ETHYLENE OXIDE MASTER FILE PILOT PROGRAM

FREQUENTLY ASKED QUESTIONS

Q: What is the Ethylene Oxide (EO) Sterilization Master File Pilot Program?

A: In an effort to advance innovation in medical device sterilization with ethylene oxide (EO) and reduce the threat of shortages of EO-sterilized medical devices by providing a streamlined and flexible regulatory process, FDA introduced the Ethylene Oxide Sterilization Master File Pilot Program (Pilot Program) in late 2019. This program allows manufacturers of Class III medical devices, marketed under a premarket approval (PMA), to modify their EO sterilization process, for example, through the STERIS Sustainable EO® sterilization services program, without needing to submit a PMA supplement to the FDA for approval, therefore reducing regulatory burden.

STERIS is excited to participate in this program as it supports our MISSION TO HELP OUR CUSTOMERS CREATE A HEALTHIER AND SAFER WORLD by reducing the amount of ethylene oxide necessary to sterilize medical devices, as well as providing redundancy in processing locations and chambers.

Q: What is the STERIS Sustainable EO® sterilization services (SEO) program?

A: Through the STERIS AST Sustainable EO sterilization services program, STERIS is committed to providing innovative and sustainable solutions to EO sterilant reduction while achieving prescribed Sterility Assurance Levels (SAL).

Optimizing the amount of EO sterilant used in processing can result in lowering of product residuals, improving occupational safety, generating fewer fugitive emissions released into the environment and improved supply chain efficiencies due to reduced aeration of EO gas.

For further information on SEO, ref. https://www.steris-ast.com/services/sustainable-eo-sterilization-services/

Q: What is a Sustainable EO cycle?

A: When Customers take advantage of STERIS AST's full offering, and choose to validate through our EO TechTeam®, they have access to our innovative approaches to optimum cycle design, validation strategies and process challenge device design expertise for their unique products, all intended to achieve an objective of an SEO cycle of less than 400mg/L while maintaining the highest level of quality standards and compliance to ISO 11135 – Ethylene Oxide Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices.

Customers who choose to validate SEO cycles with eligible medical devices (see question below for definition of eligible medical devices) through our EO TechTeam, following our process qualification requirements (process, protocol and final report) are eligible to participate in the STERIS AST EO Master File Program.

Q: What is a Device Master File (MAF)?

A: A Device Master File (MAF) provides proprietary data about a material, component, or a manufacturing process (i.e., sterilization) that the holder of the MAF (i.e., STERIS AST) wishes to make available to FDA on behalf of their Customers, in support of their device-related submissions to FDA.

In turn, FDA references the content of STERIS AST's MAF during evaluation of the Customers pre-market approval (PMA), investigational device exemption application (IDE), 510(k) or post-market PMA supplements, 30-day notices, etc.

In addition to Class III medical devices marketed for use in the United States under a PMA subject of the EO Sterilization Master File Pilot Program, all medical devices are eligible to leverage STERIS AST's MAF in support of their FDA regulatory submissions.

FOR MORE INFORMATION

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Q: What are the benefits of utilizing the FDA's Pilot Program?

A: In addition to accessing the validation services of our EO TechTeam, Customers with eligible medical devices will have the benefit of leveraging our EO Master File as an alternate mechanism for adding processing redundancy and/or converting to a SEO cycle in lieu of submitting a 180-day site change supplement or a 30-day change notice to the FDA respectively.

Optimizing the amount of EO sterilant used in processing can result in lowering of product residuals, improving occupational safety, fewer fugitive emissions released into the environment, and improved supply chain efficiencies due to reduced aeration of EO gas.

When Customers validate through our EO TechTeam, they have access to our innovative approaches to optimum cycle design for their unique products, validation strategy and process challenge device design, all intended to achieve the objective of an EO cycle of less than 400mg/L.

Q: What EO sterilization process changes are eligible under the FDA's Pilot Program?

A: There are two types of changes eligible under the Pilot Program:

1. Changes in validated cycle parameters from a traditional EO cycle validated at STERIS, to an EO cycle utilizing a reduced amount of ethylene oxide, such as the STERIS Sustainable EO® sterilization services (SEO) program.

2. Increased flexibility in processing redundancy, for example, adding a secondary STERIS AST site for EO processing and/or validating in multiple chambers within a STERIS AST EO processing facility.

Q: What EO sterilization process modifications are not eligible under the FDA's Pilot Program?

A: EO sterilization process modifications that include cycle parameters (for example, increased temperature, pressure, humidity) outside of validated tolerances that may impact device specifications, device performance, EO residuals biocompatibility or toxicology from the approved PMA device are outside the scope of the Pilot Program.

Changes to device design specifications, materials, packaging, and load configuration/composition are also outside the scope of the Pilot Program.

Our EO TechTeam® professionals can assist in making the determination if your EO sterilization process modifications (i.e., reduction in ethylene oxide concentration) are eligible for the Pilot Program.

Go here to view the full list of changes outside the scope of the Pilot Program.

Q: What if I don't currently have an active validation for my eligible medical devices at a STERIS AST facility?

A: If you do not currently process or do not have an active validation for the eligible medical device(s) at a STERIS AST EO facility and intend to transfer these medical devices to processing at STERIS AST, or establish STERIS AST as an alternate sterilization provider, these products are not immediately eligible under the Pilot Program.

In order to become eligible under the Pilot Program, the Customer must validate their process through the STERIS EO TechTeam, then submit a site change PMA supplement that identifies STERIS AST as the new, or alternate sterilization provider. Once the site change PMA is approved by the FDA, the Customer's medical device(s) become eligible for participation under the Pilot Program.

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Q: Is the EO Master File validation different from previous validations?

A: No. The validations conducted by the EO TechTeam subject of the Pilot Program, as with all validations conducted by our EO TechTeam, are in compliance with the requirements of ISO 11135 – Sterilization of health-care products – Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.

Q: Can I use my Company's own process and protocol for the validation and reference STERIS AST's EO Master File?

A: No. Customer designed validations whereby the Customer supplies their own protocol and report, and the validation is executed by the respective STERIS AST EO processing facility are not considered part of the Pilot Program, until or unless their process is revalidated utilizing our defined ethylene oxide process qualification in accordance with our internal work instructions and executed by our EO TechTeam.

Submission under the Pilot Program represent that the Customer's validation was executed under a protocol and process accepted by the FDA under this pilot program and consistently applied by our EO TechTeam.

Q: What medical devices are eligible under the FDA's Pilot Program?

A: FDA regulated medical devices categorized as Class III, marketed under a Premarket Approval (PMA) that have been validated at STERIS.

In addition to Class III medical devices marketed for use in the United States under a PMA, subject of the Pilot Program, all medical devices validated at STERIS are eligible to leverage STERIS AST's Device Master File in support of their FDA regulatory submissions.

Q: What medical devices are not eligible under the FDA's Pilot Program?

A: FDA regulated medical devices not categorized as Class III/ not marketed under a Premarket Approval (PMA), reusable devices, reprocessed single-use devices or devices that are provided non-sterile.

Devices with alternate sterility assurance levels other than 10^{-6} or those with specialized requirements for biocompatibility, sterilant residual compatibility or sterilant residual limits that differ from the minimum allowable limits outlined in section 4.3 of ISO 10993-7 "Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals" are also not eligible for the Pilot Program.

Our Regulatory Affairs Department can assist in making the determination if your medical devices are eligible for the Pilot Program.

Q: What actions are necessary to implement a sterilization process change under the pilot program?

A: Upon determination of device eligibility for the Program, the Customer will be requested to submit a Letter of Intent (LOI, also referred to as the post-approval letter) to STERIS AST. This LOI signifies the Customer is ready to proceed with initiating use of the STERIS AST Master File for the indicated device(s). STERIS AST will then issue a Letter of Authorization (LoA) to the device manufacturer and will provide a copy to FDA, along wtth a copy of the final LOI.

Once this letter is electronically delivered to FDA, STERIS AST will add the device to our Master File and the device manufacturer may now use the validated, master file compliant cycle and/or processing redundancy.

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Q: How can Customers coordinate with STERIS to take advantage of the Pilot Program?

A: Customers should contact their STERIS AST Account Manager to request that a device/validation be subject under the EO Sterilization Master File Pilot Program.

The STERIS Regulatory Affairs Department will then confirm eligibility of the device.

Once the device is confirmed to meet the requirements, the validation will be completed by the EO TechTeam in accordance with the protocol on file within the STERIS AST Device Master File.

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