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
- Examples of applicable FDA requirements and what the FDA expects companies to be complying with
- A review of other industry standards that apply to drug and device manufacturing
- What FDA investigators look for during inspections and the most common violations found in Form 483s and Warning Letters
- Which violations tied to human errors and manufacturing are trending up
- The various types of human errors are commonly found on manufacturing floors
- How we got here — why is human error reduction such an important topic
- **Interactive Exercise!** Do we also err? Attendees will be broken into groups and asked to describe the most common human errors within their facilities. The workshop will then reconvene and break-out group leaders will describe what they uncovered. A list of the most common problems will be tallied to help focus the 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!** When to do what?

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

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.

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
- **Interactive Exercise!** Discuss group discussion

4:45 p.m. – 5:00 p.m. **Review and Key Insights Materials**

- Copies of the presentations
- Current FDA regulations
- Pertinent guidance documents
- Articles on Human Error
- Manual Tools
- Interviewing guide
- Report Example
- Root Cause Determination Tool

5:00 p.m. **Adjourn Workshop**