INSIDE STORY

Ethylene Oxide (EO) Sterilization may be the only method that effectively sterilizes heat- and moisture-sensitive medical devices without damaging the device during the sterilization process. Medical devices made from certain polymers (plastic or resin), that have multiple layers of packaging, or hard-to-reach places (for example, catheters) are likely to be sterilized with ethylene oxide. To find out more about the expertise required to establish a safe and effective EO Sterilization for medical devices, *MDB* recently spoke with Elizabeth Sydnor, Director of Microbiology, for Eurofins Medical Device Testing (Lancaster, PA).

***MDB:* With upcoming changes to the U.S. environmental regulations, is that going to impact the use of EO moving forward?**

Elizabeth Sydnor: There are many regulations regarding the use of EO. Specifically, the Environmental Protection Agency (EPA) has concerns regarding the amount of EO emissions. There are established regulations, such as the Clean Air Act, for facilities releasing certain chemicals into the air. This impacts EO sterilization facilities and will continue to change the industry over time as a result. There will be some considerations that we will have to watch, but I believe that we'll be using EO to sterilize medical devices for years to come. Eurofins Medical Device Testing's laboratories will not be impacted from a device testing perspective by these potential changes.

***MDB:* Are EO validation standards applicable to the EU?**

Sydnor: AAMI is an accredited organization by American National Standards Institute (ANSI), which ensures that the procedures meet essential requirements. The International Organization for Standardization (ISO) standards and other industry guidance documents are widely used and leveraged in the EU and the United States, as well as many other countries. Eurofins Medical Device Testing's laboratories are ISO 17025 accredited and capable of testing to industry standards and guidance documents to assist in EO Sterilization validations.

***MDB:* What organism is a concern for EO sterilization?**

Sydnor: *Bacillus* spores are the most resistant species to EO gasses. One of the common biological indicators used during the validation of an EO cycle is *Bacillus atrophaeus*.

***MDB:* How soon should a lab get involved during the validation process?**

Sydnor: The laboratory should get involved immediately. There may be other considerations that potentially need testing, such as packaging or biocompatibility. Reaching out to our laboratory right away to begin collaborating will help you set up a program that checks all the boxes needed to ensure that necessary testing is understood upfront.

***MDB:* If a sterilization cycle is validated, is additional quarterly audit testing needed?**

Sydnor: This will be different from a gamma sterilization validation where quarterly dose audit testing is common. For EO, there is routine testing that would be required for the sterilization validation. EO is validated using Annex B, which is the overkill approach. This would cause a parametric release, which is normally done by a biological indicator, or process challenge device (PCD), which is a representation of the load after each cycle.

***MDB:* How often is revalidation or product testing required?**

Sydnor: Normally, you consider revalidation if there is a change to a process or product. Depending on the outcome of that assessment, validation could be required along with other testing. As for product testing, this would be required after each lot release. For every lot released, there is a requirement to show the cycle has been successfully completed and rendered the product sterile. Product testing will happen routinely; however, revalidation is subject to change.

***MDB:* How would the relevance of AAMI TIR28: 2016/(R)2020 – Product Adoption and Process Equivalence for Ethylene Oxide Sterilization when audited by notified body correspond with the overall validation process?**

Sydnor: This technical report focuses on making changes to an existing validated cycle or adding a new product into an existing cycle.

***MDB:* Can you give some information on how to select a PCD?**

Sydnor: ISO 11135 provides items to consider about a PCD. It states in Section 3.28 Note 2: "In this International Standard, a distinction is made between an internal PCD and an external PCD. An internal PCD is used to demonstrate that the required product Sterility Assurance Level (SAL) is achieved. A PCD located within the confines of the product or product shipper case is an internal PCD, whereas a PCD located between shipper cases or on the exterior surfaces of the load is an external PCD. An external PCD is an item designed to be used for microbiological monitoring of routine production cycles."

***MDB:* How often do EO sterilization processes, parameters, etc. have to be revalidated?**

Sydnor: Requalification should be assessed and documented based on the outcome of the review. ISO 11135 gives guidance on this, along with items to consider. This should be performed at least every two years per the "Requalification" section of the document.

To learn more about Eurofins Medical Device Testing, visit www.eurofins.com/medical-device.