

Basics of Vaporized Hydrogen Peroxide (VHP) Sterilization and Decontamination Practices

Part of the Sterilization Professional Certification Program

DIRECTED BY

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ACCREDITED
COURSE

Course Topics Include:

- History and Regulations Governing Vaporized Hydrogen Peroxide (VHP) Sterilization
- Advantages and Disadvantages of VHP Sterilization process
- Stages of VHP Sterilization process
- VHP Sterilization Validation process

about the course

For products that claim a desired Sterility Assurance Level (SAL), proof of a defined SAL (specification) is achieved through the product's sterilization and sterility assurance controls. Compliance Observations cited each year by the FDA on Form 483's that relates to Sterilization and Sterility Assurance processes shows that there are deficiencies associated with these key processes that are critical to a product's sterility including inappropriately qualified and trained personnel required as key staff to implement a fully compliant sterilization process. This can potentially lead to Product Failures (Sterility Failures), product Non-conformances, Product Recalls, FDA's Warning Letters, Consent Decrees and discontinuance of commercial operations which may negatively impacts a company's profitability. FDA regulated industries that produce products with a defined SAL are obligated to have adequately trained and knowledgeable staff or Subject Matter Experts (SMEs) within sterilization and sterility assurance to provide applicable regulatory guidance with the impacted systems.

This 2-hour accredited training introduces both new and existing employees to the requirements of ISO 14937:2009 (R2015), ANSI/AAMI ST58, AAMI TIR17:2008 guidelines and other applicable regulations. The role of Vaporized Hydrogen Peroxide (VHP) sterilization used for sterilizing certain products, ancillary systems, room decontamination and other healthcare supplies cannot be overemphasized. Having a clear understanding of the detailed requirements of VHP sterilization process and its impact on a product's material of composition is critical to determining the suitability of the application process. This training describes the history, rules, basic routine and validation key requirements of VHP Sterilization and Decontamination process and its role in today's manufacturing activities.

This training is part of the 10-course series required for the Sterilization Professional Certification Program.

Attend this as a step in the certification process or as a stand-alone course for personal career advancement and training.

who should attend

This online training will benefit professionals working in the Pharmaceutical, Biotechnology, Drug, Biologics, Medical Device, Compounding Pharmacies and In-vitro Diagnostics Product Manufacturing industries. It will be especially valuable for personnel and management within the following areas:

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| • Sterilization Engineers and Specialists; Microbiologists | • Laboratory; Testing Analysts and Technicians |
| • Sterility Assurance Auditors; Quality Assurance Supplier Auditors | • Quality Assurance; Quality Control |
| • Manufacturing; Shipping; Receiving; Facility; Maintenance; Engineering | • Validation; Regulatory Affairs |
| • Suppliers and Vendors of Pharmaceutical Gas Systems | • Materials Management |
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learning objectives

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

- Describe the history, overview and examples of VHP Sterilization and Decontamination
- List the advantages and disadvantages of VHP Sterilization process
- Describe the Features, Parameters and Routine Process Steps associated with VHP Sterilization and Decontamination
- Summarize the 4 stages of VHP Sterilization and the typical process conditions of VHP in rooms
- Describe the five (5) Steps of VHP Sterilization Validation process key requirements
- Summarize the routine process requirements of VHP Sterilization

course outline

Review of Learning Objectives

Module 1: Rules, History and Overview of Vaporized Hydrogen Peroxide (VHP) Sterilization and Decontamination

- VHP Sterilization and Decontamination Guidelines
- History and Reasons for use of VHP
- Review of VHP Sterilization and Decontamination
- Types of VHP Systems
- Advantages of VHP Sterilization
- Disadvantages of VHP Sterilization

Module 2: Vaporized Hydrogen Peroxide (VHP) Sterilization Features, Parameters and Routine Process Steps

- Gas Plasma VHP Sterilization Process Steps
- 10 Things to Know about Gas Plasma VHP Sterilization
- VHP Sterilization Features and Parameters
- Summary of Four (4) Stages of VHP Sterilization
- Typical VHP Sterilization Cycle (from Bioquell)
- H2O2 Vaporization Typical Process Conditions in Rooms
- Example of the Breakdown of VHP During Sterilization

Module 3: Vaporized Hydrogen Peroxide (VHP) Sterilization Validation and Routine Processing Requirements

- VHP Sterilization Validation Guidelines
- Five (5) Steps of VHP Sterilization Validation
- VHP Sterilization Validation Key Requirements
- VHP Sterilization Routine Process Parameters

Assessment Opportunity

course instructor

Charity Ogunsanya is the CEO and founder of Pharmabiodevice Consulting LLC (www.pharmabiodeviceconsultant.com). Ms. Ogunsanya has over 30 years of extensive practical and management experiences in various Fortune 100 Pharmaceutical, Biotechnology, Biologics, Cell-Therapy, Diagnostics, Food and Cosmetics, Compounding Pharmacy, Research and Development, Radio-pharmaceutical, Contract Manufacturing Organization (CMO) and Medical Device/IVD companies.

Throughout her corporate career within these diverse industries, she held various high level, high visibility and business critical roles within the Quality Control and Quality/Compliance divisions for major Fortune 100 companies both as their Subject Matter Expert (SME), Site Manager, Multi-site Manager and Director Levels respectively.

Her technical expertise includes the interpretation, administration and set up of New Cleanroom/Facility Design, Operations, Validation, Monitoring, Manufacturing Operations, Food Safety, Quality Assurance, Quality/Compliance, Quality Engineering, Aseptic Processing, Contamination Control, Regulatory Affairs, Quality Control, Microbiology, Sterility Assurance, Stability, Vaccine Development, New Product Design, Raw Material Testing, Environmental Controls, Product Release Testing and Medical Device Sterilization (Ethylene Oxide (EtO), Gamma, Radiation, VHP sterilization) processes for compliance to various regulations.

Ms. Ogunsanya's has a Bachelor of Science degree in Microbiology from the University of Benin-Nigeria and a master's in biotechnology (Biodefense Concentration) from The Johns Hopkins University Advanced Academic Program.

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 2 contact hours, or .2 CEUs. For further information, visit www.iacet.org