TRAINING TITLE:

Human Errors Investigator Certification (CERT-005)

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:

35 contact hours

BEC is authorized by IACET to offer
3.5 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: Human Errors Investigator 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 – 9:30	**Opening Remarks and Pre-Test**
9:30 – 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 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
12:00 – 13:00	**Lunch**
13:00 – 14:30	**QSIT: Auditing the CAPA System** • Purpose and Importance of the CAPA System • CAPA Inspectional Objectives
14:30 – 15:00	**Current Regulatory Trends** • Top Observations in the Pharmaceutical Industry • Top Observations in the Medical Device Industry • CAPA Subsystem Warning Letters Summary
15:00 – 15:15	**Break**
15:15 – 17:00	**Risk Management and CAPA** • Regulatory Requirements • The Risk-Based Matrix • Integration of Risk Management and CAPA • A Systematic Approach

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Human Errors Investigator 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 – 9:00	**Introduction**
9:00 – 10:15	**Elements of an Investigation Report** • Event Information • Description of the Issue • Immediate Actions Taken • Initial Impact Assessment • Investigation Details • Conclusions About Root Causes • CAPA Plan • Final Disposition and Approval • Executive Summary
10:15 – 10:30	**Break**
10:30 – 12:00	**Problem Solving Methodology** • Focus of the Model • Defining the Problem • Chronological Analysis • Change Analysis • Searching for Trends • Flowchart
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Problem Solving Methodology (cont.)** • Is/Is Not Matrix • Problem Definition Case Study • Barrier Control Analysis • Causal Factor and Root Cause Identification
15:00 – 15:15	**Break**
15:15 – 16:00	**Root Cause Analysis Tools** • Fishbone • 5 Whys • Fault Tree Analysis
16:00 – 17:00	**Final Thoughts** • How to Investigate Human Errors • Root Cause Categories

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Human Errors Investigator 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: Human Errors Investigator 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 • 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	• 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: Human Errors Investigator 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 (cont.)	
13:45 – 14:30	• Documentation Style Manual o Grammar and Usage o Correct and Preferred Usage of Words
14:30 – 15:00	**Sentence Construction** • Imperative Sentences • Active vs. Passive Sentences
15:00 – 15:15	**Break**
15:15 – 17:00	**Writing Effective Documents** • Writing Styles • Executive Summary • The Technical Writing Process o Planning and Organizing the Document ▪ Organizing Information: Visual Aids ▪ Uses of Graphs o The Outline o Drafting Documents o Revising-Editing Documents o Proofreading • Things to Avoid o Alarm Words • Writing for Effectiveness o Clarity o Economy o Readability o Correctness • Good Writing Practices

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Human Errors Investigator 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	**Regulatory Importance of Statistical Process Control** • Process Control within the Code of Federal Regulation, FDA Guidances, and International Guidances & Standards
9:00 – 9:15	**SPC and the Life Sciences Regulated Industry** • Recent observations about misuse of statistical process control
9:15 – 9:45	**Process Variation** • The causes of variation
9:45 – 10:15	**Basic Principles About Statistics** • Descriptive Statistics • The Importance of Descriptive Statistics • The Importance of Addressing Normality of the Data
10:15 – 10:30	**Break**
10:30 – 11:00	**Graphical Tools** • Describing the Data: Histogram and Dot Plot • Comparing Groups: Box plot • Prioritizing Our Actions: Pareto diagram • Analyzing Relationships: Scatter Plot • Time is an Important Consideration • Looking for Non-Randomness: Run chart
11:00 – 11:30	**Process Capability** • Analyzing Process Capability • Process Capability Indices • Process Capability Example
11:30 – 12:00	**Control Charts** • Types of Control Charts • Control Chart Selection • Variables control charts • Attributes control charts
12:00 – 13:00	**Lunch**
13:00 – 14:00	**Final Thoughts**
14:00 – 14:45	**Training Wrap Up and Test Review**
14:45 – 15:00	**Break**
15:00 – 17:00	**Post-Test**