BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

Effective CAPA Systems (WORK-002)

OVERVIEW:

There have been several Form 483's and Warning Letters being issued to companies by the FDA as it relates to inadequate CAPA investigations. Most investigators do not know the differences among corrections, corrective actions, and preventive actions. Thus, many investigations are not effective because they focus on the symptoms instead of the root causes. The purpose of this workshop is to help authors and reviewers of CAPA investigation reports to improve the quality of their regulatory documents and ensure the effectiveness of those CAPA investigations.

TARGET GROUP FOR THE TRAINING:

This workshop will benefit manufacturers of FDA-regulated products to improve their CAPA investigation reports in order to avoid FDA or other regulatory bodies' inspection findings. 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.

LEARNING OBJECTIVES:

Upon completing this workshop, participants will be able to:

- Identify the major opportunities of the CAPA system
- Apply effective corrective and preventive actions
- Define an adequate CAPA effectiveness statement

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.

Solmarie Vélez Rivera is a training consultant within the FDA-regulated industries with over 20 years of experience. She has a Bachelor Degree in Industrial Engineering from the University of Puerto Rico at Mayaguez Campus. She also has a Master Degree in Business Adminitration from University of Phoenix, Puerto Rico Site. Since year 2013, she is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training on ASQ Certified Quality Auditor Academia, Internal Audits Program, Quality Systems Regulations (21CFR820), CAPA, Root Cause Analysis, Technical Writing, and other topics. She is an ASQ Certified Quality Auditor, Manager of Quality & Organizational Excellence, Biomedical Auditor, and HACCP Auditor.

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.

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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	**Elements of the CAPA Plan** • Corrections • Corrective Actions • Preventive Actions • Generating Corrective and Preventive Actions • Effectiveness Evaluation
10:15 – 10:30	**Break**
10:30 – 12:00	**Eleven Biggest CAPA Opportunities** • Timeliness • Everything is an Isolated Event • Root Cause Not Identified • Correcting the Symptoms Instead of the Cause
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Eleven Biggest CAPA Opportunities (cont.)** • Lack of Interim Corrective Actions • Root Cause Identified But Not Corrected • Lack of True Preventive Actions • Lack of Effectiveness Verification of Action Taken • Multiple CAPA Systems Without Correlation • Abuse of Human Error and Retraining • Over-Customization of the CAPA System
15:00 – 15:15	**Break**
15:15 – 17:00	**CAPA Effectiveness Examples**