Thermal Validation in Moist Heat Sterilization

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Since the advent of the Parenteral Drug Association's technical report on the validation of moist heat sterilization processes (PDA, 2007), it has been recognized that both the physical and the biological characteristics of a cycle should be included in the validation.

Biological challenges are used to ensure that the cycle is efficacious inactivating microorganisms. The effectiveness is evaluated in terms of spore log reduction (SLR), or log reduction (LR), or equivalent biological lethality (F_{bio}). The ability to determine the physical lethality required in a cycle is based upon the number and resistance of the microorganisms used in the challenge as well as the desired probability of a non-sterile unit (PNSU) at the end of a cycle.

A commonly used phrase, "the microbes don't lie" is used to remind us that since a sterilization cycle is designed to inactivate microorganisms they are the ideal system to use to ensure cycle efficacy. However, achieving microbial kill in the cycle is dependent upon the physical parameters of the cycle. One of the most important physical parameter is temperature, which is how heat is delivered to the items being sterilized.

While some concepts of microbial lethality and microbial validation are presented in this book, the focus of the book is the physical validation. Since the main physical parameter being evaluated is temperature, this is also known as thermal validation.

The various authors cited in this book have a wealth of practical experience in thermal validation of moist heat sterilization processes that has been incorporated into their writing.

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