Registration Form

CAPA System EXPERT Certification

Name _____

Email _____

Company_____

Postal Adress_____

_____

Tel:_____ **Fax:**_____

Tuition and Payment Methods

Registration = $. Includes:

* Continental breakfast, lunch and refreshments
* Parking
* Course Materials
* Certificate upon completion of level I, II and III of Training Effectiveness Evaluation

(5% discount for two or more participants from the same company)

☐

☐ **Send Invoice: PO #** _____

☐ ☐ **Check** payable ☐ to Business Excellence Consulting

Visa **MasterCard** **American Express**

Card # _____

Exp. Date_____ **Security Code**_____

Cardholder Name _____

How to Register

*Mail this form to PO Box 8326, Bayamón, PR 00960
*Fax this form to 787-730-0851
*Email this form to pepe@calidadpr.com

☎ 787.525.3014

Course Description

The CAPA System certification is a comprehensive course consisting of seven modules with a total duration of six days equivalent to 48 contact hours. Approximately 35% of this time will be devoted to practice exercises. This certification will cover the following areas:

* Problem Detection
* Problem Description
* Root Cause Analysis
* CA-PA Plan
* Effectiveness Evaluation

A very comprehensive training effectiveness evaluation system will be conducted using the four levels of the Kirkpatrick model. Each participant must complete at least three investigation reports successfully to become certificated.

Course Director

Pepe Rodriguez-Perez, PhD is a process improvement and training consultant mainly within the FDA regulated industry. He worked with Abbott Diagnostic Division for twelve years reaching the position of technical director of the Barceloneta (PR) manufacturing plant leading a group of more than one hundred scientists and technicians.

Since May 2005 he is fully devoted as a consultant for his own company (Business Excellence Consulting), focusing on training and implementation of lean-six sigma initiatives and CAPA-Root cause Analysis workshops.

He's ASQ Certified Six Sigma Black Belt, Certified Quality Manager, Certified Quality Engineer, Certified Quality Auditor, Certified Biomedical Auditor and Certified HACCP Auditor. Senior member of ASQ and former President of the PR ASQ Section (2003-05). Also a member of RAPS and PDA. Professor of the Industrial Engineering graduated program at the PR Polytechnic University in San Juan. In February 2009 he became Science Advisor of the San Juan District Office of the FDA.

ASQ Certification holders may earn recertification units (RU) for attending this program.
PR Licensed Chemists may earn continuous education credits for attending this program.

Passion for Quality

Passion for Quality

CAPA System Expert Certification

for the FDA Regulated Industries

Certification Director:

Pepe Rodriguez-Pérez PhD

ASQ CQE, CQA, CSSBB, CMQ-OE, CHA & CBA

Business Excellence Consulting

The Best Regulatory Training available in PR

www.calidadpr.com

CAPA System Expert Certification Content (48 h contact)

Module 1: Regulatory Importance of CAPA - 4 h

1. CAPA and Regulations
   - Key Definitions
   - US 21 CFR 211 & 820
   - ISO 13485:2003
2. The QSIT: CAPA subsystem
3. Regulatory Trends (FDA-wide) and San Juan FDA District Office

Module 2: Root Cause Analysis - 12 h

1. Causal factors and root causes
   - Root Causes classification
2. Problem Description
   - Chronology of Events
   - Comparative Analysis: Is/Is Not matrix
   - Flowchart: Task Analysis
   - Change Analysis
3. Barrier Analysis
   - Physical controls
   - Administrative Controls
4. Root Cause Analysis
   - Cause and Effect Analysis
   - FTA (Fault Tree Analysis)
   - Determining the most probable root cause(s)

Module 3: Effective CAPA - 8 h

1. The CaPa Plan
   - Correction
   - Corrective Actions
   - Preventive Actions
2. Verification and Validation of Corrective and Preventive Actions
3. Implementation of Corrective and Preventive Actions
4. Effectiveness Evaluation
5. Dissemination of CAPA information
6. Management of the CAPA System
7. Ten Biggest Opportunities
   - Timeliness
   - Everything is an Isolated Event
   - Root Cause not identified
   - Correcting the Symptoms Instead of the Cause
   - Lack of Interim Corrective Actions
   - Root Causes Identified but not Corrected
   - Lack of True Preventive Actions
   - Lack of Effectiveness Verification of the Action Taken
   - Multiple CAPA Systems without Correlation
   - Abuse of Human Error and Retraining

Module 4: Human Factors and Human Errors - 8 h

1. Human Factors and Human Errors Overview
   - Human Errors in the Industry
   - Human Errors for the FDA
   - Human Errors Probabilities
   - Types of Human Errors
   - Frequency, Risk and Trending of Human Errors
2. Investigating Human Errors
   - Casual Factors versus Root Causes
   - Barriers and Current Controls for Human Errors
   - Collecting data: Interviewing and Documenting Human Errors
   - Trend and Statistical Analysis of Human Errors
   - Training Issues related to Human Errors
   - Root Cause Analysis for Human Error: Fault Tree Analysis
   - List of Root Causes tied to Human Errors
3. Corrective and Preventive actions for Human Errors
   - Determining the best Corrective and Preventive actions for the identified Root Causes: How to improve procedures and working instructions
   - Verifying and/or Validating actions
   - Implementing actions
   - Effectiveness evaluations for implemented actions

Module 5: Compliance Writing - 8 h

1. Measures of Excellence
2. Regulatory Aspects of Writing
3. Documentation Style Manual
4. Writing Effective Regulatory Documents
   - Sentence Construction
   - Emphasizing Text
   - Content Development
   - Organizing Information
   - Writing for Clarity
   - Writing for Economy
   - Writing for Readability
   - Writing for Correctness
5. Elements of the Investigation Report
6. Assessment of Investigation Report's Quality

Module 6: Risk Management of CAPA - 4 h

1. Risk Management and the FDA
2. Definitions (ISO 14971: 2007 & ICH Q9)
3. What is Quality Risk Management Process
4. Risk-Based Approach
5. Quality Risk Management Process
6. The Risk Management Plans (RMP) – Integration into CAPA
7. Devices Risk Management: ISO 14971: 2007 overview

Module 7: CAPA Metrics & Process Trending - 4h

1. CAPA System Scorecard
   - Main CAPA metrics
   - Non-conformance metrics
   - In-conformance metrics
   - Your Company metrics
2. Process Monitoring for Problem Detection
   - FDA Regulations and Definitions
   - Environmental Monitoring Process
   - Alert and Action Levels
   - Product Specification Vs. Process Limits
   - Run Charts: Runs and other Rules
   - Control Charts
   - Pre-Control Charts
   - Regression Analysis

Includes:

- Investigation Report Template
- Investigation Report Content Checklist
- Investigation Report Assessment Checklist
- **Evaluation of CAPA & Investigation procedures of participant's company**

Certification Process

Elements of Certification
a) Pre-Requisites: minimal experience requirement and previous internal training
b) Evaluation of Training Effectiveness
a) **Reaction** (Survey after each module)
b) **Learning** (Exam: pre and post)
c) **Behavior** (by instructor, evaluating at least three investigation reports per candidate to become certified)
d) **Results** (by sponsor and instructor based on pre-established metrics)
c) **Recertification** Process: Good CAPA Practices annual refresher