The Bacterial Endotoxins Test:
A Practical Approach

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FOREWORD

Scott Sutton

It is an honor to have been asked to write the foreword to this important book on the Bacterial Endotoxins Test. This volume is significant not only because of the timing of the work, coming as the field is in a state of flux with new technologies and new regulations, but also because of its practical, bench-level focus.

There are several books available on the Bacterial Endotoxins Test. Some approach it from an ecological perspective, focusing on the horseshoe crab and the impact that farming is having on its population. Others address the topic from a clinical and chemical perspective, heavy on theory and academic considerations. These are valuable contributions to the literature and their review is recommended for anyone who wishes a broad grounding in the development and science of the test. However, they are not directed specifically at the needs of the lab worker in regulated industries. In fact, this book is one of a very limited number of technically competent works directed to the QC lab worker in any topic and for that reason alone warrants a place on the serious quality professional's bookshelf.

Even beyond this consideration, it has to be noted that it is difficult to bring a diverse group of workers together and produce a book that is readable and technically challenging at the same time. The top-rank authors assembled herein have produced such a book, and done it without yielding to the temptation of promoting their own products. This is especially noteworthy in that most of the authors work for companies that are in direct competition with each other, and are generally not shy about disagreeing with each other. The discussions in this book are remarkable in the absence of commercial promotion — science and technical methodology take center stage throughout.

Enjoy the time you spend with this book. It won't really matter if you are looking for a historical perspective on the development of the test or an explanation of exactly why the y-intercept is an important consideration of the standard curve, you will almost certainly learn something new about the bacterial endotoxin test and the role it plays in QC operations in pharma, biopharma, medical devices and all healthcare-related regulated industries

Scott Sutton, Ph.D.
Microbiology Network, Inc.
April, 2011

AUTHOR'S PREFACE

Welcome.

The goal of this book is to provide sensible and useful information for those who are responsible for the performance and interpretation of the Bacterial Endotoxins Test (BET). The concept was to create a user-friendly reference tool for BET analysts, laboratory managers and regulatory/compliance specialists that is part lab manual, part textbook, part tutorial, and part non-commercial consultant.

For those laboratories new to BET, this book lays a solid foundation by providing information and tips for qualifying the laboratory, calculating endotoxin limits, verifying USP test methodology, resolving test interferences and performing routine tests for parenteral drugs, biologics and medical devices.

For those laboratories that are experienced in BET, this book builds on basic testing requirements by discussing topics such as

setting endotoxin limits for noncompendial articles, structuring a depyrogenation study, setting action and alert limits and identifying endotoxin-specific critical control points in manufacturing.

The content of this book represents an amazing 200+ author-years of experience in the field. With many thanks to Alan Baines, Ron Berzofsky, Jim Cooper, Mick Dawson, John Dubczak and Marilyn Gould for their extraordinary contributions to this effort, their remarkable perspective and their expert sage advice, I hope that the information in this book will help everyone to take a practical approach to the Bacterial Endotoxins Test.

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April, 2011