies researched in this project demonstrated that effective SOPs improve the individual and organizational performance and they have a significant and direct impact in the training material development and in the reduction of errors during execution. An effective SOP System is measured based on the following criteria:

- The process has been identified and validated with the Subject Matter Experts prior to writing the SOP document.
- It is written for performers.
- The steps are specific and simple, in a sequential order, and easy to follow.
- The steps are illustrated with pictures, diagrams and flowcharts.
- The learning time is reduced and the comprehension is improved.
- The quality, safety and operational goals are met.

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