Technical Report No. 51 Biological Indicators for Gas and Vapor-Phase Decontamination Processes: Specification, Manufacture, Control and Use

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Biological Indicators Task Force

Authors

Tim Coles, Pharminox Isolation (Cambridge) Ltd.

James Drinkwater, Bioquell (UK) Ltd.

Mike Edgington (Deceased)

Neil Grumbridge, Consultant (formerly with the UK Health Protection Agency)

Jon Nottingham, Cape Europe Ltd.

Emmanuelle Sansoë-Bourget, Altran AG Switzerland

Graham Steele, Ph.D., University of Bedfordshire

David Watling, Ph.D., Bioquell (UK) Ltd.

Contributors

Caroline Coles, B.A., Pharminox Isolation (Cambridge) Ltd.

Joseph Dalmasso, Ph.D., Apex Laboratories

Stewart Davenport, Pfizer

Kathryn Davies, B.Sc.

Didier Meyer, Getinge Life Sciences

Brian Midcalf, Ph.D., University of Leeds

Jeanne Moldenhauer, Excellent Pharma Consultants

David Morley

Murray Nicholson, Steris

Doug Thorogood, Ph.D., Eurostar

Ian Thrussell, MHRA

Peter White, Ph.D., Nova Pharmaceuticals

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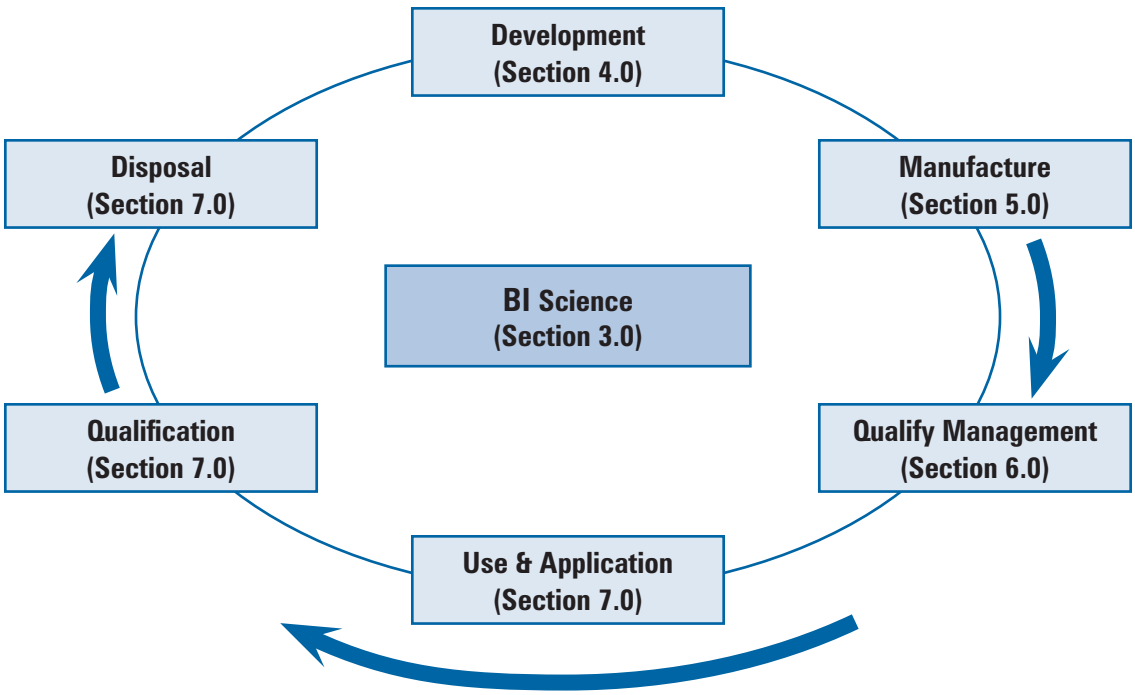
1.0 Introduction

Biological Indicators (BIs) are used during cycle development and the qualification of processes in which sterilization, sanitization, or decontamination is claimed. BIs currently are considered the only available tool capable of integrating the results of many parameters involved in achieving target kill at representative points throughout an enclosed space. These guidelines relate to sporicidal gas and vapor-phase decontamination processes where biological decontamination of surfaces inside contained volume areas is conducted. These areas include isolators, cleanrooms, containment rooms, and separative enclosures/devices. Some of these principles, however, may be applicable to the use of BIs for other processes.

This technical report provides a comprehensive review of an area not adequately addressed in current guidance documents. The report is intended to provide recommended specifications for BIs to be used with sporicidal gas and vapor-phase decontamination cycles together with guidance regarding their manufacture, quality control, and use. The principles described in this report are based upon the manufacture and use of BIs prepared from spore suspensions; however, they can be equally applied to the preparation of BIs from other sources.

Figure 1.0-1 illustrates processes regarding the science of BIs and specifications discussed in this report. Each subsequent process is then described, beginning with development and proceeding through manufacture, quality management, qualification, use, and disposal.

Figure 1.0-1 Biological Indicator Lifecycle



PDA requested the formation of a task force to develop a comprehensive set of guidelines to address the manufacture and use of BIs for sporicidal vapor-phase decontamination processes. The task force was composed of European BI manufacturers, academia, members of the pharmaceutical industry, and regulatory professionals. This report underwent a global technical peer review that included feedback from North America and Europe. References to regulatory documents, standards, and scientific publications are included to provide more detail and supportive data.

