FDANEWS PRESENTS THE

This interactive workshop teaches you how to reduce your manufacturing error rates by 50% - Attendance Is Limited. **Act Today!**

REDUCE HUMAN ERROR ON THE DRUG AND DEVICE MANUFACTURING FLOOR

Reduce Errors By 50% or More

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

YOUR EXPERT SPEAKER:

GINETTE COLLAZO, PH.D.,
— a 15 year veteran of helping drug, biologic and device firms reduce manufacturing errors by 50 percent or more — will conduct a one-of-a-kind workshop that teaches quality managers and manufacturing excellence professionals how to reduce errors and improve quality metrics.

"Love her personality and passion. Great job! She was experienced and shared her past experiences which were very relevant to our cause."

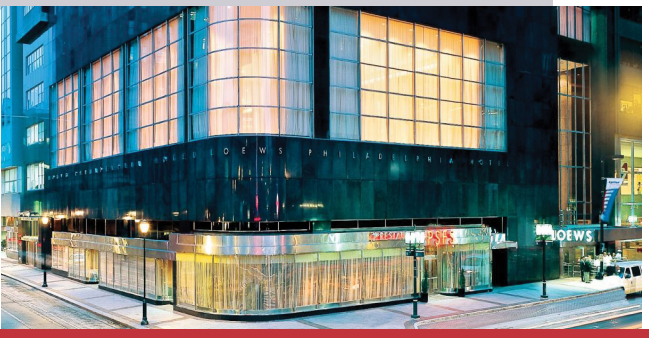
—Ron Carrea, Sr. Assoc. Manufacturing Performance & Dev., Biogen Idec

MARCH 25-26, 2015
LOEWS PHILADELPHIA HOTEL
PHILADELPHIA, PA

SEPT. 17-18, 2015
RALEIGH MARRIOTT CITY CENTER
RALEIGH, NC

This 2-day interactive workshop will teach you:

- How to understand the implications of human error events — how they affect product quality, business operations and regulatory compliance
- Best practices for diagnosing your error tolerance, how to get an error reduction program started and how to measure its effectiveness
- How to identify the relationship between CAPA and human reliability and performance expectations
- Destructive human behavior factors and how to create the effective recommendations to modify them
- 5 key elements of an effective human error CAPA system — strategies to address essential system safeguards that must be put in place to prevent and correct problems
- How to unlock the mystery of root cause analysis and human error
- How to understand key obstacles in existing practices — why correctives don't correct, and preventives don't prevent
- Trending and tracking — how to assure that improvement is not by chance but by design
- Insights into how to leap past hurdles and predict errors



www.DrugDeviceErrors.com | (888) 838-5578

FDANEWS

REDUCE HUMAN ERROR ON
AND DEVICE MANUFACTURIN

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
- 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 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 foe effective human error investigations

- How to report issues to mae 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.

2:45 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! Work with various common metrics and benchmarks. Determine what constitutes acceptable and non-acceptable results.

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. WORKSHOP ADJOURNS

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

YOUR EXPERT SPEAKER

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, and 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.

"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.

"[Ginette is] very knowledgeable with great industry examples. Very spunky! Great delivery."

—Irene Rockwell, Manufacturing Compliance, Biogen Idec

FDANEWS PRESENTS THE

REDUCE HUMAN ERROR ON THE DRUG AND DEVICE MANUFACTURING FLOOR

Reduce Errors By 50% or More

☐ **Yes!** Sign me up for the **Reduce Human Error on the Drug and Device Manufacturing Floor Workshop**

Attendee 1: Name _____

Title _____ Email _____ $1,797

Attendee 2: Name _____ *Call for Discounts*

Title _____ Email _____

Attendee 3: Name _____ *Call for Discounts*

Title _____ Email _____

www.DrugDeviceErrors.com
Toll-free: (888) 838-5578

TOTAL:

INFORMATION:

Name _____

Title _____ Company _____

Address _____

City _____ State _____ ZIP _____

Phone _____ Fax _____

Email _____

PAYMENT OPTIONS:

☐ **Check Enclosed:** payable in U.S. funds to FDAnews ☐ **Charge my**: ☐ Visa ☐ MasterCard ☐ AmEx

Card # _____ Exp. Date _____

Signature _____

CANCELLATION / SUBSTITUTIONS

Written cancellations received at least 21 calendar days prior to the start date of the event will receive a refund -- 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.

HOTEL INFORMATION INFORMATION

To reserve your room, call the hotel at the number below. Be sure to tell the hotel you're with the FDAnews Workshop to qualify for the reduced rate. Only reservations made by the reservation cutoff date are offered the special rates, and space is limited. Hotels may run out of discounted rates before the reservation cutoff date. The discounted rate is also available two nights before and after the event based on availability. Hotel may require first night's room deposit with tax. Room cancellations within 72 hours of the date of arrival or "no-shows" will be charged for the first night's room with tax.

Dates/Location:

March 25-26, 2015
Loews Philadelphia Hotel
1200 Market Street
Philadelphia, PA, 19107
Toll Free: (888) 575-6397
+1 (215) 627-1200
www.loewshotels.com/philadelphia-hotel
Room rate: $239 plus 15.5% tax
Reservation cut-off date: March 3, 2015

Sept. 17-18, 2015
Raleigh Marriott City Center
500 Fayetteville Street
Raleigh, NC 27601
Toll Free: (888) 236-2427
+1 (919) 833-1120
www.marriott.com
Room rate: $179.00 plus 12.75% tax
Reservation cut-off date: Aug. 25, 2015

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. Call +1 (703) 538-7600 for details.

WORKSHOP

Tuition includes all workshop sessions, workshop written materials, two breakfasts, two lunches and daily refreshments.