TRAINING TITLE:

Internal Auditing Workshop (WORK-008)

OVERVIEW:

GMP regulations worldwide as well as FDA and ICH guidances require that companies have in place an internal quality audit program. Auditing is also a powerful management tool in establishing how effectively a company controls the quality of its products and ensures compliance. The workshop will deal primarily with auditing tools and techniques needed when conducting effective internal and external GMP audits. This practical workshop will consist of lectures, interactive discussions and hands-on workshops including a role playing session.

TARGET GROUP FOR THE TRAINING:

This practical workshop is designed for those individuals who have recently been involved or expect to be involved in internal or external GMP audits. The program will benefit individuals in the pharmaceutical, medical device and related industries like diagnostics, cosmetics, food, biotechnology as well as suppliers and contract organizations. The course can be of interest to top management responsible for GMP audit programs in their companies as well as to professionals in a variety of functions such as: Quality Assurance, Quality Control, R&D, Production, Packaging, Engineering, Documentation Management, Regulatory Compliance, and so on.

LEARNING OBJECTIVES:

- Identify the most widely used auditing tools and techniques
- Apply the appropriate tools for each situation faced on a daily basis by an internal quality auditor

MATERIALS:

Each participant will receive:

- MS PowerPoint presentations
- Certificate of Attendance
- Final Exam (70% minimum score required to approve the course

TRAINING DURATION:

14 contact hours

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:

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.

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 Adminitration 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.

Gloryvee Maldonado Pérez is a training consultant within the FDA-regulated industries with more than 10 years of pharmaceutical and medical devices industry experience, in the areas of quality assurance, quality control, regulatory, validation, manufacturing, and packaging. She has a Bachelor Degree in Chemistry from the University of Puerto Rico at Rio Piedras Campus. She also has a Master of Science in Manufacturing Competitiveness, with a specialization in pharmaceutical products, from the Polytechnic University of Puerto Rico in Hato Rey, P.R. Since year 2012, she is fully devoted to consulting under Business Excellence Consulting Inc, focusing on training on related Quality sectors. She is an ASQ Certified Six Sigma Black Belt, and Certified Quality Engineer. She is also a CAPA System Expert Investigator and ISO 13485 Lead Auditor.

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Internal Auditing Workshop (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	**Opening Remarks**
9:00 – 9:45	**Audit Basics** • Audit Stages • Audit Performance Elements • Definitions • General Types of Audits • Audit Purpose and Objectives • Audit Evidence • Analysis of Audit Nonconformities
9:45 – 10:15	**QMS Auditor Qualifications** • Qualification Criteria for Auditors • Personal Attributes • Knowledge and Skills of Auditors • Knowledge and Skills of Audit Team Leader • Maintenance and Improvement of Competence • Auditor Evaluation
10:15 – 10:30	**Break**
10:30 – 11:15	**Roles and Responsibilities of Auditors** • Audit Roles and Responsibilities • Auditor Independence • Auditor Objectivity
11:15 – 12:00	**The Audit Checklist** • Purpose of the Audit Checklist • Benefits and Risks of Audit Checklists • Requirements of Questions on Audit Checklists • Contents of the Audit Checklist
12:00 – 13:00	**Lunch**
13:00 – 14:00	**Practice Exercise #1** • Writing Good Checklist Requirements

14:00 – 15:00	**Documentation in the Quality System** • Relationships • Documents, Data, Forms, and Records • Important Differences • QMS Document Structure o Quality Manual o Procedures o Instructions • Use of Documents During Audits
15:00 – 15:15	**Break**
15:15 – 17:00	**Planning and Conducting Audits** • Audit Planning Elements • Audit Notification • The Audit Cycle • Initiating the Audit • Conducting Document Review • Preparing for On-Site Activities

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Internal Auditing Workshop (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	**Planning and Conducting Audits (cont.)** • Conducting On-Site Activities o The Opening Meeting
9:00 – 10:15	**Practice Exercise #2** • Preparing for an Opening Meeting
10:15 – 10:30	**Break**
10:30 – 11:15	**Planning and Conducting Audits (cont.)** • Conducting On-Site Activities o Communication During the Audit o Interviews o Tips for Gathering Information During the Audit o Generating Audit Findings o Preparing Audit Conclusions
11:15 – 12:00	**The Closing Meeting and Audit Report** • Conducting the Closing Meeting • Elements of the Audit Report • Writing the Audit Report
12:00 – 13:00	**Lunch**
13:00 – 13:30	**Practice Exercise #3** • Evaluation of Corrective Action Requests
13:30 – 14:00	**Audit Follow-Up and Closure**
14:00 – 15:00	**Practice Exercise #4** • Audit Performance and Report
15:00 – 15:15	**Break**
15:15 – 17:00	**Practice Exercise #4 (cont.)** • Audit Performance and Report