1. What types of SOP training does your facility do? (check all that apply)

    89%    Read and understand
    68%    Classroom training
    82%    Demonstration
    74%    Trainee practice under supervision
    32%    Physical simulation
    11%    Virtual simulation
    18%    E-learning modules
    Other:
- Online read with quiz
- PowerPoint read with quiz
- Trainee takes written quiz on changes to SOP
- Computer based awareness training and assessment prior to practical skill practice, a few identified (derived using PDAs Risk Assessment Methodology) SOPs have been listed that require major training and so will have classroom training and assessment. Some others too, when identified by its author as requiring major training are assessed, apart from R&U, as part of training completion. Some SOPs are also part of on-the job training
-

2. Do you currently evaluate the effectiveness of SOP training?

    63%    Yes
    24%    No
    Note:  Some left this question unanswered
    Comments:
- Only in operations and lab areas
- Only if OJT is involved, and then not always the strongest evaluation, but something is done
- It depends on the change being made to a current SOP, some require qualification that the function can be completed.

3. How do you evaluate the effectiveness of SOP training? (check all that apply)

     61%    Written test
     18%    Oral test
     71%    Trainee demonstration
     11%    Do not evaluate
              Other/comments:
- A few identified (derived using PDAs Risk Assessment Methodology) SOPs have been listed that requires major training and so will have classroom training and assessment. Some others too, when identified by its author as requiring major training are assessed, apart from R&U, as part of training completion.
- Occasionally we use tests, but most are read and sign
- Functional test that they can perform the job requirements
- Assessments built into e-learning modules
- Look at quality system routines, trace back to human error, then back to links for ineffective SOPs
- Varies by process
- E-learning

4. If you use written tests to evaluate the effectiveness of SOP training, what is your minimum grade for passing?

     16%    100%
      3%     85%
     45%    80%
      5%     75%
      5%     70%
     18%    Do not use written tests
              Other:
- It depends
- Unknown

5. If you use written tests to evaluate the effectiveness of SOP training, what do you do when an employee fails a test? (check all that apply)

     13%    Retrain in group, retake test
     42%    Retrain individually, retake test
     34%    Reread SOP, retake test
      0%    No action taken
              Other/comments:
- There is discussion between trainer & trainee to identify areas that need a more intense review with coaching and feedback.
- Retrain only if it is classroom assessed. If through LMS, the trainee can attempt unlimited, until scores to successful completion.
- Unknown

6. Does your SOP training typically cover any of the following? (check all that apply)

      42%    What to do if problem
      45%    Who to contact if problem
      55%    How to document a problem
      13%    How to troubleshoot a problem
      45%    The "why" behind the SOP
      37%    What might happen if not followed
      42%    Only cover actual steps in SOP

            Other/comments:
- Use process flowchart and visual aids
- We use structured OJT which includes the what, the why and defect awareness.

7. Do you think SOP training SHOULD cover any of the following? (check all that apply)

      74%    What to do if problem
      61%    Who to contact if problem
      68%    How to document a problem
      55%    How to troubleshoot a problem
      68%    The "why" behind the SOP
      68%    What might happen if not followed
      63%    All of the above

            Other/comments:
- Defect recognition and avoidance
- Job specific SOPs have instructions related to work.
- None of the above – too much information

Graph showing difference between "what is covered" answers vs. "what should be covered" answers.
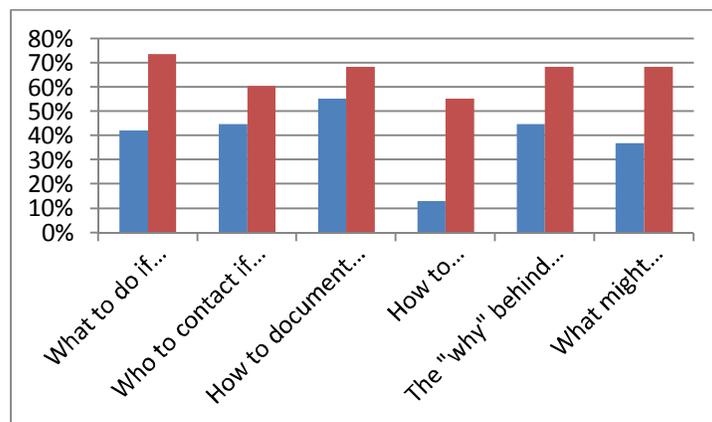


■ "What is covered"        ■ "What should be covered"

8. Does your company do anything that hasn't been mentioned to train employees on what to do when a SOP process starts to go wrong?

- Production/Manufacturing employees are instructed to immediately notify their supervisor when there is any issue with an SOP.
- SOPs that require hand on training have a quiz assessment in our LMS, but for the OJT portion there are step by step training instructions and practical and verbal assessments.
- Capturing these through the Deviations and CAPA SOP.
- If possible observe associate from video surveillance when they are not being physically watched.   A picture is worth a thousand words.
- We outsource all manufacturing and testing – rely heavily on our LMS for online delivery of training.  Need to have a culture shift around the importance of training/learning.
- Use visual aids in process areas and on production floor
- Informal meetings
- Job hazard analysis (JHAs)