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

From the Blog

Sterilization Validation

November 2nd 2026

Sterilization is a vital process in the production of medical devices and pharmaceutical products. Before a product can be marketed with a sterile claim, manufacturers must prove that their chosen sterilization method consistently achieves the necessary level of microbial inactivation without compromising the product's quality or functionality.

Sterilization validation provides documented proof that a process is effective, reproducible, and suitable for a specific product or product line. This involves assessing product characteristics, packaging configurations, sterilization parameters, and microbiological performance.

Two commonly used technologies are EO and Steam Sterilization, each requiring specific validation approaches based on materials, product design, and intended use.

Medistri supports manufacturers throughout sterilization validation projects, combining EO and steam sterilization capabilities with laboratory testing and technical support across its facilities in Switzerland and Hungary.

Why Sterilization Validation Is Necessary

Sterilization validation is essential to demonstrate that a defined process can reliably achieve the specified Sterility Assurance Level (SAL). For terminally sterilized medical devices, a SAL of 10^{-6} is typically applied, indicating a probability of no more than one non-sterile unit in one million.

Validation also ensures that sterilization conditions remain compatible with the product and its packaging. The main objectives include:

- Product Safety: Ensuring effective microbial inactivation while maintaining product functionality.
- Process Reliability: Confirming that sterilization conditions are consistent and reproducible.
- Regulatory Compliance: Meeting relevant requirements, including ISO 11135 for EO and ISO 17665 for steam sterilization.
- Quality Assurance: Establishing documented evidence to support routine sterilization and product release.

Validation is necessary before introducing a new sterilization process and must be reassessed when changes could impact its effectiveness.



EO and Steam Sterilization: Understanding the Differences

EO and steam sterilization operate on different microbial inactivation mechanisms. Choosing the right technology depends on the product's material characteristics, geometry, packaging, and tolerance to processing conditions.

EO Sterilization

EO sterilization utilizes ethylene oxide gas under controlled temperature, humidity, and exposure conditions. It is often chosen for heat-sensitive products, polymer-based medical devices, and complex assemblies that require gas penetration.

Validation according to ISO 11135 assesses critical parameters such as gas concentration, temperature, humidity, and exposure duration. Microbiological testing is conducted to confirm that the process meets the required sterilization performance.

Steam Sterilization

Steam sterilization employs saturated steam under pressure to achieve microbial inactivation through moist heat. It is commonly used for heat- and moisture-resistant medical devices, surgical instruments, and compatible pharmaceutical components.

Validation according to ISO 17665 focuses on temperature distribution, exposure time, steam penetration, and process reproducibility. Both methods require documented qualification before being implemented into routine production.

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How Does Sterilization Validation Work?
Sterilization validation follows a structured process designed to demonstrate that the selected method consistently meets predefined acceptance criteria. Although specific requirements differ between EO and steam sterilization, validation projects typically include the following stages:

- **Validation Protocol:** Definition of the product, sterilization method, process parameters, testing requirements, and acceptance criteria.
- **Product and Load Preparation:** Selection of representative product configurations, microbiological samples, and appropriate challenge locations.
- **Microbiological Evaluation:** Assessment of bioburden and applicable biological indicators or sterility testing to evaluate microbial inactivation.
- **Validation Cycles:** Execution of defined sterilization cycles to demonstrate process effectiveness and reproducibility.
- **Laboratory Testing:** Evaluation of applicable product safety requirements, including EO residuals, packaging integrity, or functional performance.
- **Final Validation Report:** Review of qualification results, deviations, and acceptance criteria to approve the validated process specification.

EO validation may include reduced-exposure and half-cycle studies, depending on the selected validation approach. Steam validation typically includes thermal distribution and penetration studies to ensure that the required exposure conditions are achieved throughout the load.

The number and type of validation cycles are determined according to the applicable standard and product-specific requirements.

From Validation to Routine Sterilization
Successful sterilization validation establishes the operating parameters and controls required for routine production.

The final validation report documents the results of qualification activities and confirms whether the process meets the approved acceptance criteria. These results support the definition of routine monitoring requirements, permitted load configurations, and process specifications.



The Role of Laboratory Testing
Laboratory testing provides supporting evidence of sterilization effectiveness and product safety during validation. Depending on the sterilization method and product characteristics, testing may include:

- Bioburden Testing (ISO 11737-1): Evaluation of the microbial population present before sterilization.
- Sterility Testing (ISO 11737-2): Testing used during the definition, validation, or maintenance of sterilization processes.
- EO Residual Analysis (ISO 10993-7): Assessment of applicable residual EO and ethylene chlorohydrin limits following EO sterilization.
- Packaging Integrity Testing (ISO 11607): Evaluation of sterile barrier performance following sterilization exposure.
- Product Functional Testing: Verification that sterilization conditions have not affected the device's intended performance.

Integrating laboratory testing into the validation project allows manufacturers to assess microbiological performance alongside material compatibility, packaging integrity, and product safety.

When Is Revalidation Required?
Sterilization validation is not limited to the initial qualification of a product. Once a process has been validated, its continued effectiveness must be maintained throughout routine

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Sterilization validation connects product development with controlled industrial production, ensuring that the selected sterilization process remains effective and reproducible.

Through its EO and steam sterilization services, supported by laboratory testing and validation expertise, Medistri assists manufacturers in establishing sterilization processes aligned with international standards and product-specific requirements.

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

– The Medistri Team

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production. Additional evaluation or revalidation may be necessary following:

- Changes to product materials, design, or packaging
- Modifications to sterilization parameters or equipment
- Changes in load configuration or manufacturing location
- Significant process deviations or unexpected monitoring results
- Periodic process reviews identifying a need for requalification

The extent of revalidation depends on the potential impact of the change and the requirements of the applicable sterilization standard.

Routine monitoring, equipment maintenance, and documented change control help maintain the validated state of the process.