PDA Technical Series: Sterilization

Compilation of Technical Reports and Journal Articles on Pharmaceutical Sterilization

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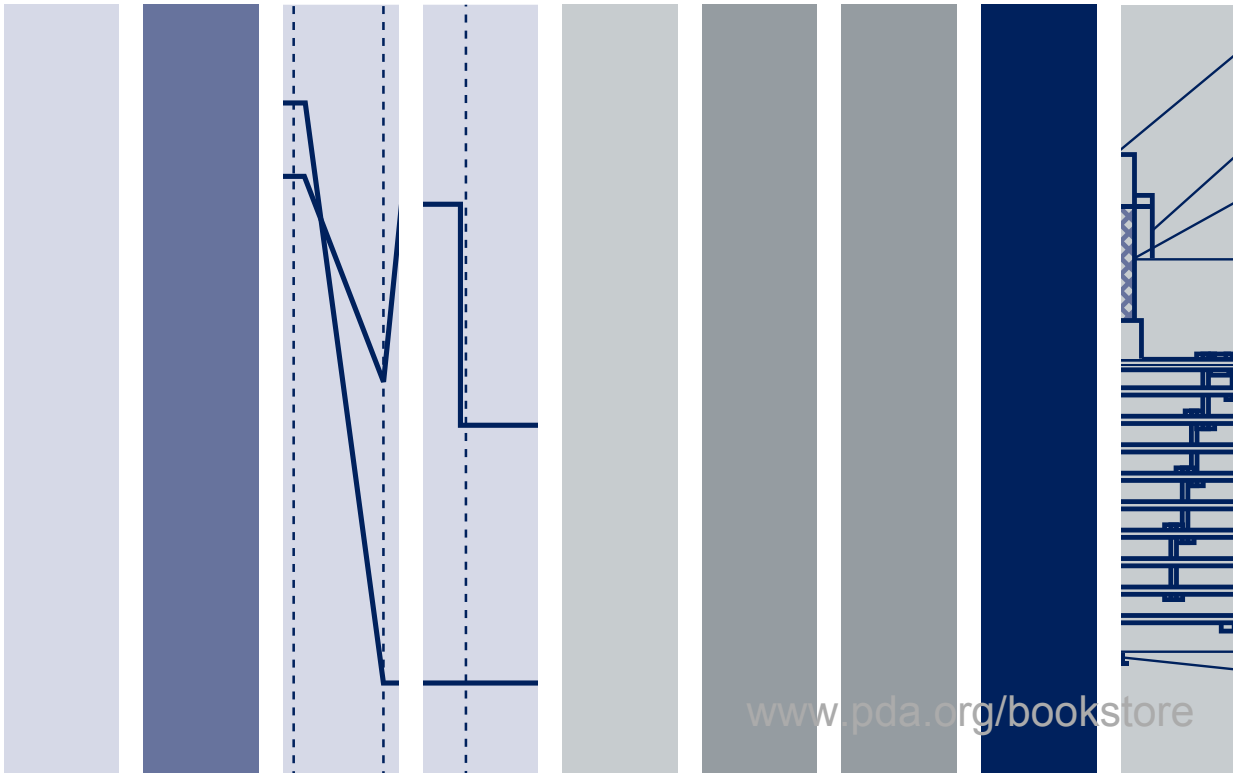
Parenteral Drug Association



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Compilation of Technical Reports and Journal Articles on Pharmaceutical Sterilization

Validation of Moist Heat Sterilization Processes:
Cycle Design, Development, Qualification and Ongoing Control
Technical Report No. 1

Validation of Dry Heat Processes Used for Depyrogenation and Sterilization
Technical Report No. 3 (Revised 2013)

Parametric Release of Pharmaceutical and Medical Device Products
Terminally Sterilized by Moist Heat
Technical Report No. 30 (Revised 2012)

Moist Heat Sterilizer Systems:
Design, Commissioning, Operation, Qualification and Maintenance
Technical Report No. 48

Steam In Place
Technical Report No. 61

Selected Articles from the *PDA Journal of Pharmaceutical Science Technology*

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Parenteral Drug Association, Inc.
4350 East West Highway, Suite 200
Bethesda, MD 20814
tel: 1+ (301) 656-5900 fax: 1+ (301) 986-0296

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Foreword

A core area of focus for PDA's membership is sterilization of pharmaceutical products. The very first technical guidance written by PDA members was on best practices for the validation of moist heat sterilization processes (PDA Technical Monograph No. 1), published in 1977. This document was updated and published as PDA Technical Report No. 1 in 2007. It serves as the basis for all subsequent sterilization-related technical reports published by PDA. Technical Report No. 1 and related technical reports draw on the expertise of industrial sterilization leaders who have participated in PDA for the past four decades.

PDA Technical Series: Sterilization Processes – A Compilation of Technical Reports on Sterilization provides readers a convenient, one-stop reference for the following five PDA Technical Reports:

- *Technical Report No. 1 (Revised 2007): Validation of Moist Heat Sterilization Processes: Cycle, Design, Development, Qualification and Ongoing Control*
- *Technical Report No. 3 (Revised 2013): Validation of Dry Heat Processes used for Depyrogenation and Sterilization*
- *Technical Report No. 30 (Revised 2012): Parametric Release of Pharmaceutical and Medical Device Products Terminally Sterilized by Moist Heat*
- *Technical Report No. 48: Moist Heat Sterilizer Systems: Design, Commissioning, Operation, Qualification and Maintenance*
- *Technical Report No. 61: Steam in Place*

Drafted by all-volunteer Task Forces of PDA members and subject matter experts with expertise in the design, validation and operation of sterilization processes commonly used in pharmaceutical/biopharmaceutical manufacturing, these best-practices documents are essential tools for anyone involved in the manufacturing of sterilized products.

This book also includes related articles from the *PDA Journal of Pharmaceutical Science and Technology*. Articles are grouped with the relevant Technical Reports, when appropriate. Some of the articles are referenced in the Technical Reports. The final chapter includes Journal articles on alternative sterilization methods.

A NOTE ON PDA TECHNICAL REPORTS

PDA Technical Reports are global consensus documents, prepared by member-driven Task Forces comprised of content experts, including scientists and engineers working in the pharmaceutical/biopharmaceutical industry, regulatory authorities and academia. While in development, PDA Technical Reports are subjected to a global review of PDA members and other subject-matter experts, often including regulatory officials. Comments from this global review are then considered by the authoring Task Force during preparation of the final working draft. The level of expertise of Task Force members and those participating in the global review ensure a broad perspective reflecting best thinking and practices currently available.

The final working draft is next reviewed by the PDA Advisory Board or Boards that sanctioned the project. PDA's Advisory Boards are: Science Advisory Board, Biotechnology Advisory Board, Regulatory Affairs and Quality Committee, and Audit Guidance Advisory Board. Following this stage of review, the PDA Board of Directors conducts the final review and determines whether to publish or not publish the document as an official PDA Technical Report.

Walter Morris
Director of Publishing
PDA, Inc.

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