BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

Human Errors and Human Factors
(WORK-003)

OVERVIEW:

There have been several Form 483's and Warning Letters being issued to companies by the FDA as it relates to CAPA investigations because of the abuse of the "human error" as root cause and "retraining" as corrective action approach. The purpose of this workshop is to help authors and reviewers of CAPA investigation reports related to human errors to improve the quality of their regulatory documents.

TARGET GROUP FOR THE TRAINING:

This workshop will benefit manufacturers of FDA-regulated products in documenting their CAPA investigation reports related to human errors in order to avoid FDA or other regulatory bodies' inspection findings in these areas. It will be a great resource to Quality Assurance, Manufacturing, Regulatory Affairs, Supplier Quality and Quality Control personnel and management within the Pharmaceutical, Biotechnology and Medical Device companies. Although the workshop focuses on identifying the root causes and controls to avoid human errors, it will also apply for other CAPA investigations as well.

LEARNING OBJECTIVES:

Upon completing this workshop, participants will be able to:

- Identify the root causes that lead to human error
- Identify the controls that could avoid the human error

MATERIALS:

Each participant will receive:

- MS PowerPoint presentations
- Certificate of Attendance
- Final Exam (70% minimum score required to approve the course

TRAINING DURATION:

7 contact hours

ACCREDITED IACET PROVIDER

BEC is authorized by IACET to offer
0.7 CEUs for this program.
FULL attendance to the learning event
is mandatory to receive CEUs.

COURSE INSTRUCTOR:

Manuel E. Peña-Rodríguez is a process improvement and training consultant within the textiles, electronics, and FDA-regulated industries with more than 20 years of experience in those fields. Since January 2006, he is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training and implementation of Lean Six Sigma initiatives and CAPA / Root Cause Analysis workshops. He also serves as professor in the graduate program in biochemistry at the University of Puerto Rico, Medical Sciences Campus, in San Juan. Manuel received his J.D. degree from the Pontifical Catholic University of Puerto Rico and his master's of engineering in Engineering Management from Cornell University in Ithaca NY. He is also a licensed Professional Engineer registered in Puerto Rico. Manuel is an ASQ Certified Six Sigma Black Belt, Manager of Quality & Organizational Excellence, Quality Engineer, Quality Auditor, Biomedical Auditor, and HACCP Auditor. He is also a Senior member of ASQ and former Chair of the Puerto Rico ASQ Section. He is the author of the book "*Statistical Process Control for the FDA-Regulated Industry*", published by ASQ Quality Press in April 2013 and co-author (with José Rodríguez-Pérez) of the article "*Fail-Safe FMEA*" published in the January 2012 edition of the ASQ Quality Progress magazine.

Frances M. Cartagena Vargas is a professional with over 15 years of experience in the pharmaceutical industry. She has a Bachelor Degree in Chemistry from Interamerican University of Puerto Rico's Metropolitan Campus. She also has a Master Degree in Business Adminitration from University of Phoenix, Puerto Rico Site with a Major in Technology Management. As a professional in the areas of Quality Systems, Regulatory Compliance, Manufacturing, Parenteral Environment, Validation Activities and Technology/Product Transfer, she has working experience in Consent Decree, US and EU agencies interaction, among others. She is an ASQ Certified Six Sigma Green Belt.

Gloryvee Maldonado Pérez is a training consultant within the FDA-regulated industries with more than 10 years of pharmaceutical and medical devices industry experience, in the areas of quality assurance, quality control, regulatory, validation, manufacturing, and packaging. She has a Bachelor Degree in Chemistry from the University of Puerto Rico at Rio Piedras Campus. She also has a Master of Science in Manufacturing Competitiveness, with a specialization in pharmaceutical products, from the Polytechnic University of Puerto Rico in Hato Rey, P.R. Since year 2012, she is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training on related Quality sectors. She is an ASQ Certified Six Sigma Black Belt, and Certified Quality Engineer. She is also a CAPA System Expert Investigator and ISO 13485 Lead Auditor.

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Lunch from 12:00 – 13:00.

Coffee break: 15 min. each during morning and afternoon session. Time schedule are rough estimates and may vary consequently.

Agenda	
8:30 – 9:00	**Introduction**
9:00 – 10:15	**Human Errors and Human Factors** • Key Points to Consider • From Human Error to Defect • Dealing With Human Errors • Types of Human Failures • Origins of Errors: the GEMS Model • Memory Slips and Lapses • Mistakes • Attention, Memory, and Human Errors
10:15 – 10:30	**Break**
10:30 – 12:00	**Human Errors and Human Factors (cont.)** • Human Factors Analysis and Classification System • Latent Failures • Human Errors and U.S. Healthcare • Human Factors Natural Mappings
12:00 – 13:00	**Lunch**
13:00 – 14:00	**Investigating Human Errors** • Causal Factor and Root Cause Identification • How to Investigate Human Errors • Interviewing, Not Interrogating • Human Error Investigation Form • Root Cause Categories • Human Error Investigation Key Points
14:00 – 15:00	**Human Error + Retraining** • Training as Human Factor • Root Cause Categories Related to Training • The Kirkpatrick Model • How to Reduce the Probability of Human Errors • Human Errors and Memory • Areas to Focus
15:00 – 15:15	**Break**
15:15 – 17:00	**Human Error Investigation Case Study**