BUSINESS EXCELLENCE CONSULTING Inc.

Passion for Quality

TRAINING TITLE:

General Concepts of Thermal, Radiation, Chemical and Filtration Sterilization Validation (WORK-032)

OVERVIEW:

The sterilization course covers the basic concepts of the entire range of sterilization processes utilized in the pharmaceutical, biotechnology, medical device and other related industries. Sterilization Technologies included in the course are sterilization using Steam, Steam sterilization-in-place, Dry heat sterilization and Depyrogenation, Gas and Vapor sterilization (including isolator decontamination), E-beam and Gamma sterilization, and Filtration sterilization. Topics included as part of the workshop includes regulatory requirements, Types of sterilization methods, why specific sterilization methods are used in particular applications, Microbiology of Sterilization, Biological Indicators, Safety and Environmental Considerations, Cycle Design and Development, Sterilization Validation 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 sterilization validation activity. This practical workshop is designed for all levels of management who need to understand the science of sterilization validation. The program will benefit individuals in the pharmaceutical, medical device and related industries like biotechnology as well as suppliers and contract organizations. The course can be of interest to top management responsible for all aspects of sterilization 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, Regulatory Compliance, and so on.

LEARNING OBJECTIVES:

- Identify the most widely used elements of the sterilization validation lifecycle approach, including design/development of the cleaning process, validation and ongoing validation maintenance.
- Describe the use of the guidelines (such as PDA and ISO/AAMI/ANSI) and regulations requirements.

MATERIALS:

Each participant will receive:

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

TRAINING DURATION:

21 contact hours.

ACCREDITED IACET PROVIDER

BEC is authorized by IACET to offer 2.1 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.

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Title: General Concepts of Thermal, Radiation, Chemical and Filtration Sterilization 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 General Concepts of Thermal, Radiation, Chemical and Filtration Sterilization Validation
8:45 – 10:30am	• Scope and Agenda • Objectives • Introduction • Sterilization Methods
10:30 – 10:45	**Break**
10:45 – 12:00	• Sterilization Method Selection: Points to Consider • Safety and Environmental Considerations • Fundamentals of Microbial Death
12:00 – 13:00	**Lunch**
13:00 – 14:30	• Biological Indicators • Cycle Development Approach • Thermal Sterilization o Steam and Steam in Place Sterilization
14:30 – 14:45	**Break**
14:45 – 17:00	• Sterilizing Agent-Steam

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Title: General Concepts of Thermal, Radiation, Chemical and Filtration Sterilization 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 – 9:00	• Day 1 Recap
9:00 – 10:30	• Steam, Steam in Place and Dry-Heat Sterilizing Systems o Design, Installation and Operational Qualification
10:30 – 10:45	**Break**
10:45 – 12:00	• Product and Packaging Considerations • Sterilization Cycle o Design and Performance Qualification
12:00 – 13:00	**Lunch**
13:00 – 14:30	• Depyrogenation • Radiation Sterilization o Gamma o Electron Beam
14:30 – 14:45	**Break**
14:45 – 17:00	• Sterilizing Systems o Design, Installation and Operational Qualification • Materials Considerations • Dose Establishment

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Title: General Concepts of Thermal, Radiation, Chemical and Filtration Sterilization Validation (Day 3)

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	• Day 2 Recap
9:00 – 10:30	• Radiation Sterilization Validation • Chemical Sterilization o Gas – Ethylene Oxide o Vapor- Vapor Hydrogen Peroxide
10:30 – 10:45	**Break**
10:45 – 12:00	• Sterilizing Systems o Design, Installation and Operational Qualification • Product and Packaging Considerations
12:00 – 13:00	**Lunch**
13:00 – 14:30	• Sterilization Cycle o Design and Performance Qualification • Filtration Sterilization
14:30 – 14:45	**Break**
14:45 – 16:00	• Filtration Sterilization
16:00-17:00	**EXAM**