FDANEWS PRESENTS THE

Multi-attendee discounts are available!

HOW TO PERFORM A COGNITIVE LOAD ASSESSMENT FOR HUMAN ERROR REDUCTION

AN INTERACTIVE WORKSHOP PRESENTED BY GINETTE COLLAZO, PH.D. 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

JULY 12-13, 2016 | EMBASSY SUITES RALEIGH-DURHAM AIRPORT/BRIER CREEK

This workshop emphasize human factors linked to cognition and human performance and will focus on individual performance related errors.

Attention, memory and decision making errors are directly associated with cognition overload and mistakes. This course explores the human mind, human factors and cognitive overload in GMP related environments.

Through a combination of discussion and interactive exercises attendees will learn:

- **How to perform a cognitive load assessment.** Participants will begin the course by learning how to perform a cognitive load assessment to reduce errors. Attendees will also be provided examples of poor human factor, engineering and workplace conditions that contribute to errors.
- **Human error reduction techniques.** Participants will be taught how and when to apply engineering controls to correct and prevent errors. Participants will work with fellow attendees to create and analyze results through the use of a box plot chart.
- **Human error investigation.** Participants will be taught the proper steps to take for an effective human error investigation from beginning to end. They will be taught how to gather data when analyzing cognitive load. They will also be taught how to perform an effective interview and how to properly report issues to management in a way that they will listen.

Through the use of a case study, participants will conduct a full cognitive load assessment including a root cause analysis and CAPA development plan.

DAY ONE

8:00 a.m. – 8:30 a.m. | REGISTRATION & CONTINENTAL BREAKFAST

8:30 a.m. – 10:00 a.m.

How to perform a cognitive load assessment for human error reduction

- Definitions and Theory
- The regulation and human error: Examples of applicable FDA requirements and what the FDA expects companies to be complying with
- Definitions and Theory on Human Error and Cognitive Load
- Understanding the latest on cognitive load and attention, memory, and decision making errors — how they commonly occur on the manufacturing floor
- Cognitive Load Assessment: scenarios and applications
- Human Errors Types and Cognitive Load
- Human Error Cause Categories for Cognitive Load
- 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 related to cognition, within their facilities. The workshop will then reconvene and break-out group leaders will describe what categories were identified as root causes.

10:00 a.m. – 10:15 a.m. | BREAK

10:15 a.m. – 12:00 p.m.

Cognition and Human Error

- Human limitations on memory, attention and decision making
- How cognitive load affects productivity
- The various types of cognition related human errors commonly found on manufacturing floor
- Common examples of poor human factors, engineering and workplace conditions that contribute to human error
- When training is appropriate and when we should stop
- When is individual performance and cognitive load 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. – 4:30 p.m.

Cognitive Load Tool Content

- Definition of Human Factors Categories (HFC)
- How our senses control how we react — it's more important that you think.
- Importance of each HFC and latest investigation on cognition and productivity
- Learn the Human Error Risk Multipliers and risk level
- How to develop recommendations for each HFC
- How to prepare for the Cognitive Load Floor Assessment
- Workshop #1 – Floor Assessment Simulation
- How to use the excel tool
- Workshop # 2 – Data Entry using excel tool

DAY TWO

8:30 a.m. – 10:00 a.m.

Human Error Reduction Techniques (Cognitive Load)

- Discussion of insights from Day 1
- Understanding the Human Error level of Risk
- What is the level of risk and how to determine it?
- Reporting the level of risk: tools and criticality assessment
- Creating the Box Plot
- Report Content
- How and when to apply engineering controls to correct and prevent human error deviations
- What to do when individual performance is the major contributor
- Additional contributors for human errors will be discussed

Interactive Exercise: Creating and analyzing results. Create and export the Box Plot Chart

10:00 a.m. – 10:15 a.m. | BREAK

10:15 a.m. – 12:00 p.m.

Human Error Investigation (Cognitive Load Issues)

- Human error investigation process defined from beginning to end
- Individual performance: slip, mistakes and violations
- How to gather data in the human error investigation process when analyzing cognitive load?
- How to perform an effective interview: there's more than meets the eye?
- Important steps for effective human error investigations

AD ASSESSMENT FOR HUMAN ERROR REDUCTION

- How to report issues to make sure management listens?
- When to involve Human Resources in CAPA

12:00 p.m. – 1:00 p.m. | LUNCH

1:00 p.m. – 2:30 p.m.

Cognitive Load Assessment- Interactive Exercise: Full experience on Cognitive Load Assessment. A case study will be analyzed for root cause analysis, determination and CAPA development.

2:30 p.m. – 2:45 p.m. | BREAK

3:00 p.m. – 4:00 p.m.

Writing recommendations

- How to determine the kind of recommendation based on the type of error?
- High and low end recommendations: benefits and challenges
- Type of recommendations based on the type of error (random, systemic and sporadic errors)
- How to present to management and make sure you are taken seriously

4:00 p.m. – 4:30 p.m.

Metrics and Human Error

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

4:30 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.

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☐ **Yes!**

Sign me up for How to Perform a Cognitive Load Assessment for Human Error Reduction

Attendee 1: Name _____

Title _____ **Email** _____ $1,797

Attendee 2: Name _____ *Call for Discounts*

Title _____ **Email** _____

Attendee 3: Name _____ *Call for Discounts*

Title _____ **Email** _____

TOTAL:

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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.

July 12-13, 2016

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www.RaleighDurhamAirportBrierCreek.EmbassySuites.com

Room rate: $179.00 plus 12.75% tax
Reservation cut-off date: June 27, 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

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