Technical Report No. 3 (Revised 2013)

Validation of Dry Heat Processes Used for Depyrogenation and Sterilization

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PDA Validation of Dry Heat Processes Used for Depyrogenation and Sterilization Technical Report Team

Authors

Deborah A. Havlik, Hospira, Inc., Technical Report Team Leader

Bruce Bear, Bear Consulting Services

Stewart M. Davenport, Pfizer, Inc.

Mike Davies, Lonza Biologics, UK

Steve B. Folio, Althea Technologies

Jill K. Giulianelli, West-Ward Pharmaceuticals

Brian G. Jordan, Valsource, LLC

Peter S. Lee, Mattell Inc.

Hans Melgaard, Despatch Industries

Christian G. Supina, Baxter Healthcare Corporation

Rita Welser, Boehringer Ingelheim, Germany

Robyn F. Wong, Celgene Corporation

Contributor

James F. Cooper, Consultant

Disclaimer: The content and views expressed in this Technical Report are the result of a consensus achieved by the Technical Report Team and are not necessarily views of the organizations they represent.

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1.0 Introduction

This technical report is an update of PDA's *Technical Report No. 3, Validation of Dry Heat Processes used for Sterilization and Depyrogenation* which was issued in 1981. The technical report focuses on the microbiology and engineering qualification of dry-heat sterilization and depyrogenation processes and the general approach to sterilization and depyrogenation science in batch and continuous sterilizers (ovens and tunnels). This technical report is based on standard depyrogenation and sterilization science.

The primary objective of the Technical Report Team was to develop a scientific technical report on dry-heat depyrogenation and sterilization processes that provides recommendations for use by industry and regulators. References to appropriate and current scientific publications, international regulatory documents, journal articles, technical papers and books are used where more detail and supportive data can be found.

The Technical Report Team is composed of diverse international team of professionals to ensure the methods, terminology and practices of dry-heat depyrogenation and sterilization processes reflect sound science and can be used globally. This technical report was disseminated in draft for public review and comment prior to publication to ensure its suitability as a recommendation of best practices to industry.

1.1 Purpose and Scope

This technical report provides information to the manufacturers of pharmaceutical products for validating dry-heat depyrogenation and sterilization processes. The concepts and methods presented within this technical report are not intended to be a regulatory standard, but rather as points to be considered during the validation of dry-heat processes. Other technically equivalent methods may exist and may be used if they can be supported by sound scientific methods.

This technical report is intended to give information about current industry practices and approaches to validating dry-heat depyrogenation and sterilization processes. In addition, sections will cover various aspects of dry-heat sterilization using biological indicators.

This technical report is organized in a chronological fashion, starting with a discussion of the general concepts of depyrogenation and sterilization science which are the foundation upon which to build a robust process. This includes use of biological indicators and endotoxin indicators. Also included are points to consider in equipment design, equipment verification, process development and performance qualification for new systems and the development and validation of processes for existing systems.

In the discussion of process development, particular attention has been given to the load type, loading patterns, and temperature profiles for depyrogenation and sterilization in both ovens and tunnels. The sections are followed by a brief discussion of items for consideration during routine processing and ongoing maintenance of the validated process.

The background sections on depyrogenation/sterilization science and endotoxin/biological indicators are not comprehensive—but provide information specific to dry-heat processes. Information within the technical report is applicable to both forced hot air dry-heat batch processes (chambers) and to continuous processes (tunnels). Information within this technical report does not apply to dry-heat processes used for the sterilization of oil bases and oil based products, fixed processing streams or to those processes using infrared and microwave heating media.

