Validation Requirements for Gaseous Sterilization Using Ethylene Oxide

By **Tim Sandle Oct 31, 2017 7:00 am PDT**

Introduction

Gaseous sterilization is long-established but it is increasingly being reassessed and adopted due to the growth in the markets for medical devices and for single-use sterile disposable technologies for pharmaceuticals. Gaseous sterilization is not an exact term and there are different types of gaseous sterilization (and a further distinction between gases and vapors). The first division is with the agents and here sterilizing gases include: formaldehyde, ethylene oxide, propylene oxide, ozone, and chlorine dioxide (1). A second division is with vapors, such as peracetic acid and hydrogen peroxide. In drawing out the gas-vapor distinction, a gas is a substance that has a single defined thermodynamic state at room temperature; in contrast, a vapor is a substance that is a mixture of two phases at room temperature, namely gaseous and liquid phase (2).

Of these sterilants, the most commonly applied substances to sterile manufacturing are ethylene oxide and vapor phase Hydrogen peroxide. Ethylene oxide is used to sterilize many plastics; vapor phase hydrogen peroxide is typically used to decontaminate barrier systems (such as isolators).

In relation to sterilization, gases are more penetrating, more uniform in concentration and less subject to variations in temperature and relative humidity than vapors. In contrast, vapors have different concentrations in each phase. Furthermore, the kill rates in the gas and liquid phase appear to be substantially different reflecting the different concentrations and available water in each phase. Thus, conventionally, gas and vapor are considered to be separate sterilization processes.in a separate chapter (gaseous sterilization is distinct from vapor sterilization because with gas, the condensation of the agent is not a consideration in the execution of these processes).