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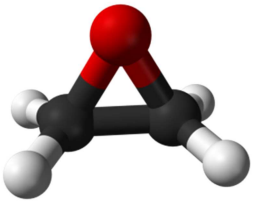

Ethylene Oxide Sterilisation Training

Prism Industrial Controls have been conducting their Ethylene Oxide Sterilisation Training for over 8 years and in that period trained personnel in many companies over a wider range of departments. Our training course was developed due to demand from our customers and was very much compiled as a "hands on" process training course that included the theory as an overview rather than a purely theoretical course often offered by other companies. Our many years of experience and specialized knowledge in engineering, sterilisation, cycle/product development and project management allowed us to cover all aspects from companies setting out with a new installation to staff training for seasoned process users.

Our course attendees vary greatly and have been tailored to meet all our clients' requirements. The list below gives an idea of departments that have undertaken our training

- Plant and sterilisation managers
- Quality & Validation Personnel
- Health and Safety teams
- Site Emergency response teams
- Maintenance & Engineering Personnel
- Process Supervision & Operator personnel

Our aim is to make sure that our training will provide our Customers with the knowledge and specialist information about EO sterilisation for the regulated industry.

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Ethylene Oxide Sterilisation Training

1. Introduction

- Overview of why Ethylene Oxide (EO) is used
- Brief History on EO and sterilisation
- Implications of using EO
- What can we sterilize with EO

2. Ethylene Oxide Gas Appreciation

- Properties of EO
- How EO is handled
- Process In Built Safety
- EO monitoring
- Explosion triangle appreciation
- Different gas mixtures

3. EO Sterilisation Cycle Appreciation

- Achieving sterility
- Sterilisation cycle stages
- Methods of preconditioning
- Methods of degassing

4. Meeting the Standards

An overview of the control and monitoring needed to meet standards

- Control and Monitoring
- System control architecture
- Design and Installation Requirements
- 21CFR Part 11

5. Notes on Steam and Humidity

- Steam Under Vacuum
- Dew Point and Humidity

6. Process Qualification

- Regulatory Standards
- Validation Overview
- Validation Life Cycle
- Implications of 21CFR Part 11

7. Mechanical and Electrical Components and Installation

- ATEX Review
- Local and National Requirements
- Insurance Requirements
- ATEX/Ex electrical equipment
- Intrinsic Safety
- Explosion/flame protection
- Electrical Installation requirements
- Mechanical equipment with Ethylene Oxide
- Mechanical Installation requirements
- Typical process safety interlocks
- Maintaining the process

8. Cycle/Product Qualification

- Regulatory Standards
- Key Sterility components
- Qualification methods
- Maintaining cycle/product qualification

9. Process Key Components

- Sterilisation Chamber
- Doors and interlocks
- Vacuum System
- Preconditioning Equipment
- Degassing Equipment
- Service Equipment
- Deluge
- Safety monitoring

10. Process Summary and Installation

- Summarizing the Process
- Typical Installation Costs
- Typical Running Costs
- Typical personnel levels
- Installation time schedules
- Operation Time Schedules
- Typical Operating Procedures