



**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:

ASQ Certified Quality Auditor Academia
(ACAD-001)

OVERVIEW:

The Certified Quality Auditor is a professional who understands the standards and principles of auditing and the auditing techniques of examining, questioning, evaluating, and reporting to determine a quality system's adequacy and deficiencies. The Certified Quality Auditor analyzes all elements of a quality system and judges its degree of adherence to the criteria of industrial management and quality evaluation and control systems.

TARGET GROUP FOR THE CONFERENCE:

This training is aimed at all persons interested in preparing for the ASQ Certified Quality Auditor exam provided twice per year. Attendees will obtain a better understanding of some of the auditing standards and principles required to become a quality auditor.

LEARNING OBJECTIVES:

- Identify the most widely used auditing tools and techniques
- Apply the appropriate tools for each situation faced on a daily basis by a quality auditor
- Prepare for the ASQ Certified Quality Auditor exam

MATERIALS:

Each participant will receive:

- *CQA Primer and Solution Text*, published by Quality Council of Indiana
- *The ASQ Auditing Handbook*, published by ASQ Quality Press
- Certificate of Attendance

TRAINING DURATION:

21 contact hours



BEC is authorized by IACET to offer 2.1 CEUs for this program. FULL attendance to the learning event is mandatory to receive CEUs.

COURSE INSTRUCTOR:

Arlene Delgado Velázquez is a training consultant within the FDA-regulated industries and educational sectors with over 20 years of experience. She has a Bachelor Degree in Industrial Microbiology from the University of Puerto Rico, at Humacao Campus. She also has a Master Degree in Industrial Engineering in Manufacturing Competitiveness and Quality Management from the Polytechnic University of Puerto Rico, in Hato Rey, P.R. Since year 2013, she is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training on related Quality sectors. She also serves as professor in the Humacao Community College for Biology, Biotechnology, Microbiology and Validation, and GMP courses. She is an ASQ Certified Six Sigma Green Belt, Manager of Quality & Organizational Excellence and Certified Quality Auditor.

Solmarie Vélez Rivera is a training consultant within the FDA-regulated industries with over 20 years of experience. She has a Bachelor Degree in Industrial Engineering from the University of Puerto Rico at Mayaguez Campus. She also has a Master Degree in Business Administration from University of Phoenix, Puerto Rico Site. Since year 2013, she is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training on ASQ Certified Quality Auditor Academia, Internal Audits Program, Quality Systems Regulations (21CFR820), CAPA, Root Cause Analysis, Technical Writing, and other topics. She is an ASQ Certified Quality Auditor, Manager of Quality & Organizational Excellence, Biomedical Auditor, and HACCP Auditor.

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: ASQ Certified Quality Auditor Academia (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 – 9:00	Certification Overview
9:00 – 10:15	Auditing Fundamentals <ul style="list-style-type: none"> • Quality and audit terms • Audit types • Audit purpose and scope • Audit criteria
10:15 – 10:30	Break
10:30 – 12:00	Auditing Fundamentals (cont.) <ul style="list-style-type: none"> • Audit responsibilities • Professional conduct • Liability issues • Practice exercises
12:00 – 13:00	Lunch
13:00 – 15:00	Auditor Competencies <ul style="list-style-type: none"> • Auditor Characteristics • On-site resource management • Conflict resolution • Communication and presentation techniques • Interviewing techniques
15:00 – 15:15	Break
15:15 – 17:00	Auditor Competencies (cont.) <ul style="list-style-type: none"> • Team dynamics • Team building • Team facilitation • Team development stages • Practice exercises



Title: ASQ Certified Quality Auditor Academia (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	Audit Preparation and Planning <ul style="list-style-type: none"> • Audit planning elements • Auditor selection • Audit related documentation • Audit logistics
10:15 – 10:30	Break
10:30 – 12:00	Audit Performance <ul style="list-style-type: none"> • On-site audit management • Opening meeting • Data collection and analysis • Closing meeting • Practice exercises
12:00 – 13:00	Lunch
13:00 – 15:00	Audit Reporting and Follow-Up <ul style="list-style-type: none"> • Audit reporting • Audit follow-up • Practice exercises
15:00 – 15:15	Break
15:15 – 17:00	Audit Program Management <ul style="list-style-type: none"> • Program management • Business and financial impact • Practice exercises



Title: ASQ Certified Quality Auditor Academia (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 – 10:15	Quality Tools and Techniques <ul style="list-style-type: none">• Quality and problem solving tools• Process improvement techniques• Basic statistics
10:15 – 10:30	Break
10:30 – 12:00	Quality Tools and Techniques (cont.) <ul style="list-style-type: none">• Measures of dispersion• Process variation• Sampling methods
12:00 – 13:00	Lunch
13:00 – 15:00	Quality Tools and Techniques (cont.) <ul style="list-style-type: none">• Change control• Verification and validation• Risk management tools• Practice exercises
15:00 – 15:15	Break
15:15 – 17:00	Case Study Examples <ul style="list-style-type: none">• Case studies• Practice exercises