BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

Root Cause Analysis (WORK-001)

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 follow a systematic root cause analysis approach for their investigations. 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 during their CAPA investigations 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.

LEARNING OBJECTIVES:

Upon completing this workshop, participants will be able to:

- Use an array of tools during a CAPA investigation to find the root causes
- Identify corrective and preventive actions that address the root causes
- Compose an investigation report to optimize understanding and clarity

MATERIALS:

Each participant will receive:

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

TRAINING DURATION:

14 contact hours

ACCREDITED IACET PROVIDER

BEC is authorized by IACET to offer
1.4 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.

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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Title: Root Cause Analysis (Day 1)

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 – 9:45	**Introduction** • The Vicious Cycle • The Correct CAPA Flow • Root Cause Identification • The Closed-Loop CAPA Process
9:45 – 10:15	**CAPA and the Regulations** • Adulteration • CAPA in the Pharmaceutical Industry • CAPA in the Medical Devices Industry • The CAPA Link Between Pharmaceutical and Medical Devices • Main FDA Findings • Eleven Opportunities of the CAPA System
10:15 – 10:30	**Break**
10:30 – 12:00	**Risk Management and CAPA** • Regulatory Requirements • The Risk-Based Matrix • Integration of Risk Management and CAPA • A Systematic Approach
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Elements of an Investigation Report** • Event Information and Description of the Issue • Immediate Actions Taken • Initial Impact Assessment • Investigation Details • Conclusions About Root Causes • CAPA Plan • Final Disposition and Approval • Executive Summary
15:00 – 15:15	**Break**
15:15 – 17:00	**Problem-Solving Methodology** • Problem Description o Chronology of Events o Change Analysis o Trending o Comparison Matrix

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Title: Root Cause Analysis (Day 2)

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 – 10:15	**Problem-Solving Methodology (cont** • Problem Description o Comparison Matrix (cont.) • Barrier Control Analysis o Physical Controls o Administrative Control
10:15 – 10:30	**Break**
10:30 – 11:15	**Root Cause Analysis Tools** • Cause and Effects Diagram • 5 Whys • Fault Tree Analysis
11:15 – 12:00	**How to Investigate Human Errors**
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Root Cause Categories** • Personal Performance • Training Equipment • Human Reliability Factors • Procedures and Instructions • Materials • Environment • Supervision and Management Factors
15:00 – 15:15	**Break**
15:15 – 17:00	**Root Cause Analysis Case Study**