ISO 11135:2014 TRAINING

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PSB Philippines

Ethylene Oxide Sterilization: Awareness Training in ISO 11135:2014

INTRODUCTION:

This training program is intended as an introductory course in understanding the ethylene oxide sterilization of medical devices. Presently, the standard, ISO 11135:2014 sets forth requirements for process design, validation and control. Compliance with these requirements must be demonstrated as part of the conformity assessment of the medical device. As such, manufacturers and contract sterilizers must ensure that the requirements of the latest version of this important standard are understood and fulfilled.

Participants of this program will be provided with a structural introduction to the requirements set forth in this important standard.

Particular attention shall be paid to state of the art industrial practices which serve as means to fulfill requirements of the standard.

Discussions will also focus related aspects such as environmental control and bioburden and sterility testing.

COURSE CONTENT:

Day One:

Session 1-1: ISO 11135: An introduction to the state of the art in the quality assurance of medical device sterilization by Ethylene Oxide

Session 1-2: Process Validation Requirements and Concerns in Ethylene Oxide Sterilization

Session 1-3: Process control & Product Release in Ethylene Oxide Sterilization

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Day Two:

Session 2-1: Contamination control of the manufacturing environment

Session 2-2: Introduction to Bioburden and Sterility Testing

Session 2-3: Changes in ISO 11135:2014

Session 2-4: Question & Answer

Intended Participants:

Supervisors, Executives and Managers representing the departments of:

- Quality Assurance
- Production
- Logistics and Warehouse
- Plant Engineering

Prequalification:

None

DURATION: 2 whole days
TIME: 9:00AM to 5:00PM
AMOUNT: Php 12,500.00 (w/o VAT)
Php 14,000.00 (with VAT)

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