FDANEWS PRESENTS THE

Multi-attendee discounts are available!

HOW TO WRITE ERROR FREE PROCEDURES AND INSTRUCTIONS

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

JUNE 14-15, 2016 | EMBASSY SUITES RALEIGH-DURHAM AIRPORT/BRIER CREEK

This course offers practical approaches to address writing rules to reduce the likelihood of procedures.

This workshop is designed for people who are responsible for writing procedures, instructions, batch records, forms, validations or any other controlled document.

Through a combination of discussion and interactive exercises, this workshop will teach attendees the proper way to write procedures and other documents to minimize the human factors that lead to human errors. Attendees will learn:

- **The reason for procedures.** Participants will begin the course with a discussion of the importance of using procedures and how they can be used to train, execute and troubleshoot to prevent human error. Participants will also learn when, how and why to categorize procedures as a root cause.
- **How to create and maintain procedures.** Participants will be taught the 7 steps needed to write error-proof procedures and then work with fellow attendees to develop a working plan and checklist to execute the steps.
- **Writing rules and content development.** Participants will practice writing steps, sub-steps and conditional statements. Each submission will be evaluated in a group discussion and changes will be suggested. By the end of the exercise you will have all the tools needed to write clear and succinct procedures.
- **Human error deviations.** Participants will be taught when to perform a process vs. procedure analysis and why it is important to do so before establishing a procedure revision as a CAPA for human error.

The workshop will conclude with participants using case studies to brainstorm root causes. Using situations identified throughout the workshop, participants will try and apply the appropriate tool to identify the error.

DAY ONE

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

8:30 a.m. – 10:00 a.m.

How to write error free procedures

- Introduction
- Human error basics
- Background and best practices in other industries
- Human error vision, error types and initial classification
- Human error taxonomy, framework and methodology
- Human error cause categories
- Performance shaping factors associated to procedures

Interactive Exercise: Attendees will be asked to identify, based on examples, the error type, classification, and possible PSP for the initial solution. The workshop will then reconvene and break-out group leaders will describe what they uncovered.

10:00 a.m. – 10:15 a.m. | BREAK

10:15 a.m. – 12:00 p.m.

Procedures and regulations- The importance for human error prevention, training and other uses

- The purpose of procedures and the importance for human error prevention
- Regulatory compliance background and agencies' expectations for procedures
- Importance of procedures
- Universal purpose of procedures: training, execution, and troubleshooting
- The Human perspective and instructions writing: how do we understand written instructions?
- Procedures as a root cause: when, how and why do we categorize procedures as a root cause?
- Why resistance to procedures?
- Documentation hierarchy: from policies to record documents, documentation levels and level of detail

12:00 p.m. – 1:00 p.m. | LUNCH

1:00 p.m. – 2:30 p.m.

The human perspective

- The thinking and reading process
- The human brain and errors of interpretation
- Cognitive process and impact in manufacturing execution
- Perception and understanding
- Brain function and instructions development
- Human thinking model: how we react to stimuli and process information
- Rule based behavior and skill based behavior: impact on execution
- Common mistakes and causes found in the industry

2:30 p.m. – 4:30 p.m.

How to create and maintain procedures

- Facts about effective procedures.
- How to accomplish procedures main goal?
- Six step process:
  - plan,
  - investigate,
  - organize,
  - draft,
  - draft revision,
  - validation (field test),
  - maintenance

Interactive Exercise: Create a plan for procedure development using tools learned in class

DAY TWO

8:30 a.m. – 10:00 a.m.

Human Engineering Procedures

- Discussion of insights from Day 1
- Writing rules and content development
- Writing steps, sub-steps, and conditional statements
- Page format: Font size, spacing, use of white space, title structure, control features, and other requirements

Interactive Exercise: Practice writing steps, sub-steps and conditional statements

10:00 a.m. – 10:15 a.m. | BREAK

10:15 a.m. – 12:00 p.m.

Human Engineering Procedures (cont.)

- Procedure styles
- Format styles: when to use which?
- Making sure procedures are complete: what-if analysis and FMEA
- Electronic vs. Paper based procedures: advantages and disadvantages
- Validation and field testing steps
- Procedure maintenance and change management
- Document configuration and control system

Interactive Exercise: Practice: evaluate your procedure and suggest changes. Group discussion

12:00 p.m. – 1:00 p.m. | LUNCH

1:00 p.m. – 2:30 p.m.

Human error deviations related to procedures

- Root cause analysis
- Procedure related near root causes and root causes

OCEDURES

- CAPA and procedures: be very careful
- Process vs. procedure assessment
- 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
- How to avoid deviations related to procedures

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. – 3:45 p.m.

Writing recommendations and final thought on metrics

- High end and low end recommendations
- KPI's
- Human error rate
- 1st time pass rate
- Trending
- Tracking

Interactive Exercise: Group discussion and final practice

3:45 p.m. – 4:00 p.m.

Review and Key Insights Materials

- Copies of the presentations
- Current FDA regulations
- Pertinent guidance documents
- Articles on Human Error
- Manual Tools
- Writing rules
- Page format checklist
- Root Cause Determination Tool

4:00 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.

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HOW TO WRITE ERROR FREE PROCEDURES AND INSTRUCTIONS

☐ **Yes!**

Sign me up for How to Write Error Free Procedures and Instructions

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Title _____ **Email** _____

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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.

June 14-15, 2016

Embassy Suites Raleigh-Durham Airport/ Brier Creek
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www.RaleighDurhamAirportBrierCreek.EmbassySuites.com

Room rate: $179.00 plus 12.75% tax
Reservation cut-off date: May 30, 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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