Sotera Health

Sterigenics® A Sotera Health company | Nelson Labs® A Sotera Health company

The 3Rs of EO Sterilization

REDUCE
REUSE
RECLAIM™

Supporting our Customers in Reducing EO Use

Ethylene oxide (EO) sterilization technology **plays a vital role** in enabling critical medical products and devices to safely reach patients worldwide.

"Ethylene oxide is the most common method of sterilization of medical devices in the U.S. and is a well-established and scientifically-proven method of preventing harmful microorganisms from reproducing and causing infections. More than 20 billion devices sold in the U.S. every year are sterilized with ethylene oxide, accounting for approximately 50 percent of devices that require sterilization".

— FDA Statement, October 25, 2019

The same properties which make EO an effective sterilant require that it be carefully controlled to protect workers, communities and patients.

We are committed to developing **innovative new solutions** to further enhance the safe and sustainable use of EO.

We have set a goal to reduce the amount of EO by **↓50%**

BENEFITS OF REDUCING THE AMOUNT OF EO

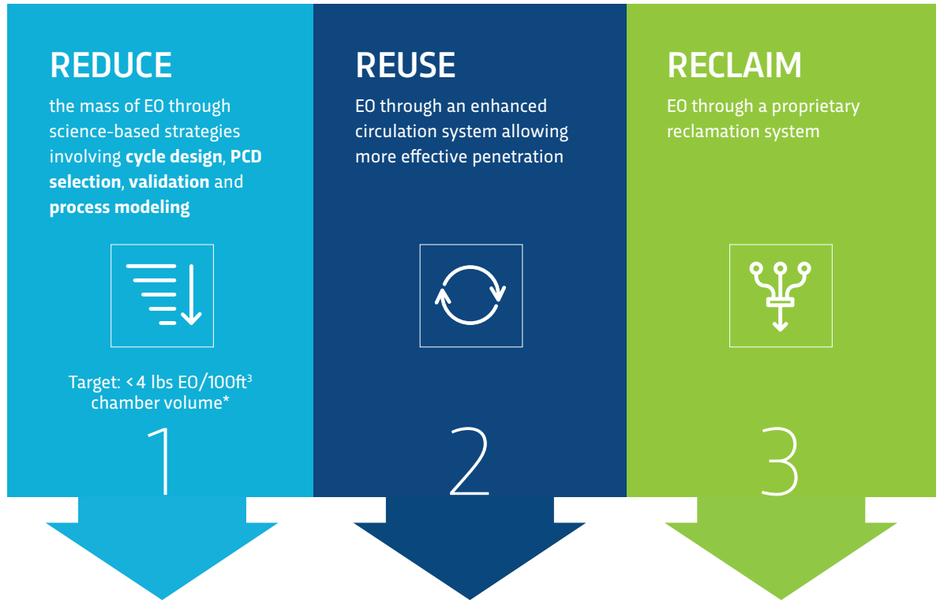
for employees, customers and communities

- Continued safe usage of EO, the most widely used sterilization technology
- Lower residuals – performing better than patient safety regulations
- Allows for reduction in required aeration times, resulting in improved customer supply chain efficiencies
- May reduce cycle time, resulting in additional capacity for manufacturers
- Further reduce fugitive emissions to enhance health and safety

Sterigenics® A Sotera Health company Nelson Labs® A Sotera Health company

The 3Rs of EO Sterilization.

We will reach our goal by employing this innovative and principled program. Each pillar was designed by our industry leading technical experts, engineers and safety specialists in collaboration with customers, regulators and industry associations.



For existing products, we will partner with you to **REDUCE** the mass of EO in your current sterilization process, as appropriate.

As part of our continuous process improvement efforts, Sterigenics is undertaking facility equipment and operational enhancements to **REUSE** and **RECLAIM** EO. Our goal is to capture and eliminate 100% of all fugitive emissions.

FOR NEW PRODUCT DEVELOPMENT

Contact your Expert Advisor or Account Manager **early** in your product development lifecycle to optimize your EO sterilization process.

*<645g EO/1m³ chamber volume

Premier Partner Program

EXCLUSIVE for EO Reduction Customers

CORE SERVICES

FREE EXPERT ADVISORY SERVICES

PAID EXPERT ADVISORY SERVICES

Technical support and priority services, so you are “front of the line” **every time**.

CORE SERVICES

Priority Service

Scheduled placement in testing queue to minimize turnaround times — STAT testing available for a fee.

Single Point of Contact

Dedicated project manager to coordinate transit to and from our lab, coordinate the testing of all project samples, and communication between lab scientists, Sterigenics’ facility management, expert advisor, account manager and customer.

FREE EXPERT ADVISORY SERVICES

One-hour Complimentary Telephone Consultation with Expert Advisory Services

- Design Review – Discuss product design with customer to identify possible design changes that may be effective in reducing the required sterilization cycle time
- Material Selection – Review product material choices to determine compatibility with multiple sterilization modalities
- Packaging Selection – Review product packaging for EO sterilization optimization
- Palletization review to consider the optimal EO flow into and out of the product
- Exposure/Aeration Review – Review EO exposure cycles and consider possible aeration time adjustments,, shortening overall turnaround time at sterilization facility

Historical File Review (Up to 3 hours complimentary at our location, or a paid consult on site)

Customer must gather and organize their files prior to this review

- Explore if additional cycle optimization opportunities exist based on an in-depth product history assessment
- Consider whether the product’s sterilization cycle has been optimized
- Assess historical EO residual validation approach for potential enhancements
- Explore the possibility of using parametric release
- Review manufacturing records to identify options for reducing the customer’s manufacturing facility’s bioburden levels
- Help to determine if the customer’s manufacturing facility is “audit ready”

Standards Training (Free webinar available soon; periodic industry updates presented by Nelson Labs and Sterigenics’ experts)

- Help assess if the customer is current with the latest standards and regulatory requirements
- Provide updates on the latest guidance on EO sterilization from ISO and AAMI
- Quarterly review of regulatory updates from FDA and other regulatory bodies
- Review any special regulatory considerations regarding EO (e.g. European residual levels, special neonate considerations, etc.)

PAID EXPERT ADVISORY SERVICES

Process Challenge Devices (PCDs)

- Help customers with PCD selection and transition (free). Work with the customer to determine which PCD would represent the optimized challenge for their product and then develop the transition plan
- Execute the PCD validation testing (normal rates)
- Cycle design and optimization for product specific applications

NOTE: This should be completed during cycle development phase

EO Residual Reduction

- Better understand EO dissipation by developing a decay curve to help identify opportunities for further EO residual reduction
- Analyze how best to reduce fugitive EO emissions
- Global considerations and EO residual requirements

NOTE: Sterigenics Expert Advisory Services will complete protocol development and Sterigenics’ processing facility selection

Sterigenics® A Sotera Health company Nelson Labs® A Sotera Health company

Sotera Health

Sterigenics®
A Sotera Health company

Comprehensive Sterilization Solutions and Expert Advisory Services

Sterigenics is a global leader in comprehensive sterilization solutions and advisory services. We are over 1600 engineers, scientists and safety specialists with deep expertise across Gamma, EtO, NO_2, E-Beam and X-Ray sterilization. Our operations span 48 facilities in 13 countries to ensure we are the "point of safe" for our customers.

Safegarding Global Health® –with every product we sterilize.

sterigenics.com

Nelson Labs®
A Sotera Health company

Expert Lab Testing & Advisory Services

Nelson Labs is the industry-leading provider of global lab testing and expert consulting services. We perform microbiological and analytical laboratory tests across the medical device, pharmaceutical, and tissue industries. The company is regarded as a best-in-class partner with a strong track record of collaborating with customers to solve complex issues.

Safegarding Global Health® –with every test we complete.

nelsonlabs.com

Learn more about how The 3Rs of EO Sterilization can benefit you.

Contact your Sterigenics Account Manager or Expert Advisor today.

sterigenics.com

US +1 800.472.4508
EMEAA +32 (478) 30 70 11
LATAM +52 (773) 7329-450