

# ETHYLENE OXIDE STERILIZATION AUDIT SITUATIONS & FINDINGS – CASE STUDY

**DCVMN, Hyderabad – INDIA**

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## Introduction

Ethylene oxide is commonly used for primary packaging containers (e.g. prefilled syringes in tubs). This process is carried out by contract service companies due to the inherent risks involved in handling this gas.

## Case

A vaccine manufacturer audited a contract ETO sterilization service last year. Now, the auditors are performing a follow-up audit based on the original findings.

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## Instructions to the group

1. Briefly, discuss and prepare an audit checklist including the associated documentation to request. Categorize findings based on risk, and justify.
2. Briefly, write in bullet-point format in your flipchart.
3. Make a brief presentation to the class.

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## Quality Control – Ref.: C.02.15

The availability, content, and/or maintenance of the Quality Agreements between the supplier, fabricator, tester, packager, labeler, distributor, importer and/or wholesaler was inadequate. Quality agreements did not have the following terms:

- a. No subcontracting of work without written authorization.
- b. Retention of analytical results and support documentation.

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Sterile products – Ref.: C.02.029

The company's validation of EO sterilization was inadequate. There was no written assessment of the airflow and air circulation for the aeration stage (inside the chamber) after EO sterilization, as described by ISO 11135. Aeration steps controls used were pressure (vacuum 850 mmbar) and time without consideration of the airflow and volume of air changes.

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Records – Ref.: C.02.020

The recorded information or details were inadequate:

- a. Checklist steps for startup were not attributable to an operator in each step.
- b. Log sheet for EO cycle (load details) was not completed contemporaneously, and did not clearly specify the information taken from the PLC printout.
- c. BI sterility test reports dated on April 3, 2017 were filled out incorrectly; “incubation completed date” was already dated for April 7, 2017.
- d. Sterilization start-end-hold times were not accurate in sterilizer log book. Times were different from the source equipment record.

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Manufacturing controls – Ref.: C.02.011

- a. Batch record EO sterilization section XX did not have descriptive instructions and/or did not refer to the relevant SOPs with the required instructions. There was no specific instructions and records for the placement of Bis in the shippers.
- b. There was no specific instructions to label shippers XX of XX in order to satisfy placement of shippers in the EO sterilization chamber as per loading protocols.
- c. Compressed air pressure acceptance criteria of  $> 4$  BAR was not included in the EO cycle startup checklist.
- d. According to procedures, it was possible to reprocess an EO cycle (e.g. in case of power loss or equipment malfunction); however, validation documentation did not include assessment of EO residues in a possible extended cycle.