PROCEDURES FOR PERFORMANCE:
Ways to achieve improved performance

(Suggested course time: Day one – 8:30 to 16:30; Day two 8:30-16:00)

SUGGESTED VIDEO LINK: https://vimeo.com/51442647

Course goal
Use a structured way to write standard operating procedures (SOPs) and provide the appropriate in order to achieve effective, efficient task performance.

Course description
Procedures are an important way of describing how a task is to be performed so personnel can perform the task correctly, consistently, safely, and efficiently. Despite their critical role in making pharma and biopharma products as well as medical devices, writing a clear, easy to follow procedure —and then training people on it — isn't as simple as it sounds.

This two-day workshop looks at procedures as one of several methods for managing, capturing, and transferring knowledge. Various formats of procedures will be examined and critiqued along with an examination of current regulatory requirements. Using a unique data collection form, participants will collect information that would be included in a procedure and then write (or re-write) a procedure. Participants will have an opportunity of writing (or re-writing) a procedure based on an actual need they have.

Frequently seen "error traps" in procedures will be examined along with ways to reduce procedure-related "human error" performance mistakes.

GMPs require that people be trained on the procedures before using them but there are a variety of methods that can be used, some of which give higher levels of confidence that people can actually perform the task properly. Different procedure training approaches will be discussed and compared. Ways of assessing performance and evaluating the effectiveness of the procedure training will be examined.

Who should attend
Those who write or review procedures and those who provide procedure training, including those in quality, operations, technical services, and maintenance/engineering.

Course objectives
- Identify regulatory requirements and expectations related to procedures and training on procedures.
- Discuss how procedures and procedure training contribute to knowledge management.
- Discuss the differences and similarities between policies, procedures, work instructions, job aids, and performance support systems.
- Evaluate several examples of procedural instructions, describing how they contribute or don't contribute to achieving a goal.
- Discuss common flaws and problems seen in procedures.
- Examine alternative ways (other then text) of providing procedural information.

- Given a task, write a procedure.
- Using a checklist, evaluate a procedure.
- Identify various options to provide training on a procedure including e-learning, "read-and-understand", and hands-on training.
- Identify various options to assess performance of the procedure and evaluate its effectiveness.

Course outline

Day One

1. **Workshop Introduction and Objectives**

2. **Knowledge management and the role of procedures**
   - Knowledge management as described in ICH Q10
   - Explicit and tacit knowledge
   - Sticky and leaky knowledge
   - How do procedures and procedure training fit in?

3. **Regulatory requirements and expectations regarding procedures and procedure training**
   - Examples of requirements from EU, US, CA, and WHO
   - Examples of citations regarding procedures
   - What the regulations do *not* say

4. **What can we learn from recipes?**
   - Activity: What makes a good procedure?
   - Activity and discussion: Applying the criteria to recipes
   - Other examples of procedures
   - Level of detail – how much information should be included?

5. **The range of "functional documents"**
   - Policies, procedures, work instructions
   - What procedures can look like: alternatives to traditional formats
   - Job aids
   - Checklists
   - Other performance support tools

6. **The procedure writing process**
   - Knowing the users
   - Flow charting / process mapping
   - Who does what?
   - Critical hows
   - Activity: Using a data collection form
   - Reviews and approval
   - Periodic reviews

- How much should be included in a procedure?

7. Human error and procedures
- What the aviation and nuclear power industries can teach us
- Points to consider when writing a procedure
- Activity: ways to reduce error traps

8. Writing and reviewing a procedure
- Activity: Writing (or re-writing) a procedure
- Activity: Reviewing a procedure and giving feedback

9. Training on procedures
- Options – training on individual procedures or competencies
- What does the person need to know: Know about? Know what? Know how?
- The problem with "read and understand"
- Assessments and effectiveness checks
- Activity: Creating a training plan for a set of SOPs

10. Performance support
- Checklists – what they are and what they are not
- Other ways to support performance – job aids

11. Wrap-up and summary
- How will you be able to use this information?
- How do you view procedures differently now?

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