



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:

Laboratory Equipment Qualification
(WORK-031)

OVERVIEW:

Laboratory equipment should be calibrated and/or qualified to demonstrate suitability for the intended use. This course will provide the basic knowledge and tools to plan, develop and qualify laboratory equipment. Topics included as part of the workshop includes regulatory requirements, Design, Installation, operational and performance qualification between others. This practical workshop will consist of lectures, interactive discussions and practice exam.

TARGET GROUP FOR THE TRAINING:

This practical workshop is designed for those individuals who prepare, coordinate, review, approve and support any laboratory equipment qualification activity. This practical workshop is designed for all levels of management who need to understand the requirements of analytical and microbiological test method validation. The program will benefit individuals in the pharmaceutical, medical device and biotechnology industries as well as suppliers and contract organizations. The course can be of interest to top management responsible for all aspects of analytical and microbiological laboratory equipment qualification 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, Regulatory Compliance, and so on.

LEARNING OBJECTIVES:

- Identify the most widely used elements involved in lab equipment qualification.
- Describe the use of the guidelines (such as, ISO/AAMI/ANSI) and regulations requirements (FDA).

MATERIALS:

Each participant will receive:

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

TRAINING DURATION:

7 contact hours.



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

COURSE INSTRUCTOR:

Myrelis Aguilar Cepeda is a Validation and Quality Assurance Systems consultant within the FDA-regulated industries with more than 12 years of experience. She has a Bachelor Degree in Biology from the University of Puerto Rico at Rio Piedras campus, PR. and a Medical Technology Certification from the Interamerican University Cupey Campus, PR. She also has a Master Degree in Industrial Engineering Manufacturing Competitiveness/ Quality Management 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 and Technical sectors. She is an ASQ Certified Quality Auditor.



Title: Laboratory Equipment Qualification (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 -8:45am	Welcome to Laboratory Equipment Qualification Academy
8:45 – 10:30am	<ul style="list-style-type: none">• Scope and Agenda• Objectives• Introduction• Regulations & Standards
10:30 – 10:45	Break
10:45 – 12:00	<ul style="list-style-type: none">• Planning and Design Qualification• Installation Qualification
12:00 – 13:00	Lunch
13:00 – 14:30	<ul style="list-style-type: none">• Operational Qualification• Performance Qualification
14:30 – 14:45	Break
14:45 – 17:00	<ul style="list-style-type: none">• Validation Maintenance
16:00-17:00	EXAM