



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:

Essential Elements for the Manufacture for Aseptically Produced Sterile Products (WORK-029)

OVERVIEW:

This course will provide the knowledge of the requirements associated with the manufacture of sterile products to properly evaluate and improve your aseptic processes in order to reduce the risk of contamination. Topics included as part of the workshop includes regulatory requirements, basic microbiology concepts, facility and utilities design and qualification, media fill, personnel requirement, environmental monitoring, equipment, sterilization and disinfectants, 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 aseptic process activities. This practical workshop is designed for all levels of management who need to understand the requirements aseptic process. The program will benefit individuals in the pharmaceutical and biotechnology industries like biotechnology as well as suppliers and contract organizations. The course can be of interest to top management responsible for all aspects of aseptic process 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 establishing a facility for the manufacture of aseptically produces sterile products.
- Describe the use of the guidelines (such as PDA, ISO/AAMI/ANSI) and regulations requirements (FDA, EMA).

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.



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 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.

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: Essential Elements for the Manufacture for Aseptically Produced Sterile Products (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

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| 8:30 -8:45am | Welcome to Essential Elements for the Manufacture for Aseptically Produced Sterile Products Workshop |
| 8:45 – 10:30am | <ul style="list-style-type: none"> • Scope and Agenda • Objectives • Introduction <ul style="list-style-type: none"> ○ Microbiology Basic Concepts |
| 10:30 – 10:45 | Break |
| 10:45 – 12:00 | <ul style="list-style-type: none"> • Regulations and Standards • Facility Design |
| 12:00 – 13:00 | Lunch |
| 13:00 – 14:30 | <ul style="list-style-type: none"> • Facility Design <ul style="list-style-type: none"> ○ Room Classification ○ HVAC System |
| 14:30 – 14:45 | Break |
| 14:45 – 17:00 | <ul style="list-style-type: none"> • Cleanroom Alternatives <ul style="list-style-type: none"> ○ Isolators ○ RABS • Facility Qualification • Facility Cleaning Program • Environmental Monitoring |



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Title: Essential Elements for the Manufacture for Aseptically Produced Sterile Products (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

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| 8:30 – 9:00 | <ul style="list-style-type: none"> • Day 1 Recap |
| 9:00 – 10:30 | <ul style="list-style-type: none"> • Pharmaceutical Water Systems Design <ul style="list-style-type: none"> ○ Purified Water ○ Water for Injection |
| 10:30 – 10:45 | Break |
| 10:45 – 12:00 | <ul style="list-style-type: none"> • Pharmaceutical Water Systems Qualification • Clean Steam Systems |
| 12:00 – 13:00 | Lunch |
| 13:00 – 14:30 | <ul style="list-style-type: none"> • Compressed Gases Systems Design and Qualification • Equipment <ul style="list-style-type: none"> ○ Blow Fill Seal ○ Lyophilization |
| 14:30 – 14:45 | Break |
| 14:45 – 17:00 | <ul style="list-style-type: none"> • Sterilization Technologies <ul style="list-style-type: none"> ○ Steam ○ Steam In-Place ○ VHP ○ Dry-Heat (Depyrogenation) ○ Filtration |



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Title: Essential Elements for the Manufacture for Aseptically Produced Sterile Products (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

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| 8:30 – 9:00 | <ul style="list-style-type: none"> • Day 2 Recap |
| 9:00 – 10:30 | <ul style="list-style-type: none"> • Sterilization Technologies (continue) <ul style="list-style-type: none"> ○ Steam ○ Steam In-Place ○ VHP ○ Dry-Heat (Depyrogenation) |
| 10:30 – 10:45 | Break |
| 10:45 – 12:00 | <ul style="list-style-type: none"> • Personnel Requirements • Media Fill |
| 12:00 – 13:00 | Lunch |
| 13:00 – 14:30 | <ul style="list-style-type: none"> • Media Fill |
| 14:30 – 14:45 | Break |
| 14:45 – 16:00 | <ul style="list-style-type: none"> • Media Fill |
| 16:00 – 17:00 | EXAM |