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Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance

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Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance Task Force

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Table of Contents

FIGURES AND TABLES INDEX

1.0 Introduction

Moist Heat Sterilization is a process that uses moist heat as the lethal agent to render liquid and porous/hard goods items free of viable microorganisms. There are two main types of processes used in moist heat sterilization: saturated steam sterilization and air overpressure sterilization. Saturated steam sterilization is used primarily for porous, hard goods loads, while air overpressure is used for liquid loads.

Sterilizers are used to sterilize many types of articles, including:

- Porous/hard goods, e.g., equipment, tools, laboratory glassware, product components, packaging, or devices
- Product components that are not part of a porous or liquid load, e.g., vials and syringes
- Cleaning materials and product intermediates
- Product in final containers (terminal sterilization)
- Heat labile media
- Biological solutions and products, equipment, tools

Air over-pressure applications are used to minimize destruction or distortion of plastic containers or syringes containing liquids.

The primary objective of the task force was to develop a science based technical report on moist heat sterilizers that may be used in all regulatory environments and can be used by organizations to develop their own program for equipment qualification. To this end, prescription has been avoided, and region-specific regulatory expectations are not always addressed. This report should be considered a guide and is not intended to establish standards for sterilization systems. It is intended to be a single-source overview that complements existing documents listed in the reference section. References to appropriate and up-to-date scientific publications, international regulatory documents, journal articles, technical papers and books are used where more detail and supportive data can be found.

The task force was composed of European and North American industry professionals to ensure the methods, terminology and practices of sterilization science presented reflect sound science and can be used globally. This technical report was disseminated in draft for public review and comment.

1.1 Purpose / Scope

This Technical Report addresses moist heat sterilizers intended for use in the pharmaceutical, medical device and biotechnology industries. This technical report focuses on the design and operation of moist heat sterilizers, from the development of User Requirements Specifications (URS) through equipment qualification (Installation Qualification (IQ)/Operational Qualification (OQ)) and culminating with ongoing maintenance requirements. The focus of this report does not include Performance Qualification (PQ). The reader is directed to *PDA Technical Report No. 1: Validation of Moist Heat Sterilization Processes Cycle Design, Development, Qualification and Ongoing Control* for discussion of load cycle development and process Performance Qualification. ***(1)***

This technical report addresses:

- Setting User Requirements and Specifications
- Design Qualification (DQ)
- Equipment and Control System Design
- Functional Requirements for the moist heat sterilizer and expectations for utilities supporting the sterilizer