BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

ISO 17025 (WORK-019)

TRAINING DURATION:

7 contact hours

OVERVIEW:

ISO/IEC 17025 provides a framework for the special needs of organizations that want to control their laboratory processes. Based upon ISO 9001, but written for the particular needs of laboratory management, ISO/IEC 17025 addresses the proficiency of the organization to perform the testing and calibration activities. This workshop teaches you how to develop business processes that focus on the compliance to the ISO/IEC 17025 standard.

ACCREDITED IACET PROVIDER

BEC is authorized by IACET to offer 0.7 CEUs for this program.
FULL attendance to the learning event is mandatory to receive CEUs.

TARGET GROUP FOR THE TRAINING:

The workshop is an introduction for anyone involved in the development, implementation and operation of Laboratory Management Systems (LMS) based on the ISO/IEC 17025 standard.

LEARNING OBJECTIVES:

- Identify the elements of a Laboratory Management Systems
- Recognize the requirements of the ISO/IEC 17025 standard

MATERIALS:

Each participant will receive:

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

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.

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: ISO 17025

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	**Overview of Laboratory Accreditation** • The Laboratory Process • ISO 17025 Compared to ISO 9001 • What is Accreditation • History of Lab Accreditation Standards
9:45 – 10:15	**ISO 17025 Introduction** • Overview of ISO 17025 • Scope • Normative References • Terms and Definitions
10:15 – 10:30	**Break**
10:30 – 12:00	**ISO 17025 Requirements - Management** • Organization • Quality System • Document Control • Review of Request, Tenders, and Contracts • Subcontracting of Tests and Calibration • Purchasing Services and Supplies • Service to Client • Complaints
12:00 – 13:00	**Lunch**
13:00 – 15:00	**ISO 17025 Requirements - Management (cont.)** • Control of Nonconforming Testing and/or Calibration Work • Improvement • Corrective Actions / Preventive Actions • Control of Records • Internal Audits • Management Reviews

15:00 – 15:15	**Break**
15:15 – 17:00	**ISO 17025 Requirements - Technical** • General • Personnel • Accomodation and Environmental Conditions • Test and Calibration Methods and Method's Validation • Equipment • Measurement Traceability • Sampling • Handling of Test and Calibration Items • Ensuring the Quality of Test and Calibration Results • Reporting the Results