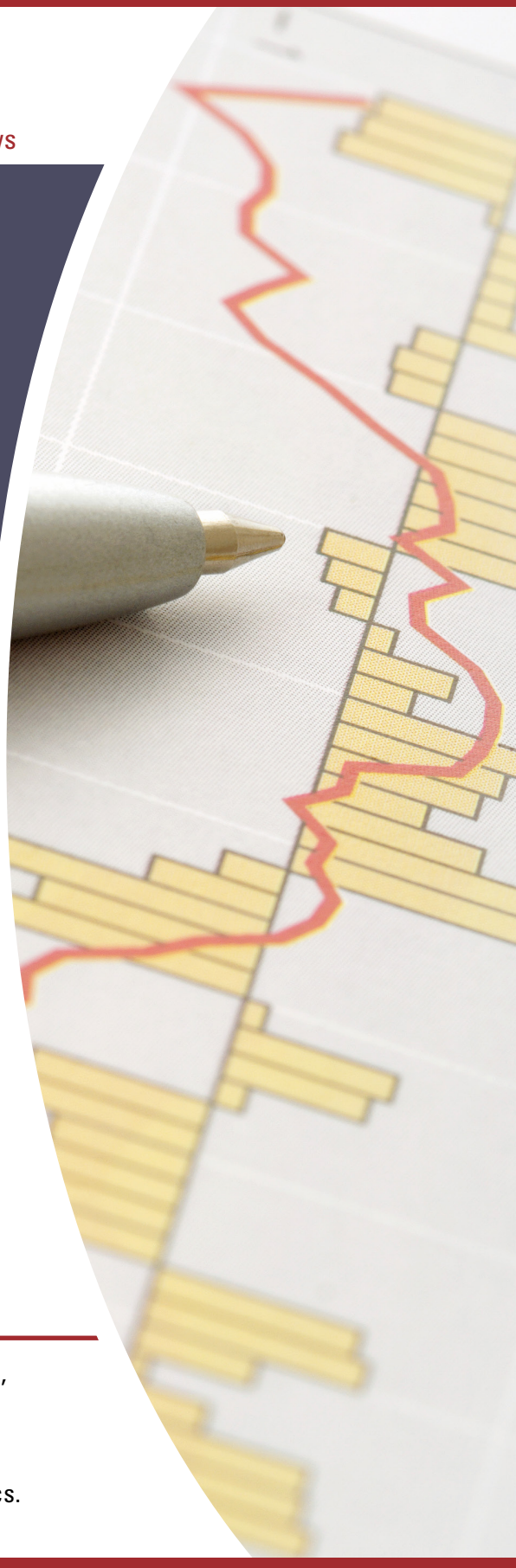
This interactive workshop teaches you how to reduce your manufacturing error rates by 50% - Attendance Is Limited. Act Today!

Sept. 16-17, 2014 • Marriott Raleigh Crabtree Valley • Raleigh, NC

An Interactive Workshop Presented by Ginette M. Collazo, Inc. and FDAnews

Reduce Human Error on the Drug and Device Manufacturing Floor

Reduce Errors By 50% or More



This 2-day interactive workshop you 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

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.

Visit www.DrugDeviceErrors.com or call (888) 838-5578

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Reduce Human Error on the Drug

Reduce Errors

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WORKSHOP AGENDA

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 commonly found on manufacturing floors
- How we got here — why human error reduction is such an important topic

Interactive Exercise! 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 nonconformances
- 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 the FDA your CAPA program is effective and you've adequately focused on human error

Interactive Exercise! Attendees will take various examples where CAPA could apply and answer the all-important question; when should you do what? This exercise will help attendees understand how human-error driven CAPAs can be best solved and tips for documenting the results.

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! There are numerous human error reduction techniques that drug and device companies could use. Attendees will be asked to review various methods and brainstorm ideas on which ones best apply to mock scenarios.

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

and Device Manufacturing Floor

By 50% or More

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- 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.

2:45 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! Got metrics? Metrics are a great tool for identifying, trending and solving HE problems. But how should they be applied to drug and device manufacturing? In this exercise, attendees will work with various common metrics and benchmark, what constitutes acceptable and non-acceptable results.

4:45 p.m. – 5:00 p.m.
Review, Additional Questions, Course Adjourned

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

WHAT YOUR COLLEAGUES HAVE TO SAY

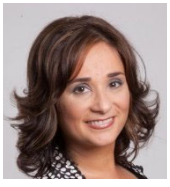
"The topic is very relevant to the needs of our business at the moment. I learned several things associated with how to train and use lean techniques to reduce the opportunity for human error. It also reaffirmed the things we are doing well that are working."

RICHARD LEACH, Director of Quality, Nosco

"The topic was very interesting, it raised some points I never thought of."

RICK CALABRESE, Director of Quality Systems, Sartorius Stedim North America 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, 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.

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LOCATIONS AND HOTEL ACCOMODATIONS

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 cut-off 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. The hotel may require the 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.

LODGING AND CONFERENCE VENUE:

Sept. 16-17, 2014
Marriott Raleigh Crabtree Valley
4500 Marriott Drive
Raleigh NC 27612
Toll Free: (800) 228-9290
+1 (919) 781-7000
www.raleighmarriott.com
Room rate: $139 plus 13.75% tax
Reservation cut-off date: Aug. 26, 2014

TUITION

Tuition rate is $1,797 per person includes the two-day workshop, all workshop materials, continental breakfast and lunch each day.

CANCELLATIONS AND 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 of 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.

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 (888) 838-5578 for details.

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

☑ **YES!** I want to attend **Reduce Human Error on the Drug and Device Manufacturing Floor.** I understand the fee of $1,797 includes the two-day workshop, all workshop materials, continental breakfast and lunch each day.

FDANEWS
300 N. Washington St., Suite 200
Falls Church, VA 22046-3431

(Please see "Team Discounts" above for tuition discounts when you send a team of three or more.)

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