CONSIDERATIONS AFTER EXPERIENCING A DOSE AUDIT FAILURE

STERIS
Applied Sterilization Technologies

TECHNICAL TIP #40

Considerations After the Occurrence of a Dose Audit Failure

A medical device that is free of any viable microorganisms is considered to be sterile. However, medical devices manufactured under standard conditions will have microorganisms. The number and type of microorganisms present on a medical device depends on the manufacturing process, manufacturing conditions and the materials used. After the manufacturing process is completed, medical devices are sterilized to inactivate these microorganisms.

International Standards specify the requirements for validation and routine control of the sterilization processes when a medical device includes a sterile claim. A sterilization validation followed by dose audit is performed using a suitable method as per ANSI/AAMI/ISO 11137-2 or ANSI/AAMI/ISO TIR13004 to assure that the product released by manufacturers into the market is sterile.

A dose audit involves performing a bioburden and a sterility testing. For a sterility test, the appropriate number of samples is irradiated using the verification dose calculated during the initial validation. The number of samples varies depending on the dose setting method used. The result is considered to be a dose audit failure if more than one positive is observed with the VDMax method, or more than two positives with the Method 1 and Method 2 approach.

In the case of a dose audit failure, a complete failure investigation should be conducted to determine the cause of failure and corrected so that the study can be repeated appropriately. Items to be considered in the investigation include:

1. Verify there is no change in the manufacturing process, environment, materials, or the source of materials.
2. Request an investigation of the laboratory to verify that the positive sterility test is not due to any laboratory contamination.
3. Consider any manipulation required for testing. Some products need significant manipulation, such as disassembly or cutting, to expose all the surfaces during a sterility test. More manipulation leads to more chances of contamination during testing. Consider preparing the samples prior to sterility testing if disassembly or cutting is required.
4. Verify if a bioburden validation was performed and ensure that the correct average bioburden was used for dose calculation.
5. If a sample item portion (SIP) of the product was tested, verify that the bioburden and verification dose audit SIP were prepared and packaged in the same way and correct SIP was tested for the verification dose audit.
6. Verify that a correct verification dose was calculated, requested and delivered to the product.
7. A sterility test positive during the dose audits may be due to increase in bioburden counts. Review the original validation program and compare the bioburden counts of the initial validation to the bioburden performed for the dose audit. If there is a significant increase in bioburden, the manufacturer should conduct a new dose setting validation.
8. If there is no significant change in bioburden counts, sterility test positives may be due to a radiation resistant organism. Try to find and fix the problem, if possible, or augment the sterilization dose. Please refer ANSI/AAMI/ISO 11137 or ANSI/AAMI/ISO TIR13004 for dose augmentation and consider reestablishing the dose using an alternate method.
9. Verify there is no potential for any contamination due to packaging. Compromised packaging can result into false positive during the sterility test.
10. If there are periodic dose audit failures or there is fluctuation in the bioburden, it means that the manufacturing process is not in control. Manufacturers should investigate the facility's environment control. The manufacturing environment, conditions and process have a significant affect on the total bioburden and type or organisms on a device. If the manufacturing process for a product requires multiple assembly steps and personnel contact, lack of cleaning may result in a higher bioburden level.
11. An assessment should be considered of the validity of the sterility of the batches processed prior to the dose audit failure up to the last successful audit. This should be a risk based assessment.

For more information, please contact:

STERIS Applied Sterilization Technologies
5960 Heisley Road
Mentor, OH 44077
877.783.7479
www.steris-ast.com

STERIS
Applied Sterilization Technologies