

Ethylene Oxide Sterilization of Medical Devices

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Ethylene Oxide (EO) is a well known sterilizing agent. However, only recently its use has significantly emerged, due to its range of applications in the field of medical devices (MDs) sterilization, especially due to the diversity of products design, types of materials and packaging configurations used on presentation of MDs in customized packs for use in specific medical and surgical procedures.

This work provides an accurate reflection on ethylene oxide sterilization of medical devices, which is a promising field to explore and develop.

Advantages of this sterilization technology over other industrial sterilization technologies are addressed with the purpose of explaining why EO, despite many predictions about its demise as a sterilization alternative, is still a dominant mode of sterilization and continues to be used for increasing volumes of MDs.

The process design and validation, including microbiological validation, which is the most challenging in this context, are out-lined. An overview of the progress in terms of EO sterilization, as well as on process conditions optimisation, is analysed and promising issues, such as parametric release, lethality modelling and EO diffusion modelling, are discussed. Emphasis is given to a critical analysis about research topics requiring further attention.

One huge challenge is related with the development of mathematical models to integrate lethality in order to allow the definition of optimal microbiological inactivation conditions and, consequently, a continuous increase of process flexibility without compromising safety. The scientific community should also focus on other important issues, such as EO diffusion in different substrates, taking into account different environmental conditions along both sterilization and aeration.

