# Making SOP Training More Effective

Life & Health

# Making SOP Training More Effective

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SOPs are critical to efficient operations, quality control and regulatory compliance. This paper reviews best practices for the Life Science industry for training on SOPs. Specifically, how the latest learning management technology has the potential to improve learner retention through automated assessments.

## Failure to Follow SOPs: A Key Audit Finding

*"Failure to establish adequate procedures for identifying training needs for ensuring that all personnel are trained to adequately perform their assigned responsibilities and for documenting training, as required by 21 CFR 820.25(b)."*

As the above statement from a recent US Food and Drug Administration Warning Letter underscores, many FDA violations in the past few years have focused on the firm's failure to properly use Standard Operating Procedures (SOPs), which is a fundamental component of current Good Manufacturing Practices (cGMPs).

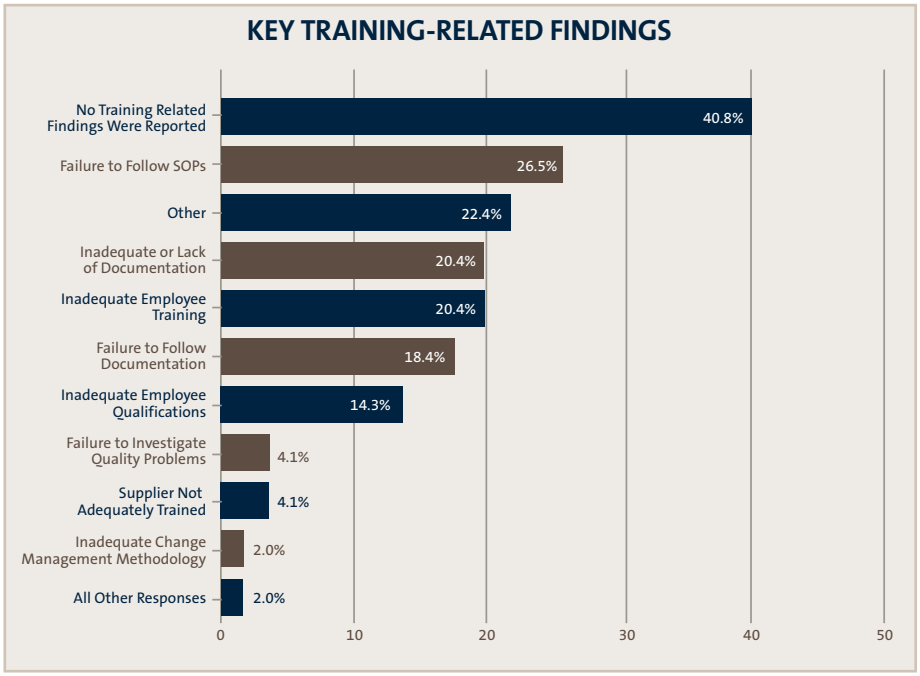
UL EduNeering surveyed our Life Science clients on audit preparation. "Failure to Follow SOPs" was noted as the most "training-related" finding for both internal and external audits. SOP compliance is required for all companies within the Life Science industry. This is why we have seen an increase in our Critical Information Control System© (CICS) tool usage, which manages SOP training. CICS allows an administrator to assign a training item to an internal document (PDF, Word, PowerPoint, etc.), thus generating an auditable record.

However, there continues to be a gap between SOP Training and the use of our SOP Assessment tool, Quiz Creator. Less than 20% of CICS assignments are being sent with a quiz associated with it. What we've learned from these numbers is that just distributing an SOP to be "read and understood" simply doesn't work. Senior management needs to ensure that learners have embedded the procedure into their daily work environment.

## SOP Training as a Regulatory Imperative

The purpose of an SOP is straightforward: to ensure that essential job tasks are performed correctly, consistently and in conformance with internally approved procedures. Clearly, employees' correct, consistent performance of essential job tasks is as much a business and quality issue as it is a regulatory requirement. By its nature, poor employee performance has a negative impact on overall operational performance. That impact may be even greater than recognized by many organizations, with some studies suggesting that up to 40% of operational inefficiencies can be attributed to employees' failure to fulfill their job responsibilities. Even companies that have implemented costly process improvement systems continue to feel the operational impacts of "human error" on their efficiencies and quality control.

Although all industries share a financial vulnerability resulting from operational inefficiency, the liability associated with compromised product quality can hit a Life Science company particularly hard. Compromised product quality can easily result in product recalls, regulatory enforcement and governmental litigation. Even the suspicion of quality problems can send a patient, health care professional or stakeholder's confidence plunging. With highly publicized product recalls still fresh in the minds of the public and regulators, Life Science companies and their products are under greater scrutiny than ever before. And, because FDA Warning Letters are public information, public scrutiny is quickly fueled by news reports from the media or internet.




*Key training-related findings from 2010 audit(s).*

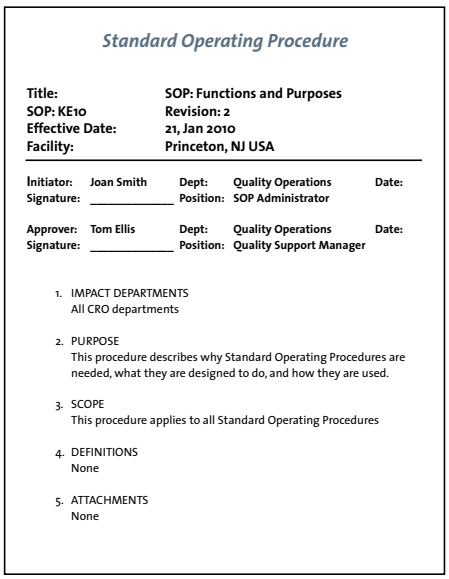
## KEY TOPICS

**SOP Compliance –** the FDA's definition of a SOP is deceptively simple. SOPs are, according to a variety of FDA regulations, written procedures that accurately describe and detail essential job tasks. For example, here is an FDA Warning Letter:

> *"...FDA found that Testing Facility Management failed to maintain an SOP for sterile preparation of dosing solutions, even though SNBL's workload included studies requiring aseptic preparation."*

In 21 CFR 211.100, the regulation states: "There shall be written procedures for production and process control designed to assure that the drug products have the identity, strength, quality, and purity they purport or are represented to possess. Such procedures shall include all requirements in this subpart. These written procedures, including any changes, shall be drafted, reviewed, and approved by the appropriate organizational units and reviewed and approved by the quality control unit."

Beyond the written procedure, SOP compliance includes a requirement to train employees on essential job tasks, something expressed in 21 CFR 211.25, which applies directly to the Pharmaceutical industry, but is applicable to all Life Science industries. "Each person engaged in the manufacture, processing, packing, or holding of a drug product shall have education, training, experience, or any combination thereof to enable that person to perform the assigned function." It is this combination of written procedure and employee training that assures the quality of a drug product or medical device being tested or manufactured and its compliance with applicable FDA regulations. Understanding the purpose of SOPs is one thing; complying with the FDA's regulatory standard for ensuring that employees have the knowledge they need to perform their job functions is something else entirely. Large companies may have thousands of job tasks, each one requiring a SOP that usually needs regular updating. Even small companies will have extensive SOP requirements, whether for regular equipment calibration or for sterile manufacturing procedures.



*Standard Operating Procedure*

**Title:** **SOP: Functions and Purposes**
**SOP: KE10** **Revision: 2**
**Effective Date:** **21, Jan 2010**
**Facility:** **Princeton, NJ USA**

**Initiator:** **Joan Smith** **Dept:** **Quality Operations** **Date:**
**Signature:** _____ **Position:** **SOP Administrator**

**Approver:** **Tom Ellis** **Dept:** **Quality Operations** **Date:**
**Signature:** _____ **Position:** **Quality Support Manager**

1. IMPACT DEPARTMENTS
   All CRO departments
2. PURPOSE
   This procedure describes why Standard Operating Procedures are needed, what they are designed to do, and how they are used.
3. SCOPE
   This procedure applies to all Standard Operating Procedures
4. DEFINITIONS
   None
5. ATTACHMENTS
   None

In fact, the FDA has specifically identified operational areas that fall under cGMP and – by extension – SOP regulation. The components for which employees must have sufficient knowledge to perform their job functions adequately, range from buildings and facilities to equipment, components, and drug product containers and closures, production and processes, packaging and labeling, holding and distribution, laboratories, and returned or salvaged drug products. SOPs are written job aids that detail the procedure of how to do a specific job task correctly.

- Many companies do not have SOPs, the most fundamental component of cGMPs.
- SOP compliance includes training employees in essential tasks.
- Systems that support compliance also can improve a company's quality control efforts.

Clients that have successful SOP compliance programs have incorporated these five activities:

1. Creation of a quality control unit responsible for ensuring SOP compliance.
2. SOPs for each job task that are updated and understandable to employees.
3. Accurate, timely distribution of SOPs to all responsible parties, including validation that the SOP has been received and read.
4. Confirmed employee comprehension of the SOPs and the ability to apply the knowledge contained in the SOP.
5. Comprehensive corrective and preventive action programs to identify, rectify and prevent quality failures.

The FDA's "...quality systems and risk management approach" to cGMP emphasized management responsibilities for quality control and assurance. That responsibility included formation of a quality control unit that "... shall have the responsibility and authority to approve or reject all components, drug product containers, closures, inprocess materials, packaging material, labeling, and drug products."

Although the compliance responsibility of the Quality Control unit is not limited to SOPs, an effective SOP compliance program is central to the unit's ability to fulfill its mandate. Although Life Science companies routinely embrace the most advanced technologies in the laboratory and manufacturing plant, they are often not as receptive to technology managing their SOP activities.

## SOP Training Technology Requirements

Given the scope of modern SOP compliance responsibilities and the consequences of noncompliance, companies increasingly recognize the value of using technology to comply with SOP mandates. Not coincidentally, the same system that supports SOP compliance can also easily serve as the foundation for improving a company's overall quality control management and assurance effort.

An effective SOP compliance program requires a technology-enabled platform that is interoperable with existing technologies and performs multiple functions, including SOP distribution, validation, testing and recordkeeping in audit-ready formats. Because SOPs require revision with every process change, equipment replacement or regulatory change, any SOP management technology should enable rapid updating.

Just as important, the system should allow for effective targeting of SOPs to the correct employees, thereby preventing them from becoming overwhelmed by SOPs not applicable to their particular job tasks.

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Learning management systems, such as ComplianceWire, enable trainers to set up assessments and automatically attach them to the SOP assignment.

## The Written Word

The FDA requires that SOPs be in a written format. Violation of that basic requirement is routinely found in FDA Form 483 or in Warning Letters for a variety of operations throughout the regulated process. Significant deviations noted by the FDA Warning Letters illustrate the range of activities that may be targeted for failure to meet the written SOP standard. For example:

1. Failure to establish and follow appropriate written procedures designed to prevent microbial contamination of drug products purporting to be sterile.
2. Failure to establish written procedures applicable to the function of the quality control unit.
3. Failure to establish written procedures for evaluating quality standards of each drug product to determine the need for changes in drug product specifications of manufacturing and control procedures.
4. Failure to develop written procedures for surveillance, receipt, evaluation and reporting of post-marketing adverse drug experiences.

   Although SOPs vary from company to company – and sometimes from facility to facility within the same company – they should all have a consistent format that reflects applicable regulatory compliance requirements and include "how-to" information specific to the job task.

Because the purpose of a SOP is to ensure consistent, compliant performance of employees and processes, SOPs should be understandable to users. Unfortunately, many SOPs are not. The FDA requires that authors of SOPs be qualified individuals with necessary technical and compliance experience and expertise in the particular subject matter addressed by the SOP. Qualified SOP authors should also possess the necessary writing, instructional design and technical skills to effectively communicate with workers with different learning needs.

## Transforming the SOP into a Course

Fortunately, technology now offers alternatives to the infamous SOP manual that afflicted generations of employees with incomprehensible material. Internet-based technologies can produce SOPs that cut through the fog created by pages of written explanations.

In fact, many Life Science companies have converted the SOP into an online course that contains images, sound, animation and interactive quizzes that assess the learner's comprehension of the procedures and processes being explained.

Skillful use of these instructional techniques can engage employees and enhance comprehension, ensuring that the SOP's intent is achieved. Optimally, SOPs are developed by teams of professionals, equally proficient in the subject matter as in technology, the learning psychology of adults, and interpersonal communications. Just as SOP instruction is not easy, neither is SOP distribution. Hundreds or thousands of SOPs that change regularly with any shift in regulation, corporate policy or production process can easily affect hundreds or thousands of employees. Tracking this distribution for audits or inspections can take weeks without the proper automation.

It is not unusual for employees to experience, within a relatively short period of time, SOP versions one, two, and three for the same job task. The FDA requires that SOPs be distributed in a timely manner and that each employee validate their receipt and understanding of it. The volume of material that must be distributed, validated and stored virtually requires a Learning Management System (LMS) that is integrated with the Electronic Data Management System (EDMS).

## Summary

The days of simply distributing information to fulfill regulatory requirements are long gone. Today, the standard of SOP compliance requires that SOPs be applied. "Failure to follow written procedures" occurs frequently in the FDA's 483s and Warning Letters, suggesting that employees neither understood nor applied the necessary knowledge to properly fulfill their job requirements.

Today's LMS must provide the ability to incorporate testing or evaluation features that clearly establish an employee's level of comprehension for any individual SOP. These assessments provide managers with instant access into who on the team knows the procedures and who doesn't. Just as important, testing documentation demonstrates to regulators that a firm is committed to effective employee education, rather than simple document distribution.

## About UL EduNeering

UL EduNeering is a business line within UL Life & Health's Business Unit. UL is a global independent safety science company offering expertise across five key strategic businesses: Life & Health, Product Safety, Environment, Verification Services and Enterprise Services.

UL EduNeering develops technology-driven solutions to help organizations mitigate risks, improve business performance and establish qualification and training programs through a proprietary, cloud-based platform, ComplianceWire®.

For more than 30 years, UL has served corporate and government customers in the Life Science, Health Care, Energy and Industrial sectors. Our global quality and compliance management approach integrates ComplianceWire, training content and advisory services, enabling clients to align learning strategies with their quality and compliance objectives.

Since 1999, under a unique partnership with the FDA's Office of Regulatory Affairs (ORA), UL has provided the online training, documentation tracking and 21 CFR Part 11-validated platform for ORA-U, the FDA's virtual university. Additionally, UL maintains exclusive partnerships with leading regulatory and industry trade organizations, including AdvaMed, the Drug Information Association, the Personal Care Products Council and the Duke Clinical Research Institute.

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