BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

Test Method Validation (WORK-033)

OVERVIEW:

Method validation is an essential part of establishing and ensuring the quality of the analytical and microbiological data. Method validation is the process that provides evidence that a test method is capable of providing data that are suitable for a particular application. This course will provide the basic knowledge and tools to plan and carry out effective validation studies. Topics included as part of the workshop includes regulatory requirements, compendial vs non-compendial, method transfer, validation requirements, 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 test method validation 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 test method validation 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, and Regulatory Compliance, and so on.

LEARNING OBJECTIVES:

- Identify the most widely used elements involved in validation analytical and microbiological test method.
- Describe the use of the guidelines (ISO, AAMI, ANSI) and regulation requirements (FDA, ICH).

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.

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:

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.

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Test Method Validation (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 Test Method Validation Training
8:45 – 10:30am	• Scope and Agenda • Objectives • Introduction to Analytical Test Method • Regulations & Standards
10:30 – 10:45	**Break**
10:45 – 12:00	• Regulations & Standards (cont.) • Parameters of Method Validation
12:00 – 13:00	**Lunch**
13:00 – 14:30	• Compendial vs Non-Compendial • Validation Requirements • Typical Acceptance Criteria
14:30 – 14:45	**Break**
14:45 – 17:00	• Method Transfer • Revalidation

BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

Title: Test Method Validation (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 -8:45am	Welcome to Test Method Validation Training
8:45 – 10:30am	• Introduction to Microbiological Test Method • Regulations & Standards • Compendial vs Non-Compendial • Microbial Enumeration (TAMC, TYMC and Specific Organisms) o Media Suitability
10:30 – 10:45	**Break**
10:45 – 12:00	o Representative Challenge Organisms and Maintenance o Suitability Testing by Direct Inoculation/Plating Methods o Suitability Testing by Membrane Filtration • Qualification of Disinfectants (In vitro and In situ testing)
12:00 – 13:00	**Lunch**
13:00 – 14:30	• Testing of Pharmaceutical Waters • Environmental and Bioburden Considerations for Air and Surfaces • Sterility Test
14:30 – 14:45	**Break**
14:45 – 16:00	• Alternative Methods in Microbiology • Validation Maintenance
16:00 – 17:00	**EXAM**