Medistri

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

Medistri's In-House Expertise

EO Sterilization Validation

In the Pharmaceutical and Medical Device industries, ensuring the integrity of your products is crucial. At Medistri, we recognize that rigorous and reliable sterilization is vital for public health and compliance with international regulatory standards. That's why we provide our comprehensive EO Sterilization Validation Services, designed to offer unmatched confidence in the sterility and excellence of your items.

EO Sterilization Validation is a precise process that verifies the effectiveness of ethylene oxide (EO) sterilization for sensitive materials, including medical devices and pharmaceutical packaging. This validation ensures that sterilization consistently meets strict safety and efficacy criteria, safeguarding integrity and patient health. It is essential for compliance with regulatory standards, including those from the FDA and European Medicines Agency (EMA). Validating your EO sterilization process reduces the risk of contamination, ensures consistency, and protects your brand's reputation.

At Medistri, we possess extensive experience in the validation of EO Sterilization for a diverse array of products, such as:

- ✔ Pharmaceutical Vials.
- ✔ Pharmaceutical Syringes.
- ✔ Pharmaceutical Cartridges.
- ✔ Surgical Instruments.
- ✔ Diagnostic Equipment.
- ✔ Implantable Devices.
- ✔ Catheters.
- ✔ Stents.
- ✔ Endoscopes.

Advantages of Partnering with Medistri for EO Sterilization Validation

1 - Expertise in High-Complexity Product Validation
Our team specializes in handling the challenges of sterilizing high-complexity products in the Pharmaceutical and MedTech sectors. With extensive experience in validating products with intricate designs and diverse materials, including sensitive pharmaceutical packaging, we ensure reliable sterilization results.

2 - State-of-the-Art In-House Laboratory Services
Medistri's in-house laboratory streamlines the sterilization validation process, ensuring that testing is thorough and aligned with your specific requirements. This approach reduces redundant testing and speeds up your time to market.

3 - Managed by Our Quality Team in Switzerland
The EO Sterilization Validation process is overseen by Medistri's expert Quality team at our Swiss headquarters. With deep knowledge of regulatory standards like ISO 11135 and ISO 14937, our team ensures compliance and provides support for training, audits, and documentation to help you navigate regulatory complexities confidently.

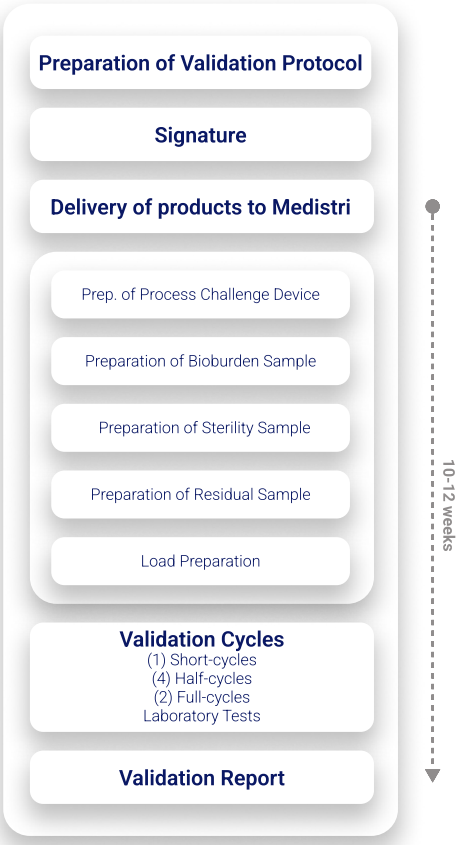
4 - Ongoing Partnership for Routine EO Sterilization
After initial validation, Medistri offers continued EO sterilization services to maintain compliance and efficiency. Our long-term support ensures your sterilization processes stay robust and adapt to changing regulatory requirements.

5 - Commitment to Sustainability
Medistri is committed to sustainability in all sterilization processes. During EO Validation, we work with you to optimize cycles, minimize environmental impact, and efficiently use resources like energy, EO gas, and materials, in line with global sustainability goals.

Trusted Globally: Initiating the EO Sterilization Validation Process
Products validated by Medistri are trusted worldwide, especially in markets where stringent U.S. and European regulatory compliance is essential. Our rigorous validation processes and extensive experience guarantee your items meet the highest standards for safety, excellence, and regulatory adherence, facilitating acceptance across international markets.

We collaborate closely with you to define specific requirements, including the quantity and type of samples needed for laboratory analysis. Our discovery phase is meticulously designed to understand your unique needs and objectives, allowing us to tailor your validation process.

Medistri's Tailored EO Validation



Medistri

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

The New Stack of Fully Integrated Services.

Laboratory Infrastructure

- Chemistry
- Biocompatibility & Toxicology
- Sterility Assurance
- Extractable's & Leachable's

Manufacturing Infrastructure

- Product Assembly
- Custom Packaging Solutions
- Quality Control & CE Marking
- Labelling & Distribution

Sterilisation Infrastructure

- Steam Sterilization
- EO Sterilization

Validation Infrastructure

- Sterilization Validation
- Cleaning Validation
- Process Validation
- Disinfection Validation

Packaging Validation

- Transport Simulation
- Sterile Barrier Integrity Testing

Medistri is continually innovating its **in-house** range of services. We're expanding our infrastructure to offer a completely integrated stack of services for healthcare companies. Organizations of every size — from startups to large enterprises use our suit of services to start, grow & optimize their business.

Within our site located at the heart of Switzerland, Medistri **combines all its technical infrastructure together** and places quality at the heart of its day-to-day operations. Allowing you to simplify your supply chain management, focus on growth & maintain excellence.

Swissmedic & FDA Registered