TRAINING TITLE:

How to Write Effective Customer Complaints Investigation Reports (WORK-013)

OVERVIEW:

There have been several Form 483's and Warning Letters being issued to companies by the FDA as it relates to customer complaint investigations because of insufficient or incomplete documentation of such investigation reports. All failures, deviations, complaints or out of specification investigations must be adequately documented, corrected, prevented and checked for effectiveness through the use of a compliant CAPA investigational system and program. The purpose of this workshop is to help authors and reviewers of customer complaints investigation reports to improve the quality of their regulatory documents.

TARGET GROUP FOR THE TRAINING:

This workshop will benefit manufacturers of FDA-regulated products in documenting their customer complaints investigation reports 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. Although the workshop focuses on writing effective customer complaints investigation reports, it will also benefit any personnel who write other regulatory documents, such as SOPs, work instructions, policies, validation protocols, batch records, DMRs, and so on. Effective writing of those documents will avoid situations that could end up in opening CAPA investigations.

LEARNING OBJECTIVES:

Upon completing this workshop, participants will be able to:

- Compose an effective investigation report to optimize understanding and clarity
- Avoid writing errors

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

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:

Pepe Rodríguez is founder and President of Business Excellence Consulting Inc., a leading Puerto Rican training and consulting organization. From 2009-11 he served as a Science Advisor for the FDA San Juan District. He has served as instructor of courses on quality and continuous improvement in several countries with thousands of professionals trained in topics such as Quality Engineering, Six-Sigma, Effective CAPA and Root Cause Analysis, HACCP and Quality Management. Pepe holds a bachelor's degree in biology and PhD in immunology, both from the University of Granada, Spain. He served as a senior member of the American Society of Quality and President of the Puerto Rico (ASQ 1500) section during the period 2003-05. He was secretary from 2005-2012. He is also a member of the Regulatory Affairs Professional Society (RAPS), ISPE, AAMI, and the Parenteral Drug Association (PDA). Pepe is also the author of the best-selling books "CAPA for the FDA-Regulated Industry", "Quality Risk Management in the FDA-Regulated Industry", and "The FDA & Worldwide Current Good Manufacturing Practices and Quality System Requirements Guidebook for Finished Pharmaceuticals", published by the American Society for Quality.

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: How to Write Effective Customer Complaints Investigation Reports

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