



**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:**

Facilities and Critical Utilities Systems Qualification (WORK-030)

**OVERVIEW:**

The construction and renovation of sterile and non-sterile facilities requires an understanding of how the processes need to operate within a facility and within the code and regulations set by the regulatory agencies. These include understanding product, personnel and process flow, contamination control regulations and utility requirements to ensure an economic and compliant design and appropriately installed utilities. Topics included as part of the workshop includes regulatory requirements, cleanroom design and classification, facility cleaning program, environmental monitoring program, pharmaceutical water systems, compressed gases qualification requirements and maintenance of validated state 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 facility and/or critical utilities qualification activity. This practical workshop is designed for all levels of management who need to understand the science of facility and critical utilities design. The program will benefit individuals in the pharmaceutical, medical device, biotechnology and related industries as well as suppliers and contract organizations. The course can be of interest to top management responsible for all aspects of facility, utilities, environmental monitoring and facility cleaning 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, Facility Engineering, Regulatory Compliance, and so on.

**LEARNING OBJECTIVES:**

- Identify the most widely used elements of the facility and critical utilities qualification lifecycle approach, including design and development, validation and ongoing validation maintenance.
- Describe the use of the guidelines (such as PDA and ISO/AAMI/ANSI) and regulations requirements (such as FDA, EMA, WHO, PIC/S, etc.).

**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:**

**Myrelis Aguilar Cepeda** is the Validation Lead and a 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.

**Harold Santana Medero** is a Quality Assurance Systems and Validation Specialist consultant within the FDA-regulated industries with more than 20 years of experience. He has a Bachelor Degree in Chemical Engineering from the University of Puerto Rico in Mayaguez Campus, P.R.



**Title:** Facilities and Critical Utilities Systems 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 Facilities and Critical Utilities Systems Qualification Academy
8:45 – 10:30am	<ul style="list-style-type: none"><li>• Scope and Agenda</li><li>• Objectives</li><li>• Introduction</li><li>• Regulations &amp; Standards</li></ul>
10:30 – 10:45	<b>Break</b>
10:45 – 12:00	<ul style="list-style-type: none"><li>• Cleanroom Design</li><li>• Room Classification</li><li>• Cleanroom Alternatives</li></ul>
12:00 – 13:00	<b>Lunch</b>
13:00 – 14:30	<ul style="list-style-type: none"><li>• HVAC System</li><li>• Facility Qualification Lifecycle</li></ul>
14:30 – 14:45	<b>Break</b>
14:45 – 17:00	<ul style="list-style-type: none"><li>• Facility Cleaning Program</li><li>• Environmental Monitoring Program</li></ul>



**Title:** Facilities and Critical Utilities Systems Qualification (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	<ul style="list-style-type: none"> <li>• Day 1 Recap</li> </ul>
9:00 – 10:30	<ul style="list-style-type: none"> <li>• Introduction to Critical Utilities</li> <li>• Pharmaceutical Water Systems               <ul style="list-style-type: none"> <li>○ Regulations &amp; Standards</li> <li>○ Types &amp; Quality of Water</li> <li>○ Design Aspects</li> <li>○ Sampling Considerations</li> </ul> </li> </ul>
10:30 – 10:45	<b>Break</b>
10:45 – 12:00	<ul style="list-style-type: none"> <li>• Pharmaceutical Water Systems               <ul style="list-style-type: none"> <li>○ Installation, Operational and Performance Qualification</li> </ul> </li> <li>• Clean Steam Systems               <ul style="list-style-type: none"> <li>○ Regulations &amp; Standards</li> <li>○ Design Aspects</li> <li>○ Installation, Operational and Performance Qualification</li> </ul> </li> </ul>
12:00 – 13:00	<b>Lunch</b>
13:00 – 14:30	<ul style="list-style-type: none"> <li>• Compressed Gases Systems               <ul style="list-style-type: none"> <li>○ Regulations &amp; Standards</li> <li>○ Design Aspects</li> <li>○ Sampling Considerations</li> <li>○ Installation, Operational and Performance Qualification</li> </ul> </li> </ul>
14:30 – 14:45	<b>Break</b>
14:45 – 15:15	<ul style="list-style-type: none"> <li>• Maintenance of Validation State</li> </ul>
15:15-17:00	<b>Exam</b>