

Ethylene Oxide

DIRECTED BY

Ricardo Franco, Founder AMSAC Group Chem. Eng. and Sterilization SME



ACCREDITED
COURSE

- Understand requirements of ISO 11135 for product adoption and change assessment.
- How to perform adoption studies for change of new products
- Understand benefits of product adoption versus full product validation
- What is Parametric Release?
- What are the benefits of this method?
- How to evaluate and implement?
- Best Practices during the Parametric Release process
- Parametric Release Validation criteria

about the course

Ethylene Oxide (ETO) Sterilization is a critical process for Medical Devices which might include Pharmaceuticals and Food Industry. Today, the challenge is to understand product adoption during material changes to simplify and have a more robust product validation process based on product families. Another benefit is to have a better understanding on Parametric Release to speed up the process turnaround times, while reducing cost and getting material faster in the market.

This 90-minute, accredited training course will focus on the specific ETO sterilization requirements of ISO 11135:2014 and how with an effective and compliant adoption process, costs can be saved, and new/revised products introduced to the market more quickly.

Since this training is highly interactive, those attending the live training event must have a webcam on their computer as well as a microphone and speakers/headset to fully participate.

who should attend

This training will provide a great resource to Medical Device, Pharmaceutical, as well as Food and Science industry personnel within the following departments:

- R&D
- Purchasing
- Regulatory
- Engineering
- Quality
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learning objectives

Upon completion of this course, you will be able to:

- Identify and analyze requirements of ISO 11135 for product adoption and change assessment as part of change control process by performing adoption studies for new products or products modified and have a better understanding on product adoptions versus full product validations
- Show the benefits for Parametric Release and benefits of this method
- Make use of procedures to evaluate and implement this method and to establish your Parametric Release Validation criteria

course outline

Review of Learning Objectives

Module 1: Product Adoption for Ethylene Oxide

- Understand requirements of ISO 11135 for product adoption and change assessment
- How to perform adoption studies for change of new products
- Understand benefits of product adoption versus full product validation

Module 2 – Single Product Batch Release

- Understanding ANSI/AAMI/ISO 11135:2014 concepts
- Understanding ANNEX E (normative) Single Lot **Release**

Module 3 – Parametric Release

- What is parametric release?
- Benefits of this method
- How to evaluate and implement
- Best Practice during the parametric release

Question and Answer Session

Assessment Opportunity

course instructor

Ricardo Franco, Senior Quality Professional with experience in Chemical, Medical, and pharmaceutical industries, is an experienced Quality Assurance professional leading as former Senior Quality Manager for diverse company for over 35 years such as EASTMAN Kodak, EASTMAN Chemical Corp, STERIS Applied Sterilization Technologies, Integra Life Sciences. He is currently Manager Quality of Commercial Operations and owner of AMSAC Group (Auditing Management and Consulting). During his career, he has led companies in establishing, executing and continuous improvement for sustainable Quality Management Systems. In the last 16 years Mr. Franco has worked in the Sterilization Process (Gamma, E-Beam and EO) which includes validation in sterilization activities and is currently participating in the MedAccred Program as contractor auditor for sterilization service provides where sponsors of this program are Baxter Corporation, Medtronic, Johnson & Johnson, and more.

Accreditations



International Accreditors for Continuing Education and Training (IACET)

Cobblestone has been approved as a CEU Accreditor by IACET and awards CEUs for participation in qualified courses. Cobblestone has demonstrated that it complies with the ANSI/IACET Standards and is authorized to offer IACET CEUs for its programs. CEUs will be awarded for participation in Cobblestone's courses at the rate of .1 CEU per contact hour upon successful completion of the entire course and 70% accuracy in the required Learners' Assessment. A minimum score of 80% is required for all courses within a Cobblestone Certification Program. This course offers a total of 1.5 contact hours, or .2 CEUs. For further information, visit www.iacet.org