Medistri

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

From The Blog

Sterilization Validation for Auto-Injectors

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Auto-injectors play a critical role in drug delivery, combining convenience, precision, and patient safety in a single-use medical device. When brought to market, these devices must meet the highest standards of sterility and performance - especially when combined with biological or pharmaceutical products.

At Medistri, our validation experts work closely with manufacturers to ensure their auto-injectors comply with global regulatory requirements and are ready for market release.

Understanding Auto-Injectors as Combination Products
Auto-injectors are classified as drug-device combination products. They are designed to deliver a precise dose of a drug, often self-administered by patients. According to FDA guidance, the category includes:

- Pen injectors
- Needle-free injectors
- Mechanically operated or electronically controlled systems

This complexity introduces additional regulatory scrutiny, particularly around the interaction between the drug, the container, and the delivery system.

The Role of Sterilization Validation
Sterilization validation ensures that the sterilization process consistently delivers the required Sterility Assurance Level (SAL) - typically ≤ 10^{-6} - under worst-case conditions. For auto-injectors, validation must account for both the device itself and, when applicable, the combination with the pharmaceutical or biological product.

Our validation approach combines:

- In-house laboratory testing.
- Fully integrated sterilization facilities.
- Protocol development aligned with ISO 11135, ISO 17665, and ISO 11737.

Each validation study is tailored to the injector's configuration, materials, and intended use.

A Risk-Based Approach to Validation
Our process follows a risk-based approach to define and challenge the worst-case conditions for your product. This includes evaluating critical variables such as material resistance, packaging integrity, and bioburden levels - ensuring your validation study meets both regulatory expectations and real-world conditions.

Partnering with Medistri for EO Sterilization Validation
Medistri brings together the full spectrum of EO sterilization validation - from protocol design and laboratory testing to final report submission. Our team supports you not only during the initial validation phase, but also throughout the product's lifecycle, including:

- Revalidation following design, material, or process changes.
- Packaging or labelling updates.
- Adaptation to evolving regulatory requirements.

With Europe's most advanced EO sterilization infrastructure and in-house ISO 17025 accredited laboratory, we deliver precise, reliable, and efficient validation solutions — tailored to the specific needs of your auto-injector.

To initiate your validation project or learn more about our services, visit our website here or contact us at sales@medistri.com.

— The Medistri Team

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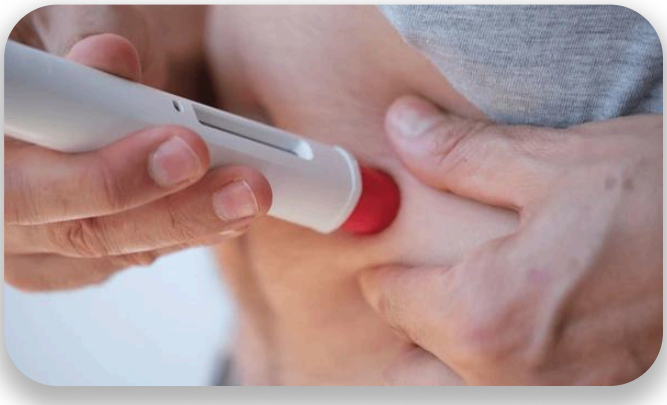

Key Considerations for Auto-Injector Sterilization
Sterilization validation for auto-injectors typically covers the following areas:

- **Device Sterility:** Validation must demonstrate that the injector achieves an SAL of 10^{-6} if provided as sterile.
- **Packaging & Materials:** All primary packaging and fluid-contact components must be validated, with evidence of being non-pyrogenic.
- **Combination Products:** For pre-filled systems or co-packaged solutions, the sterilization method must not compromise drug integrity or container closure systems.
- **Regulatory Standards:** FDA and international regulators recognize the use of standards such as:
  - ISO 11135 (EO sterilization)
  - ISO 17665 (moist heat sterilization)
  - ISO 11737 (bioburden and sterility testing)
  - ISO 11607 (packaging validation)

Each standard supports different aspects of the process, from selecting the appropriate cycle to verifying microbial inactivation and package integrity.

Environmental Considerations
As regulatory and industry focus increases on sustainability, sterilization strategies are evolving to reduce environmental impact - especially in EO processes. Medistri continuously evaluates cycle design, gas consumption, and packaging efficiency to help manufacturers meet both performance and sustainability goals.