

GMP HUMAN ERROR REDUCTION PROGRAM

The Keys to Increased Performance

JUNE 29-30, 2017
AMA EXECUTIVE CONFERENCE CENTER
ARLINGTON, VA (WASHINGTON, DC)

AN INTERACTIVE WORKSHOP PRESENTED BY GINETTE M. COLLAZO, INC. AND FDANEWS

AGENDA

Day 1

8:00 a.m. – 8:30 a.m. Registration/Continental Breakfast

8:30 a.m. – 10:00 a.m. Understanding the Basics of Human Error On The Manufacturing Floor

- How human errors intersect with manufacturing regulations
- Which violations tied to human errors and manufacturing are trending up
- The various types of human errors that commonly found on manufacturing floors
- How we got here — why is human error reduction such an important topic?
- **Interactive Exercise!** Attendees will be broken into groups and asked to describe the most common human errors within their facilities. A list of the most common problems will be tallied to help focus future discussion.

10:00 a.m. – 10:15 a.m. Break

10:15 a.m. – 12:00 p.m. Human Error In Context — What Are the Factors That Drive Human Errors?

- The taxonomy of human error; how and why drug and device companies need to focus on this in their investigation processes
- Why administrative and management systems factor so prominently into deviations and non-conformances
- The role of innovative operational controls and their role in reducing human errors
- Simple procedures that prevent human error — how they should be described and presented to maximize human error reduction
- Common examples of poor human factors engineering and workplace conditions that contribute to human error
- When training is appropriate and when we should stop
- Learn how common day-to-day communication gaps contribute to human error
- How supervision can be one of the best human error reduction strategies at your site
- When is individual performance responsible for human error and when does it become a root cause
- How to address cognition, attention, and memory failures at your site

12:00 p.m. – 1:00 p.m. Lunch

1:00 p.m. – 2:30 p.m. Internal vs. External Factors

- How our biology affects our thinking process and individual performance
- Understanding the latest on cognitive load and attention, memory, and decision making errors — how they commonly occur on the manufacturing floor
- How our senses control how we react — it's more important that you think
- Best practices for controlling human factors for optimum people performance
- How to create an organizational environment that supports human error reduction initiatives — from senior management to floor level staff
- Why our culture with regards to human error has to change; it's not an easy process but vitally necessary for drug and device companies

2:30 p.m. – 4:30 p.m. Corrective and Preventive Action (CAPA) — FDA's #1 Manufacturing Compliance Problem

- How to develop corrective actions that make sense — what's working and not working
- Creating preventive actions that truly prevent; how to stop errors that have not yet happened
- Understanding the human error prediction process and tools
- Prevention and human error control: proven ways to measure improvement and on-going trend analysis
- When to use detection mechanisms instead of preventive mechanisms — the pros and cons of each
- Human error detection and recovery rate — are you really uncovering all the errors within your facilities?
- Assuring for the FDA your CAPA program is effective and you've adequately focused on human error
- **Interactive Exercise!** Determining when human error reduction is the key to a successful solution and FDA compliance. Broken into small groups, each group will be asked to determine if a CAPA solution is effective and if human error prevention related provisions will satisfy the FDA.

Day 2

8:30 a.m. – 10:00 a.m. Human Error Reduction Techniques

- Discussion of insights from Day 1
- When is human error a human resources issue?
- How and when to apply engineering controls to correct and prevent human error deviations
- What to do when individual performance is the major contributor
- Human error and documentation: from design, construction, change management and implementation.
- Additional Contributors for human errors will be discussed.
- **Interactive Exercise!** Practice identifying techniques to be applied to real world situations. For example, when is a human error really a human resources problem? This interactive exercise will help you know what to apply and when.

10:00 a.m. – 10:15 a.m. Break

10:15 a.m. – 12:00 p.m. Human Error Investigation

- Human error investigation process defined from beginning to end
- How to gather data in the human error investigation process
- How to perform an effective interview
- Important steps for effective human error investigations
- How to report issues to make sure management listens

12:00 p.m. – 1:00 p.m. Lunch

1:00 p.m. – 2:30 p.m. Root Cause Analysis Tools

- A brief review of common tools used in determining root cause
- Hierarchy and use of the root cause determination tool for human error investigations.
- How to perform a cognitive load assessment
- The interview process and interview techniques for human error root cause analysis.
- When and how to use the human error prediction tool.
- When to perform a Process vs. procedure analysis and why it is so important to do so before establishing procedure revision as a CAPA for human error.
- **Interactive Exercise!** Brainstorm root causes for real cases with peers. Using the situations identified in the first exercise we will try and apply the applicable tool. Getting to the true root cause of an error is commonly described as the hardest part of reducing errors. We'll take your toughest problems and send you home with detailed, written solutions.

2:30 p.m. – 2:45 p.m. Break

2:45 p.m. – 4:45 p.m. Metrics and Human Error

- KPI's
- Human error rate
- 1st time pass rate
- Overall equipment effectiveness (OEE)
- Trending
- Tracking

4:45 p.m. - 5:00 p.m. Wrap up and Adjournment