BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

ASQ Certified Pharmaceutical GMP Professional Academia (ACAD-007)

OVERVIEW:

The Certified GMP Professional is a person who understands the GMP principles as regulated and guided by national and international agencies for the pharmaceutical industry.

TARGET GROUP FOR THE CONFERENCE:

This training is aimed at all persons interested in preparing for the ASQ Certified Pharmaceutical GMP Professional exam provided twice per year. Attendees will obtain a better understanding of the principles and regulations required to become a pharmaceutical GMP professional.

LEARNING OBJECTIVES:

- Identify the most widely used pharmaceutical GMP principles
- Apply the appropriate tools for each situation faced on a daily basis by a pharmaceutical GMP professional
- Prepare for the ASQ Certified Pharmaceutical GMP Professional exam

MATERIALS:

Each participant will receive:

- MS PowerPoint presentations
- CD with related material
- Certificate of Attendance

TRAINING DURATION:

14 contact hours

ACCREDITED IACET PROVIDER

BEC is authorized by IACET to offer 1.4 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 Pharmaceutical GMP Professional 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	**FDA Overview** • FDA Mission • cGMP Legal Principles • FDA Laws Overview • Adulteration and Misbranding • FDA Inspections • cGMP Implementation Tools
10:15 – 10:30	**Break**
10:30 – 12:00	**21 CFR 211 cGMP Details** • Subpart A - General Provisions • Subpart B - Organization and Personnel • Subpart C - Buildings and Facilities • Subpart D - Equipment • Subpart E - Control of Components and Drug Product Containers and Closures
12:00 – 13:00	**Lunch**
13:00 – 15:00	**21 CFR 211 cGMP Details (cont.)** • Subpart F - Production and Process Controls • Subpart G - Packaging and Labelling Controls • Subpart H - Holding and Distribution
15:00 – 15:15	**Break**
15:15 – 17:00	**21 CFR 211 cGMP Details (cont.)** • Subpart I - Laboratory Controls • Subpart J - Records and Reports • Subpart K - Returned and Salvaged Drug Products

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Title: ASQ Certified Pharmaceutical GMP Professional 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 – 9:00	**Main Inspection Findings** • Top 10 Turbo Citations
9:00 – 10:15	**QC and Micro OOS Guidances** • Key requirements of the OOS Guidance • Inspection of QC Labs • 2006 OOS Guidance o Phase I: Laboratory Investigation o Phase II: Full-scale investigation o Reporting test results
10:15 – 10:30	**Break**
10:30 – 12:00	**21 CFR 11: Electronic Records and Signatures** • Overview • Subpart A – General provisions • Subpart B – Electronic records • Subpart C – Electronic signatures
12:00 – 13:00	**Lunch**
13:00 – 15:00	**Sterile Drug Product Guidance** • Building and facilities • Personnel training, qualification, and monitoring • Endotoxin control • Sterilization of equipment, containers, and closures
15:00 – 15:15	**Break**
15:15 – 17:00	**Sterile Drug Product Guidance (cont.)** • Validation importance • Laboratory controls • Documentation practices