COBBLESTONE

COURSE ID 3142

Writing Standard Operating Procedures (SOPs) for Human Error Reduction

Including the Use of Artificial Intelligence

DIRECTED BY

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90 MINUTE

ACCREDITED COURSE

- Content development
- The Human perspective
- Common mistakes and causes
- Creating and maintaining an SOP
- Using Artificial Intelligence (AI)

about the course

Poorly written SOPs are responsible for over 40% of human error events in manufacturing and are the leading cause of regulatory citations. Well-crafted procedures are critical for both successful execution and regulatory compliance. Proper procedures need to be clear, user-friendly, and include all necessary information for regulators. However, many procedures are flawed, leading to decreased productivity, compromised quality, and poor regulatory outcomes.

This accredited 90-minute course will explore how to develop and format procedures that minimize human error and improve overall performance.

While it cannot be completely eradicated, many human performance problems are preventable. Errors often begin in the design phase, and effective procedures are key to ensuring human reliability. To reduce error rates, it's important to understand both human behavior and the psychology behind mistakes, as well as identify weaknesses in current procedures. This course will teach how to re-engineer, improve, and humanize procedures to enhance productivity and compliance.

Live interaction with the instructor enables dynamic discussions and immediate clarifications.

To verify attendance and encourage active interaction, those participating in the live training are required to have their webcams on during the course. The use of microphones and speakers or headsets is also strongly recommended.

who should attend

This online training has been designed for professionals working in GMP-regulated manufacturing facilities including Pharmaceuticals, Medical Devices, Biologics, Food and Nutrition. In addition, this training will be worthwhile for any other organization that has employees executing activities in which they can make mistakes (ALL).

Personnel holding positions in the following areas will benefit greatly from this training:

- QA/QC directors and managers
- Process improvement/excellence professionals
- Training leaders and managers
- Plant engineering
- Compliance officers
- Regulatory professionals
- Executive management
- Manufacturing operations directors
- Human factors professionals

learning objectives

Upon completion of this course, you will be able to:

- Identify the key components of effective Standard Operating Procedures (SOPs) aimed at minimizing human error.
- Explain the value of well-written SOPs in ensuring regulatory compliance and enhancing operational efficiency.
- Determine common mistakes and their cause in existing SOPs.
- Evaluate the effectiveness of SOPs to ensure continuous improvement.
- Use good procedure writing practices to draft or revise an SOP.

course outline

Review of Learning Objectives
Method Validation Data and Reports

- SOP writing outline
- Content development
    - The rationale for procedure use
    - Regulatory compliance background
    - Universal purpose of procedures
- The Human Perspective
    - Human Error as a root cause
    - The thinking and reading process
- Common mistakes and causes
- How to create and maintain a procedure
    - Goals of a procedure
    - Good Procedure Writing practices
    - Procedure styles
    - Use of electronic information networks for procedure access.
    - Use of AI to write procedures

Question and Answer Session

Assessment Opportunity

course instructor

Ginette Collazo, Ph. D., is an Industrial-Organizational Psychologist with 20 years of experience who specializes in Engineering Psychology and Human Reliability. These disciplines study the interaction between human behavior and productivity. She has held positions leading training and human reliability programs in the Pharmaceutical and Medical Device Manufacturing Industry. Nine years ago, Dr. Collazo established Human Error Solutions (HES). At this Florida-based boutique consulting firm, she has been able to position herself as one of the few Human Error Reduction Experts in the world. HES, led by Dr. Collazo, developed a unique methodology for human error investigations, cause determination, CA-PA development, and effectiveness that has been implemented and proven in different industries globally. This scientific method has been applied in critical quality situations and workplace accidents. Ginette Collazo, Ph. D., author of Human Error: Root Cause Determination Model, published in 2008. She has also spoken at significant events like Interphex, FDAnews Annual Conference, Global Conference on Process Safety, International Conference on Applied Human Factors and Ergonomics, Pharmaceutical Industry Association, and GMP International Conference.

Accreditations

International Accreditors for Continuing Education and Training (IACET)

Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 1.5 contact hours, or 0.2 CEUs. For further information, visit www.iacet.org

Regulatory Affairs Professional Society (RAPS)

Cobblestone is committed to enhancing the ongoing professional development of regulatory affairs professionals and other stakeholders through appropriate regulatory affairs learning activities and programs. Cobblestone has agreed to follow RAPS- established operational and educational criteria. This course may be eligible for up to 12 credits towards a participant's RAC recertification upon full completion. The requirements and standards for recertification are developed and administered by the Regulatory Affairs Certification Board (RACB), which manages all areas of the RAC program. Additional information about RAC is available on the RAPS website at RAPS.org/rac.

The American Society for Quality (ASQ)-Recertification Opportunities

Cobblestone is committed to enhancing the ongoing professional development of Quality professionals and other stakeholders through appropriate learning activities and programs. Many Cobblestone courses offer training that may be helpful in obtaining required ASQ's recertification education units.

For more information, visit: www.asq.org