BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

CAPA System Overview for Managers
(WORK-021)

OVERVIEW:

Medical devices, biopharmaceutical, and traditional drug manufacturing companies devote an important part of their resources dealing with incidents, investigations, and corrective and preventive actions. The corrective and preventive action system is known as the CAPA system. It is second to none in terms of frequency and criticality of its deviations, and most of the regulatory actions taken by the FDA and foreign regulators are linked to inadequate CAPA systems. This workshop provides useful and up-to-date information about this critical topic to thousands of managers and supervisors across the life sciences industries.

TARGET GROUP FOR THE TRAINING:

This workshop will benefit manufacturers of FDA-regulated products to improve their CAPA systems 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 upper and middle 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 their CAPA system
- Apply the required actions to improve the effectiveness of their CAPA system

MATERIALS:

Each participant will receive:

- MS PowerPoint presentations
- *CAPA for the FDA-Regulated Industry* book, published by ASQ Quality Press
- Participation certificate
- 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.

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Title: CAPA System Overview for Managers (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 – 9:00	**Opening Remarks**
9:00 – 10:15	**Introduction** • The Vicious Cycle • The Correct CAPA Flow • Root Cause Identification • The Closed-Loop CAPA Process
10:15 – 10:30	**Break**
10:30 – 12:00	**CAPA and the Regulations** • Adulteration • CAPA in the FDA-Regulated Industry • Main FDA Findings • Current Regulatory Trends
12:00 – 13:00	**Lunch**
13:00 – 14:30	**Risk Management and CAPA** • Regulatory Requirements • The Risk-Based Matrix • Integration of Risk Management and CAPA • A Systematic Approach
14:30 – 15:00	**Elements of an Investigation Report** • Event Information • Description of the Issue • Immediate Actions Taken
15:00 – 15:15	**Break**
15:15 – 17:00	**Elements of an Investigation Report (cont.)** • Initial Impact Assessment • Investigation Details • Conclusions About Root Causes • CAPA Plan • Final Disposition and Approval • Executive Summary **Root Cause Categories**

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Title: CAPA System Overview for Managers (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	**Human Errors and Human Factors** • Key Points to Consider • From Human Error to Defect • Dealing With Human Errors • Types of Human Failures • Memory Slips and Lapses • Attention, Memory, and Human Errors • Latent Failures • Human Errors and U.S. Healthcare • Human Factors Natural Mappings
10:15 – 10:30	**Break**
10:30 – 11:15	**Investigating Human Errors** • Causal Factor and Root Cause Identification • How to Investigate Human Errors • Interviewing, Not Interrogating • Human Error Investigation Form • Human Error Investigation Key Points
11:15 – 12:00	**Human Error + Retraining** • Training as Human Factor • How to Reduce the Probability of Human Errors • Human Errors and Memory • Areas to Focus
12:00 – 13:00	**Lunch**
13:00 – 13:45	**Elements of the CAPA Plan** • Corrections • Corrective Actions • Preventive Actions • Generating Corrective and Preventive Actions • Effectiveness Evaluation

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: CAPA System Overview for Managers (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 (cont.)	
13:45 – 15:00	**Eleven Biggest CAPA Opportunities** • Timeliness • Everything is an Isolated Event • Root Cause Not Identified • Correcting the Symptoms Instead of the Cause
15:00 – 15:15	**Break**
15:15 – 17:00	**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 **CAPA Effectiveness Examples**