BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

ASQ Certified HACCP Auditor Academia (ACAD-009)

OVERVIEW:

The Certified HACCP Auditor (CHA) is a professional who understands the standards and principles of auditing a HACCP-based (or process-safety) system. A CHA uses various tools and techniques to examine, question, evaluate, and report on that system's adequacy and deficiencies. The CHA analyzes all elements of the system and reports on how well it adheres to the criteria for management and control of process safety.

TARGET GROUP FOR THE CONFERENCE:

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

MATERIALS:

Each participant will receive:

- *The ASQ Certified HACCP Auditor Handbook*, published by ASQ Quality Press
- Certificate of Attendance

TRAINING DURATION:

21 contact hours

ACCREDITED IACET PROVIDER

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:

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.

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.

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Title: ASQ Certified HACCP 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** • Definitions • General types of audits • Other Types of audits • Audit roles and responsibilities • ASQ code of ethics • Credibility of the audit function **Auditor Competencies** • Qualification criteria for auditors • Interviewing techniques • Audit teams
10:15 – 10:30	**Break**
10:30 – 12:00	**Audit Planning and Performance** • Audit planning elements • Audit notification • Audit performance elements o Opening meeting o Interviews and Field Work o Daily briefings and caucus meetings o Closing meeting
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Audit Report and Follow Up** • Audit report elements • Audit follow up and closure • Audit program management
15:00 – 15:15	**Break**
15:15 – 17:00	**Quality and Improvement Tools** • Graphical tools • Descriptive statistics • Process capability • Control charts **Practice Exercises**

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Title: ASQ Certified HACCP 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	**HACCP Introduction** • What is HACCP • History • Do we need a HACCP plan? • Preliminary tasks
10:15 – 10:30	**Break**
10:30 – 12:00	**The Seven HACCP Principles** **Principle 1: Conduct a Hazard Analysis** • Types of hazards • Hazard identification • Hazard evaluation **Principle 2: Identify Critical Control Points** • Critical control points vs. control points • CCP decision trees • Factors leading to CCP misinterpretation **Principle 3: Establish Critical Limits** • Determination of critical limits • Parameters most commonly used
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Principle 4: Establish Monitoring Procedures** • Questions to answer when determining monitoring procedures **Principle 5: Establish Corrective Actions** • Goals of corrective actions • Steps of corrective actions **Principle 6: Establish Verification Procedures** • Verification and validation • Ongoing assessment and revalidation
15:00 – 15:15	**Break**
15:15 – 17:00	**Principle 7: Eatablish Recordkeeping and Documentation Procedures** • Internal and indirect benefits **Practice Exercises**

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Title: ASQ Certified HACCP 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	**Implementing HACCP** • Supporting structures • HACCP team formation and training • Companywide HACCP deployment
10:15 – 10:30	**Break**
10:30 – 12:00	**Applying HACCP to the Food Industry** • Sources and types of food hazards o Biological hazards o Chemical hazards o Physical hazards • Types of prerequisite programs • Consensus prerequisite programs
12:00 – 13:00	**Lunch**
13:00 – 15:00	**HACCP in the Pharmaceutical / Medical Devices Industry** • Benefits of HACCP in the medical device industry • HACCP in pharmaceutical industry **HACCP Plan Maintenance** • Routine monitoring vs. audit of the HACCP plan • Audit verification outline
15:00 – 15:15	**Break**
15:15 – 17:00	**ISO 22000** • Overview **Practice Exercises**