Medistri

Providing Sterilization & Laboratory Services for the world's most innovative healthcare companies.

From the Blog

Medistri's EO Sterilization & EO Treatment

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EO is a well-established low-temperature sterilization process widely used across the medical device and pharmaceutical industries. While EO Sterilization and EO Treatment are sometimes used interchangeably, they represent two fundamentally different approaches with important quality, validation, and regulatory implications.

EO Sterilization refers exclusively to a validated and controlled process that achieves a defined Sterility Assurance Level (SAL) in accordance with applicable international standards. EO Treatment, by contrast, describes a non-validated EO exposure, typically used during development phases. To ensure regulatory clarity and avoid misinterpretation, precise terminology is essential: only validated EO Sterilization can guarantee sterility.

Why EO?
EO is particularly suited for products that cannot tolerate high temperatures or moisture. As a vacuum-based gaseous process operating at low temperatures, EO enables effective penetration through packaging materials, narrow lumens, and complex device geometries without compromising product integrity.

EO Sterilization is commonly applied to:
- Pharmaceutical vials
- Temperature-sensitive products
- Devices with integrated electronics
- Products with integrated batteries
- Polymer-based products
- Implants
- Surgical kits
- Single-use medical devices
- Drug-device combination products

Throughout the process, critical parameters such as temperature, humidity, pressure, and gas concentration are continuously monitored to ensure both microbial effectiveness and product safety.

EO Treatment: A Development-Phase Process
EO Treatment is primarily used during R&D, feasibility studies, and pre-validation testing. It allows manufacturers to expose products to EO in order to assess material compatibility, define preliminary process parameters, or support early development activities.
While EO Treatment plays an important role during development, it does not meet regulatory requirements for commercial sterilization. At this stage, the process has not been validated by Medistri's Laboratory team and therefore cannot be considered EO Sterilization from a regulatory perspective.

Clear Terminology for Clear Assurance
EO Treatment supports early development activities. Validated EO Sterilization, including defined degassing, provides documented assurance of sterility and safety. Clearly distinguishing between these two approaches is essential to maintaining high standards of product safety, regulatory compliance, and patient protection.

To learn more about Medistri's EO Sterilization and EO Treatment services, visit our website here or contact our team at contact@medistri.com.

— The Medistri Team

From EO Treatment to Validated EO Sterilization
A validated EO Sterilization process follows a structured and documented approach, typically including:

1. **Preconditioning**
   - Products are exposed to controlled temperature and humidity to prepare them for EO exposure and to ensure reproducible process conditions.
2. **Sterilization**
   - EO is introduced into the chamber for a defined exposure period, allowing penetration of the product and effective microbial inactivation.
3. **Degassing and Aeration**
   - Following EO exposure, products undergo controlled degassing and aeration to remove residual EO and reaction by-products. Degassing is a critical phase of the EO Sterilization process and is carefully defined during validation to ensure residual levels comply with applicable safety and regulatory limits.

At Medistri, degassing parameters are established based on product materials, geometry, and packaging configuration, ensuring both patient safety and regulatory compliance.

Integrated Validation and Laboratory Support
At Medistri, EO Sterilization validation is supported by in-house laboratory testing, including:
- Sterility testing
- Residual analysis
- Endotoxin (LAL) testing

This integrated approach ensures alignment between sterilization, degassing, and laboratory verification, providing full traceability from EO exposure through to final product release.

Validation and Regulatory Compliance
Validated EO Sterilization is developed, qualified, and controlled in accordance with ISO 11135, the international standard governing EO sterilization of medical devices.

Validation confirms that:
- The sterilization process achieves the required SAL
- Degassing effectively reduces EO residuals to safe and compliant levels
- The process is repeatable and controlled across routine production

Once validated, EO Sterilization becomes a robust and compliant process suitable for commercial use.