BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

CAPA System Expert Certification (CERT-003)

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 certification provides useful and up-to-date information about this critical topic to thousands of engineers, scientists, and manufacturing and quality personnel across the life sciences industries. Understanding and improving the CAPA system as a whole is the focal point of this certification, the first of its kind dealing exclusively with this critical system within this highly regulated industry. By helping those in this industry improve their CAPA systems, it will be a crucial aid in their mission of producing safe and effective products.

TARGET GROUP FOR THE TRAINING:

This certification will benefit manufacturers of FDA-regulated products to improve their CAPA investigations 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 certification, participants will be able to:

- Identify the major opportunities of their CAPA system
- Evaluate the CAPA investigation process to identify all the root cause(s)
- Apply effective corrective and preventive actions that will avoid the recurrence or occurrence of the issues
- Measure the effectiveness of the actions implemented

The effectiveness of the certification process will be measured using the Kirkpatrick model of training effectiveness, through the use of the following materials for each phase of the model:

- **Reaction:** an evaluation form at the end of the training, covering issues such as material's organization, trainer's knowledge about the topics, and training environment.
- **Learning:** a pre-test prior to the beginning of the training, plus a post-test at the end of the training. A minimum grade of 70% in the post-test is required to pass the certification.
- **Behavior:** the submission of an existing CAPA investigation report, redlined with all the deficiencies found by applying all the knowledge acquired during the training.
- **Results:** the company might be able to measure the results of this certification process by analyzing pre- and post-certification metrics such as amount of CAPA investigations opened, time to complete CAPA investigations, and recurrence of the issues that cause a CAPA investigation, among others. A downward trend in all these metrics is expected.

MATERIALS:

Each participant will receive:

- MS PowerPoint presentations.
- Various electronic templates that can be adapted to the company's own needs
- *CAPA for the FDA-Regulated Industry* book, published by ASQ Quality Press
- CAPA Expert certificate, at the completion of the first three phases of the Kirkpatrick model

TRAINING DURATION:

49 contact hours

BEC is authorized by IACET to offer
4.9 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.

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: CAPA System Expert Certification (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

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: CAPA System Expert Certification (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**

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: CAPA System Expert Certification (Day 3)

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**

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: CAPA System Expert Certification (Day 4)

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**

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: CAPA System Expert Certification (Day 5)

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 – 9:45	**Part 1: Developing Excellent Investigation Skills** **Introduction** • The Vicious Cycle • The Closed-Loop CAPA Process • Root Cause Identification • Definitions
9:45 – 10:15	**CAPA Investigations in the FDA-Regulated Industry** • Adulteration • CAPA in the Pharmaceutical Industry • CAPA in the Medical Device Industry • The CAPA Link Between Pharmaceutical and Medical Devices • Most Frequent Pitfalls of CAPA Investigations
10:15 – 10:30	**Break**
10:30 – 11:15	**QSIT: Auditing the CAPA System** • Purpose and Importance of the CAPA System • CAPA Inspectional Objectives • FDA Inspectors Are Looking For… • Main FDA's Findings
11:15 – 12:00	**Current Regulatory Trends** • Top Observations in the Pharmaceutical Industry • Top Observations in the Medical Device Industry • CAPA Subsystem Warning Letters Summary • Recent Observations Related to CAPA Investigations
12:00 – 13:00	**Lunch**
13:00 – 14:00	**Elements of an Investigation Report** • Event Information • Description of the Issue • Immediate Actions Taken • Initial Impact Assessment

14:00 – 15:00	**Elements of an Investigation Report (cont.)** • Investigation Details • Conclusions About Root Causes • CAPA Plan • Final Disposition and Approval • Executive Summary
15:00 – 15:15	**Break**
15:15 – 17:00	**Part 2: Developing Excellent Technical Writing Skills** **Measures of Excellence** • Documentation Style Manual o Abbreviations o Numbers and Numerals o Dates and Times o Symbols o Punctuation o Capitalization o Bold and Italics o Lists

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: CAPA System Expert Certification (Day 6)

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	**Measures of Excellence (cont.)** • Documentation Style Manual o Grammar and Usage o Correct and Preferred Usage of Words
10:15 – 10:30	**Break**
10:30 – 11:15	**Sentence Construction** • Imperative Sentences • Active vs. Passive Sentences • Subject-Verb Agreement • Transition Words
11:15 – 12:00	**Writing Basics** • Writing for Clarity o Avoiding the Passive Voice o Being Positive o Removing Gender Bias
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Writing Basics (cont.)** • Writing for Economy o Cutting Who, Which, and That o Cutting Redundancy • Writing for Readability o Replacing Long Words o Breaking Long Sentences
15:00 – 15:15	**Break**
15:15 – 17:00	**Writing Effective Documents** • Writing Styles • Executive Summary • The Writing Process • Things to Avoid

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: CAPA System Expert Certification (Day 7)

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	**Regulatory Importance of Statistical Process Control** • Process Control within the Code of Federal Regulation • Process Control within the FDA Guidances • Process Control Within International Guidances and Standards
9:00 – 9:15	**SPC and the Life Sciences Regulated Industry** • Recent observations about misuse of statistical process control • SPC and CAPA
9:15 – 9:45	**Process Variation** • The causes of variation
9:45 – 10:15	**Basic Principles About Statistics** • Types of data • Sampling • Describing the sample • The Normal distribution
10:15 – 10:30	**Break**
10:30 – 11:00	**Graphical Tools** • Histogram • Box plot • Dot plot • Pareto diagram • Scatter plot • Run chart • Normality test • The importance of assessing normality
11:00 – 11:30	**Measurement System Analysis** • Overview • Metrics • Performing a gage R&R

11:30 – 12:00	**Process Capability** • Process capability and process performance indices • How to interpret the process capability and process performance indices • Process capability analysis for nonnormal data • Performing a process capability analysis
12:00 – 13:00	**Lunch**
13:00 – 14:30	**Hypothesis Testing** • Comparing means • Comparing medians • Comparing variances
14:30 – 15:00	**Regression Analysis** • Least squares method • Regression metrics • Residual analysis • Simple linear regression • Multiple linear regression
15:00 – 15:15	**Break**
15:15 – 15:45	**Design of Experiments** • Design of Experiments terminology • Full factorial experiments • Fractional factorial experiments • Blocking • Repetition and replication • Experimental strategy
15:45 – 16:30	**Control Charts** • The rational subgroup • Non-random patterns • Variables control charts and attributes control charts • Variables control charts • Attributes control charts
16:30 – 17:00	**Final Thoughts** • Order of tools • Continuous process monitoring versus once-a-year analysis and reporting • Proactive or reactive? • Next steps