



**B U S I N E S S  
EXCELLENCE**  
C O N S U L T I N G **Inc.**

*Passion for Quality*

**TRAINING TITLE:**

Root Cause Analysis and Problem Solving Tools (WORK-016)

**OVERVIEW:**

This course will enable participants to understand root cause analysis as a procedure for ascertaining and analyzing the causes of problems in an effort to determine what can be done to solve or prevent them. Consisting of lectures, practice, and role-playing, this course is designed to provide attendees with an in-depth understanding of how to analyze a system to identify the root causes of problems.

**TARGET GROUP FOR THE TRAINING:**

This workshop will benefit manufacturers of FDA-regulated products who want to improve their ability to solve recurring problems. 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 workshop, participants will be able to:

- Evaluate problem solving effectiveness by providing a model for more deeply analyzing problem situations
- Apply problem-solving techniques in situations where one is not an expert in the process or technology involved
- Show the range of tools available for analysis of problem situations

**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:**

**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.



**Title:** Root Cause Analysis and Problem Solving Tools

**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	<p><b>Introduction</b></p> <ul style="list-style-type: none"> <li>• The Vicious Cycle</li> <li>• The Correct CAPA Flow</li> <li>• Root Cause Identification</li> <li>• The Closed-Loop CAPA Process</li> <li>• Key Definitions</li> </ul>
9:45 – 10:15	<p><b>Risk Management and CAPA</b></p> <ul style="list-style-type: none"> <li>• Principles of Quality Risk Management</li> <li>• Risk Prioritization of Investigations</li> <li>• A Risk Management Tools: The FMEA</li> <li>• Integration of Risk Management and CAPA</li> <li>• A Systematic Approach</li> </ul>
10:15 – 10:30	<p><b>Break</b></p>
10:30 – 12:00	<p><b>Effective Root Cause Analysis</b></p> <ul style="list-style-type: none"> <li>• Causal Factors and Root Cause Identification</li> <li>• Problem Description <ul style="list-style-type: none"> <li>○ Chronology of Events</li> <li>○ Change Analysis</li> <li>○ Flowcharts</li> <li>○ Is / Is Not Matrix</li> <li>○ Control Barrier Analysis</li> </ul> </li> </ul>
12:00 – 13:00	<p><b>Lunch</b></p>
13:00 – 15:00	<p><b>Root Cause Analysis Tools</b></p> <ul style="list-style-type: none"> <li>• Cause and Effects Diagram</li> <li>• 5 Whys</li> <li>• Fault Tree Analysis</li> </ul>
15:00 – 15:15	<p><b>Break</b></p>
15:15 – 17:00	<p><b>Root Cause Categories Checklist for Root Cause Analysis</b></p>