To Use or Not to Use a Developmental Chamber for Ethylene Oxide Validation

A developmental chamber is usually smaller than a production chamber and used to perform studies to support Ethylene Oxide (EO) validation. There are several pros of using developmental chamber; for example, smaller sample sizes can lower laboratory testing costs. In this Industry Insight, we offer Project Management and Quality Assurance personnel within the medical device, pharmaceutical, commercial and food industries the pros and cons of using a developmental chamber for Process Definition performed as part of a validation, in adherence with ISO 11135:2014, using the Overkill Approach.

When it comes to performing runs, there are two (2) main parts to an EO sterilization validation. The first is Process Definition, which addresses the fractional work. The second is Performance Qualification (PQ). PQ addresses the Microbiological Performance Qualification (MPQ) work (half cycles) and Physical Performance Qualification (PPQ) work (full cycles). The production chamber must be used for the MPQ and PPQ runs; however, ISO 11135:2014 allows the use of a developmental chamber for the Process Definition work.

Pros

While Process Definition work does not have to be performed in a developmental chamber, there may be benefits to their use.

- Sample quantities are usually smaller when using a developmental chamber because the chamber itself is smaller. The smaller sample sizes will often mean lower laboratory testing costs.
- When using a developmental chamber, the sample pull times may be shorter so samples can be placed on test sooner and reduce the overall time of the study
- It's often easier to get fractional growth in the smaller chamber than in a larger chamber, which could lead to performing less runs during Process Definition.

Important Guidance and Requirements in ISO 11135:2014 Specific to Using a Developmental Chamber for EO Validation

- Section 8.3 states that the developmental chamber must have undergone an Installation Qualification (IQ) and Operational Qualification (OQ).
- Section 9.4.2.4 states that if a developmental chamber is used for Process Definition, the MPQ must include at least three (3) fractional or three (3) half cycles performed in the production chamber to confirm the data from the developmental chamber.
- Section D.8.3 states that using a developmental chamber does not preclude confirmation of PQ in a production chamber.
- Section D9.4.2.4 states that if a developmental chamber is used for Process Definition, consideration should be given to establish the relationship between data from the developmental chamber studies and data from the production chamber.

Cons

There are scenarios when performing Process Definition work in a developmental chamber is not the best option. If the following scenarios are not performed correctly, this could lead to regulatory scrutiny and may require additional time to put together documentation confirming the requirements and guidance was met.

- You must confirm the requirements and guidance listed in ISO 11135 for using a developmental chamber are met.
- You must determine the amount of scale up needed for the EO sterilization cycle when moving to the PQ runs in the production chamber.

What is "Scale Up"?

Scale up is the adjustment or adjustments made to the EO sterilization cycle when increasing the load size or moving to a larger chamber to make sure the required lethality can still be achieved.

What Else Should You Consider?

Here are some additional considerations to determine whether or not to use a developmental chamber for Process Definition.

- Evaluate the type of sterilization cycle being validated as certain cycles may make it more difficult to determine the appropriate amount of scale up when moving into the production chamber. These types of cycles may include, but are not limited to, shallow vacuum cycles or low temperature cycles.
- Consider the chamber size. If there is a significant difference between the size of the developmental chamber and the production chamber, there may be additional issues when determining the amount of scale up needed.
- Evaluate the ratio of the load to chamber size. Changes in the amount of head space in the chamber can impact the microbiological results and process dynamics; for example, absorption of temperature and EO when moving from a developmental chamber to a production chamber.

A developmental chamber can be used for Process Definition work if certain criteria are met. Ultimately the developmental chamber must be working appropriately and be able to provide equivalent conditions compared to the production chamber. In most cases, it is beneficial to use a developmental chamber when performing fractional runs (if the option is available); however, additional evaluation should be done before deciding to use a developmental chamber.

Additional Reading

We recommend that you read our detailed White Paper on this same topic, which is entitled, Pros, Cons, and Considerations of Using a Developmental Chamber during an Ethylene Oxide Validation.

Reference

ISO (International Standards Organization) 11135:2014, Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices.