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Providing Sterilisation & Laboratory Services for the World's Most Innovative Healthcare Companies.

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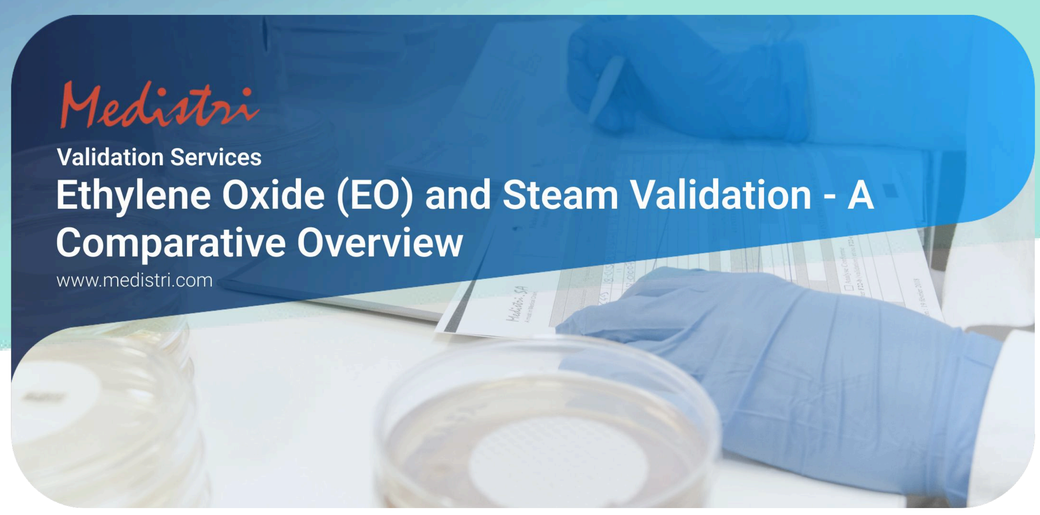

Ethylene Oxide (EO) and Steam Validation - A Comparative Overview - Medistri

🚀 Steam and EO Sterilization Validation - A Comparative Overview

Sterilization is a critical process to ensure the safety and efficacy of medical devices and pharmaceuticals, but it is the validation of this process that guarantees consistent sterility and compliance with global standards. Both Steam and Ethylene Oxide (EO) Sterilization are widely used methods, each requiring thorough validation to confirm that they meet Sterility Assurance Levels (SAL).

Sterilization validation is the process of ensuring that a sterilization method consistently achieves the desired level of sterility, as defined by international standards. This involves validating each parameter of the sterilization cycle—temperature, time, pressure, and for EO, gas concentration and humidity—ensuring that the sterilization process is effective, reproducible, and compliant.

Steam Sterilization relies on high-pressure saturated steam to eliminate microorganisms. However, to ensure the process is effective, the following validation steps are critical:

1. **Temperature and Pressure Monitoring:** Regular calibration and monitoring of autoclaves are essential. Medistri's autoclaves are equipped with built-in meters that track temperature and pressure, ensuring that the conditions remain within the validated range.
2. **Biological Indicators and Color Indicators:** These are used to test the effectiveness of the sterilization cycle, confirming that the microorganisms have been eradicated.
3. **Cycle Parameters:** The sterilization cycle must be precisely controlled to ensure steam penetration and optimal exposure time (typically between 3 and 15 minutes at temperatures between 121°C and 134°C).

EO Sterilization is typically used for heat-sensitive products, where the sterilization process is conducted under low temperature and controlled humidity. Key steps in EO Sterilization validation include:

1. **Process Parameter Control:** The EO gas concentration, exposure time, temperature, and humidity must all be validated to ensure the process is effective. Medistri uses precise control systems to adjust and monitor these parameters throughout the cycle.
2. **Aeration and Residual Gas Monitoring:** After the sterilization cycle, an aeration phase is required to ensure no residual EO gas remains on the product. Validation ensures that this step is thorough, making the product safe to handle.
3. **Biological Indicators:** Similar to Steam Sterilization, biological indicators are used to verify the lethality of the sterilization process, ensuring that microorganisms are effectively eliminated.

Both Steam and EO Sterilization methods are governed by international standards to ensure their effectiveness and regulatory compliance:

- ISO 17665 outlines the requirements for Steam Sterilization, covering everything from saturated steam exhaust systems to water immersion techniques.
- ISO 11135 provides the framework for EO Sterilization, specifying parameters for development, validation, and routine control in both industrial and healthcare settings.

ISO 17665 (Steam Sterilization)
ISO 17665 specifies the various requirements for the development, validation and routine control of a Steam sterilisation process for medical devices. The procedures that are covered by ISO 17665-1:2006 for Steam sterilization include, but are not limited to:

- Saturated steam exhaust systems.
- Saturated air/steam exhaust systems.
- Air/steam mixtures.
- Water vaporization.
- Water immersion.

ISO 11135 (EO Sterilization)
ISO 11135 is a standard that focuses on the Ethylene oxide (EO) sterilization process. Unlike Steam sterilization, which uses moist heat, ethylene oxide is a gas that is used for sterilization at low temperatures, making it suitable for items that are sensitive to heat or moisture. ISO 11135 specifies the requirements for the development, validation, and routine control of an EO Sterilisation process in both industrial and healthcare facility settings. Also, it acknowledges the similarities and differences between the two applications and provides guidance on how to establish and validate an EO sterilisation process.

1. **Process Validation:** Design and validate EO parameters (concentration, time, temp, humidity) with indicators to meet Sterility Assurance Level (SAL).
2. **Routine Monitoring:** Continuously check EO parameters to ensure consistent process and SAL.
3. **Aeration:** Remove residual ethylene oxide gas for safety.
4. **Documentation:** Keep detailed records for traceability and compliance.

Both Steam and EO sterilization play crucial roles in healthcare, each tailored to specific material and product requirements. At Medistri, our team provides comprehensive validation services, from protocol preparation to final reporting. Whether for Steam or EO sterilization, we ensure transparency, precision, and compliance at every step, offering tailored solutions to meet your needs.

🎯 To learn more about Medistri's Sterilisation Validation, visit on our website here or directly contact our team at contact@medistri.swiss.

- The Medistri Team

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