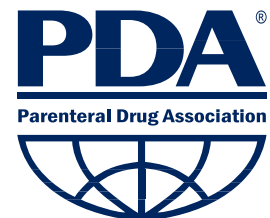


Technical Report No. 61

Steam In Place

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PDA Technical Report No. 61: Steam in Place Task Force Members

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The Steam in Place Task Force would like to dedicate this technical report in memory of Lance Morien.

The content and views expressed in this Technical Report are the result of a consensus achieved by the authorizing Task Force and are not necessarily views of the organizations they represent.

Steam In Place

Technical Report No. 61

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1.0 Introduction

PDA Technical Report No. 1, *Validation of Moist Heat Sterilization Processes: Cycle Design, Development, Qualification and Ongoing Control*, updated in 2007, focuses on the microbiology and engineering concepts of moist heat sterilization and the general approach to sterilization science in batch sterilizers (autoclaves) (1). This technical report is intended to complement PDA Technical Report No. 1 and will focus on steam in place (SIP) processes.

The primary objective of the task force responsible for this technical report was to develop a scientific technical report on SIP processes that provides recommendations for use by industry and regulators. References to appropriate and up-to-date scientific publications, international regulatory documents, journal articles, technical papers, and books are used to provide more detail and supportive data that can be found.

Steam in Place was chosen as the title because this document focuses on the various applications of steam for in situ sterilization for “sterile” applications and for in situ sanitization and other bioburden control applications widely used for systems that do not claim to be “sterilized” via steam. We also differentiate “steam in place” from the more generic term “sterilize in place” used to describe in situ sterilization using various types of gaseous or liquid sterilizing agents including steam (1).

The task force was composed of European, North American, and South American industry professionals to ensure the methods, terminology, and practices of SIP reflect sound science and can be applied globally. This technical report was disseminated for public review and comment prior to publication, to provide the widest possible review and ensure its suitability as a guide to industry.

SIP is often a pivotal step of aseptic processing for sterile product manufacture, and as such, may benefit from the application of risk management methodologies. The characterization, evaluation, and assessment of risk are useful to direct overall effort for cycle development and subsequent validation. After development of a risk assessment, more resources can be focused on mitigating risk for systems, equipment, or processes that have the highest potential for product contamination. The management of risk may be employed throughout the lifecycle of SIP equipment and processes to efficiently focus and allocate resources commensurate with the probability of impacting final product purity and safety. Descriptions of the specific steps and tools for risk management are available from a variety of sources (2,3).

1.1 Scope

The scope of this technical report is limited to discussion of SIP processes that provide moist heat sterilization and/or sanitization of equipment and systems supporting the manufacture of medicinal products. The principles discussed in this report may also be applied to those systems where portable equipment is steamed at a fixed station (steam out of place).

Application of the concepts presented in this technical report to laboratories or other non-CGMP applications, including hospitals, is not intended.

The following concepts are out of scope:

- Clean-in-Place (except where related to SIP)
- In situ media sterilization
- Product Sterilization
- Design and qualification of utilities