COBBLESTONE

COURSE ID 2607

Effective Approach to Human Error Reduction

Investigations, Root Cause Determination and CAPA Effectiveness

DIRECTED BY

Ginette Collazo — PhD, Industrial-Organizational Psychologist

90 MINUTE

ACCREDITED COURSE

Course Topics Include:

- Implementing a Human Error Reduction Program
- Human error and training: when and where
- Human error rates and measurement
- Trending and tracking

about the course

In GMP regulated industries, it is not enough to address human error deviations as an inconvenience; it is a regulatory requirement. The quality control unit is responsible for ensuring that errors are fully investigated and prevented as per the Code of Federal Regulations (21 CFR 211.22). However, human error is not a root cause but rather a result of various variables that affect human behavior, which can be controlled through design, procedures, training, and workplace environment. Understanding human behavior and the psychology of error is crucial, and implementing a dedicated process to investigate and resolve these issues is essential.

Our 90-minute accredited training course provides practical approaches and models to address human performance issues in GMP environments. We will discuss a methodology to correct, prevent, and avoid the recurrence of these issues, providing you with practical tools that can be implemented in your workplace. The course will cover human error categories, near root causes, root causes, and the latest trends in human error issues in the industry.

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:

• Training Managers and Coordinators	• Operations
• Process Excellence/Improvement Professionals	• Industrial/Process Engineers
• Regulatory/Legislative Affairs Professionals	• General/Corporate Counsel
• Manufacturing	• Compliance Officers
• Plant Engineering	• QA/QC Staff

learning objectives

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

- Explain the psychology of error
- List the regulatory requirements in GMP environment for managing human performance deviations
- Describe Root Cause Analysis and Investigation
- Use Root Cause Determination tools
- Establish the Human Error Rate at your site
- List the steps to implementing the Human Error Reduction Program
- Use proper metrics and KPIs

course outline

Review of Learning Objectives
Human Error Defined

- Regulatory expectations
- What is human error
- Types of human error

How is Human Error controlled?

- System Based
- Behavior Based
- Human Error Investigation Process
- Root Cause Determination Tool

Human error rates, monitoring and measurement.

- KPI and metrics
- CA-PA development and implementation
- Trending and tracking
- Prediction process

Question and Answer Session

Assessment Opportunity

course instructor

Ginette Collazo, Ph. D. is an Industrial-Organizational Psychologist with over 20 years of experience specializing 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.

In 2009, Dr. Collazo established Human Error Solutions (HES). At this US-based boutique consulting firm, she has positioned herself as one of the few Human Error Reduction Experts worldwide. HES, led by Dr. Collazo, developed a unique methodology for human error investigations, cause determination, CA-PA development, and effectiveness implemented and proven amongst different industries globally. Furthermore, this scientific method has been applied in critical quality situations and workplace accidents. A GMP expert also has a Keynote Speaker at significant events worldwide.

Ginette Collazo, Ph. D., is the author of several books, "Human Error: Root Cause Determination Model" and "Mission Matters: World Leading Entrepreneurs Reveal Their Top Tips to Success."

Also, and most importantly, she hosts The Power of Why Podcast—a show about human behavior in the workplace and critical thinking.

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 .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.