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Possibilities for Advancement in Sterilizing Microbiology Using Real-Time Flow Cytometric Bacterial Cell Measuring

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Abstract

Through patient contact, medical devices provide critical care and diagnostic applications. The probability that a single viable microorganism will be present on an item following a sterilization procedure is known as the sterility assurance level (SAL). Utilizing conventional laboratory-based culture media for enumeration, sterilization microbiology frequently relies on an overkill validation strategy that results in a 12-log reduction in the population of recalcitrant bacterial endospores. Sterilization microbiology relies heavily on conventional culture-based methods, which are the subject of this timely review. The inability to fully comprehend the inactivation kinetics of a sterilization process like vaporized hydrogen peroxide (VH_2O_2) sterilization and, as a result, to design effective sterilization procedures is taken into consideration. Real-time flow cytometry (FCM) is used in a specific way to explain the practical relevance of these limitations, as well as the ramifications and opportunities for the sterilization sector. Real-time kinetic inactivation modeling will be informed by the application of FCM to these culture-based limitation factors, allowing the pharmaceutical, medical device, and sterilization industries to take advantage of emerging opportunities, including potentially disruptive applications requiring less sterilant use.

Keywords: Sterilizing microbiology • Manufacture • Microorganisms

Introduction

The market for sterilization can be divided into hospital sterilization (such as at the point of use), in-house manufacturing sterilization (such as at the point of medical device manufacture, frequently inline applications), and contract sterilization (provided by contractors) where medical device manufacturers obtain sterilization services later on in the supply chain. The treatment of medical devices, whose associated global market is estimated to exceed $400 billion, is central to sterilization microbiology. The safe use of sterile medical devices in critical care and diagnostic applications, where patient contact does not result in infection, is an important consideration. The management of hospital-acquired infections (HAIs) and sepsis is a global problem that is estimated to cost the healthcare system in the United States $9.8 billion annually and $20 billion annually, respectively. In the United States, 1.7 million cases of HAIs and 700,000 cases of sepsis are estimated to occur. Terminal sterilization modalities are unlikely to be point-of-infection due to comprehensive sterilization and validation processes, despite the variety of factors associated with the occurrence of these serious infections [1,2].

Literature Review

For the sake of patient safety, the sterilization microbiology that underpins these processes provides sterile assurance far beyond the minimum requirements for sterilization. Before being used by patients, medical devices undergo a sterilization procedure in order to attain the required sterility assurance level (SAL). Most of the time, sterilization validation relies on using an overkill validation method, where the process shows a 12-log reduction in the population of recalcitrant bacterial endospores on artificial laboratory-based media. It is assumed that the shape of the inactivation kinetic plot is a straight line and semi-logarithmic when the sterilizing conditions are the same for the entire exposure time. As a result, conventional microbiology assumes that the process can be predicted using a linear inactivation kinetic death rate plot probability. McEvoy and Rowan discuss terminal sterilization procedures like gamma irradiation, electron-beam irradiation, X-ray irradiation, gaseous ethylene oxide (EO), and hydrogen peroxide in its vapour state [3,4].

The International Organization for Standardization defines SAL as the "probability of a single viable micro-organism occurring on an item after sterilization" and a sterilization procedure as a "series of actions or operations needed to achieve the specified requirements for sterility." The US Food and Drug Administration (FDA) classifies traditional technologies used in terminal sterilization as Category A sterilization processes due to their well-established, long history of use, and availability of consensus standards (administered by the ISO). These technologies include EO sterilization and radiation processing employing gamma, electron beam, or X-ray irradiation. Standards like ISO 11135:2014 help users and manufacturers understand the most important factors to consider when defining the sterilization process and then qualifying and validating it. The microbiology assessment of the challenge posed by the medical device, as well as the microbicidal effect of that process on the measured challenge, or the selection of a biological indicator (BI) to represent such a challenge, serve as the foundation for the validation of a sterilization process in accordance with an ISO standard [5-8].

Discussion

The associated microbiological testing standards, such as ISO11737-1 and ISO11737-2, which govern the testing of bioburden and sterility, respectively, support many of the sterilization standards. The measurement of a medical device's natural microflora is known as bioburden testing. A validation process is used and qualified during sterilization. "Tests of Sterility" can be used to demonstrate the process's inactivation as part of the qualification process. Plotting an inactivation curve like the one shown may be possible once these tests are finished. However, a BI population of reasonable uniformity that is

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reliably predictable in an end-point analysis, such as a fractional sterilization process performed during validation, is frequently required for conventional sterilization procedures like EO [9].

The size, shape, complexity, and variety of microorganisms include a variety of physicochemical and environmental growth requirements for those capable of independent life and possessing distinct phenotypic identities. Viruses and parasites, for example, are examples of highly complex microorganisms that cannot thrive in standard laboratory conditions. Molecular biology tools are typically used as an indirect method of enumerating the number of these meticulous microorganisms, which require mammalian cell culture or an appropriate host to propagate. It has been demonstrated that prior exposure to sub-lethal levels of stress can temper or harden microorganisms against subsequent lethal levels of the same or different stresses. Microorganisms can respond to changes in the environment. Quorum sensing allows microorganisms to communicate with one another, highlighting the significance of every cell in any population.

Gene expression and cell-to-cell interactions, such as quorum sensing, may account for the heterogenicity of bacterial cells in an evenly distributed homologous culture. As a result, in order to gain a deeper understanding of both the mechanistic and cellular responses to applied or lethal stresses, it is frequently necessary to conduct research at the individual cell level. Through signaling compounds known as auto-inducers, social interactions among bacteria are more specific than interactions with the environment. The phenotypic outcomes of these responses to stress environments further complicate the populations of microorganisms, particularly those in a stressed state, as would be expected during sterilization inactivation.

The "vitalistic theory," which holds that the resistance of individual cells in a population is not the same but follows a distribution," offered an explanation for nonlinear inactivation kinetics because the importance of phenotypic heterogenicity can manifest itself in the inactivation kinetics of a population to an environmental stress like a disinfectant or sterilization process. Further define the vitalistic theory, which states that "phenotypic variation exists such that resistance to a lethal agent is not uniform" in "a genetically homogeneous population." In addition, the significance of heterogenicity in phenotypic composition with varying germinant receptors with superdormant spores as a microbial defense mechanism is evident. Sterilization microbiology ought to take this kind of population-level phenotypic variation into account. To provide the highest level of assurance, the majority of sterilization methods rely on "overkill," or a conservative over-processing with sterilant [10].

Conclusion

However, a hazardous sterilant like EO gas or a material that affects radiation like gamma is overused as a result of this overprocessing. The need to fully comprehend the behaviors of the microbiological target becomes even more pressing if workers attempt to deliver reduced and targeted processes in the future. Understanding the aforementioned microscopic level is important as researchers strive to gain a deeper comprehension of inactivation kinetics in order to produce processes that are more measured and, potentially, reduced mechanisms and behaviours in sterilization microbiology must be considered.

Acknowledgement

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Conflict of Interest

None.

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