This workshop will provide a thorough overview of the basis for human error as well as the factors that drive them.

As technology advances, human errors in manufacturing become more and more visible every day: they account for more than 80 percent of process deviations in pharmaceutical manufacturing. This workshop explains how small improvements in manufacturing systems and employee training can deliver big results. In addition to an analysis of how and why errors occur, this workshop features multiple interactive exercises allowing you to work in small groups with your colleagues to tackle common manufacturing problems. Attendees will learn:

- **The basics of human error.** Participants will learn how human errors intersect with manufacturing regulations. Participants will also be provided with an overview of the most commonly found errors on the manufacturing floor and what investigators look for during an inspection. Participants will be break into groups and describe the most common human errors in 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 discussion.

- **The factors that drive human error.** Participants will learn why administrative and management systems factor so prominently into deviations and non-conformances. Attendees will also learn how common day-to-day communication gaps contribute to human error. Participants will also be given a list of the various internal and external factors that lead to human error.

- **CAPA.** Attendees will be taught how to determine 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.

Attendees will finish up the workshop brainstorming with other attendees the root causes for real cases. 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.
DAY ONE

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

Interactive Exercise: Important steps for effective human error investigations
- 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

DAY TWO

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

---

**WHO SHOULD ATTEND**
- QA/QC directors and managers
- Process improvement/excellence professionals
- Training directors and managers
- Manufacturing operations directors
- Human factors professionals
- Device engineering
- Compliance officers
- Regulatory professionals
- Executive management

**COURSE BINDER MATERIALS**
- Root cause determination tool
- Interviewing guide – you can take back and use immediately
- Example of well-documented HE report
- Complete copy of slide deck materials
- Copies of applicable FDA regulations referenced in the course
- Copies of pertinent FDA guidance documents
- Articles focused on human error reductions

---

**THE TOPIC IS VERY RELEVANT TO THE NEEDS OF OUR BUSINESS AT THE MOMENT. I LEARNED SEVERAL THINGS ASSOCIATED WITH HOW TO TRAIN AND USE LEAN TECHNIQUES TO REDUCE THE OPPORTUNITY FOR HUMAN ERROR. IT ALSO REAFFIRMED THE THINGS WE ARE DOING WELL THAT ARE WORKING.**

— Richard Leach, Director of Quality, Nosco

“[Ginette is] very passionate [and] high energy. A lot of take aways. Reduction of human error has been a challenge and the tools provided will be put to the test.”

— Alex Masso, QA In-Process Supervisor, Mylan Institutional Inc.

**YOUR EXPERT INSTRUCTOR**

GINETTE COLLAZO, PH.D., has spent more than 15 years in technical training, organizational development and human reliability. She has worked with Bristol-Myers Squibb, Johnson & Johnson, Schering-Plough, Wyeth and Medtronic, many more small and mid-sized drug and device companies. An active researcher in specialized studies related to human reliability, she is the author of numerous publications on these topics.
FDAnews presents the

How to Reduce Human Error on the Manufacturing Floor

☐ Yes!
Sign me up for How to Reduce Human Error on the Manufacturing Floor

Attendee 1: Name _______________________________  Email _______________________________
Title ________________________________________  $1,797

Attendee 2: Name _______________________________  Email _______________________________
Title ________________________________________  *Call for Discounts*

Attendee 3: Name _______________________________  Email _______________________________
Title ________________________________________  *Call for Discounts*

TOTAL: ______________________________________

COMPANY INFORMATION:
Organization____________________________________________________________________________
Address _______________________________________________________________________________
City __________________________________________________ State ________________  ZIP __________
Country _______________________________________________________________________________
Phone ______________________________________  Fax ______________________________________

PAYMENT OPTIONS:
☐ Check Enclosed: payable in U.S. funds to FDAnews
☐ Charge my:
 [ ] Visa  [ ] MasterCard  [ ] American Express
Card # _______________________________  Exp. Date _______________________________
Signature ___________________________________________________________________________

HOTEL INFORMATION INFORMATION:
To reserve your room, call the hotel at the number below. Be sure to tell the hotel that you're with the FDAnews workshop to qualify for the reduced rate. Only reservations made by the reservation cutoff date are offered the special rate, and space is limited. The hotel may run out of rooms before the reservation cutoff date. The discounted rate is also available one night before and after the event based on availability. The hotel may require the first night’s room deposit with tax. Room cancellations within 24 hours of the date of arrival or “no-shows” will be charged for the first night’s room rate plus tax.

May 23-24, 2016
Embassy Suites Raleigh-Durham Airport/Brier Creek
8001 Arco Corporate Drive
Raleigh, NC 27617

Toll Free: (800) EMBASSY
+1 (919) 572-2200

www.RaleighDurhamAirportBrierCreekEmbassySuites.com
Room rate: $179.00 plus 12.75% tax
Reservation cut-off date: May 8, 2016

TUITION:
Tuition includes all conference presentations, conference materials, two breakfasts, two lunches and refreshments.

TEAM DISCOUNTS:
Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount. Multi-attendee discounts are available and will be calculated at check out.

CANCELLATION AND SUBSTITUTION:
Written cancellations received at least 21 calendar days prior to the start date of the event will receive a refund or credit — less a $200 administration fee. No cancellations will be accepted — nor refunds issued — within 21 calendar days from the start date of the event. A credit for the amount paid may be transferred to any future FDAnews event. Substitutions may be made at any time. No-shows will be charged the full amount. In the event that FDAnews cancels the event, FDAnews is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

FOUR EASY WAYS TO REGISTER
Online: www.DrugDeviceErrors.com
Fax: +1 (703) 538-7676
Phone: Toll free (888) 838-5578 (inside the U.S.) or +1 (703) 538-7600
Mail: FDAnews
300 N. Washington St., Suite 200
Falls Church, VA 22046-3431 USA