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From the Blog

Sterilization Validation

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As medical devices and pharmaceutical products progress toward commercialization, regulatory compliance and documented evidence become prerequisites for market access.

For products placed on the market as Sterile, sterility must be demonstrated through a formally validated process. Sterilization validation provides objective evidence that a defined process consistently delivers sterile products under controlled conditions.

From surgical implants and auto-injectors to prefilled syringes and pharmaceutical packaging, market access depends on the demonstrated ability to achieve and maintain sterility in a consistent, reproducible, and evidence-based manner.

Regulatory Expectations and Standards
Regulatory authorities, including the FDA, the EMA, and notified bodies worldwide require validated sterilization processes before a product can be approved, marketed, and labelled as sterile. These requirements are defined through international standards. ISO 11135 governs EO sterilization validation, while ISO 17665 defines requirements for Steam sterilization. Compliance is assessed during conformity assessments, inspections, and audits.

Execution of Sterilization Validation
At go-to-market stage, validation must reflect the final commercial product and routine production conditions. EO and Steam validation follow structured, standards-driven workflows aligned with their respective ISO requirements.

Key elements include:

- Definition of scope, materials, packaging, load configuration, and acceptance criteria
- Bioburden assessment to support process challenge definition
- Worst-case configuration and load identification
- Process qualification to demonstrate reproducible achievement of SAL
  - EO: half-cycle and full-cycle studies
  - Steam: heat distribution and performance qualification
- Method-specific release criteria
  - EO: residual EO, ECH, and EG per ISO 10993-7
  - Steam: defined physical and microbiological acceptance criteria
- Final validation reporting and approval

Post-Market Validation and Ongoing Control
Sterilization validation continues after market entry. Validated processes must be routinely monitored, reviewed, and revalidated as required under quality system and change control procedures to ensure sustained compliance and uninterrupted supply.

Supporting Market Entry
Effective sterilization validation requires coordinated expertise across sterilization operations, laboratory testing, and regulatory compliance. A structured and integrated approach reduces regulatory risk and supports efficient market entry.

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

— The Medistri Team

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What Sterilization Validation Demonstrates
Sterilization validation establishes, through documented evidence, that a sterilization process, such as EO or Steam, consistently achieves a Sterility Assurance Level (SAL) of 10^{-6}, meaning the probability of a viable microorganism remaining on a sterilized unit is less than one in one million.

When Validation Is Required
Sterilization validation is required at initial market entry and must be reviewed or repeated when changes may affect sterility assurance, including:

- Initial commercialization
- Transition to routine manufacturing
- Change of manufacturing site or sterilization facility
- Modification of product materials, packaging, or load configuration
- Periodic revalidation

Each represents a regulatory checkpoint requiring documented justification.

Validation Documentation
Regulators expect a complete, traceable validation file, typically including:

- Validation protocol and rationale
- Microbiological and chemical test results
- Equipment qualification and calibration records
- Worst-case load configurations
- Final validation report

Documentation gaps may result in regulatory findings, even when sterilization performance is technically adequate.

Common Go-To-Market Risks
Validation-related delays most commonly result from:

- Inadequate worst-case representation
- Insufficient technical or statistical justification
- Late identification of EO residual constraints affecting product release

Early risk identification is critical to avoid approval delays.