

Steam Sterilization and Autoclave Performance Qualification

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Abstract: Steam Sterilization and Autoclave Performance Qualification

Purpose: To provide an overview of microbiology principles in steam sterilization and application, as well as autoclave Performance Qualification regulatory expectations and cGMPs.

Overview: Successful autoclave Performance Qualification starts with a fundamental understanding of steam sterilization microbiology. In this presentation, the steam sterilization mechanism is described as it relates to bacterial cells and endospores. The process and key terminology are defined. Understanding these fundamentals is critical to develop a successful autoclave sterilization process.

Sterilization process parameters are laid out as a basis for conducting autoclave performance qualification studies. Whether qualifying a new autoclave installation or continuing maintenance of existing equipment, there are specific expectations for steam sterilization that must be met.

Regulatory references requiring use of air removal verification tools, chemical indicators and biological indicators are provided, along with definitions for sterility assurance level, accumulated lethality, temperature mapping and biological verification.

Common questions and hot topics in industry are presented to demonstrate the practical application of understanding steam sterilization. These points exemplify how the knowledge allows for efficient troubleshooting of unexpected events and for improving processes in an autoclave.

Key Points:

- Steam sterilization on a microbial level
- Autoclave Performance Qualification expectations

- Regulatory and GMP requirements for steam sterilization
- Process verification tools for use in an autoclave
- Common questions, problems and cGMPs