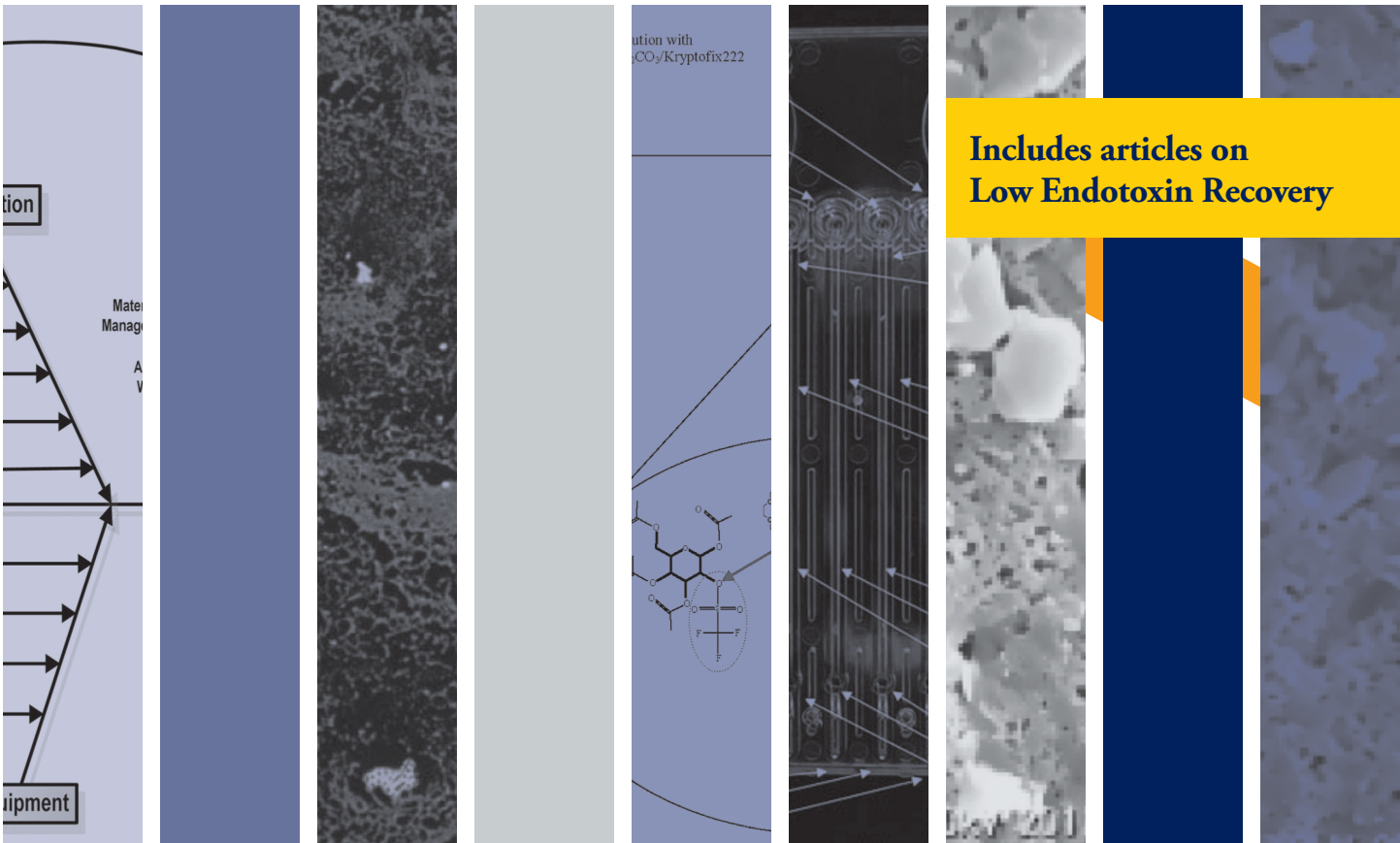
PDA Technical Series:
Endotoxin Analysis and Risk Management

Parenteral Drug Association



Includes articles on Low Endotoxin Recovery

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PDA Technical Series — Endotoxin Analysis and Risk Management

Foreword

PDA Technical Series: Endotoxin Analysis and Risk Management is a collection of published research on the topic from the *PDA Journal of Pharmaceutical Science and Technology*. The importance of endotoxin testing to the PDA community of pharmaceutical and biopharmaceutical manufacturers was summarized nicely by Richard Johnson, PDA President & CEO in the Foreword to *Technical Report No. 82: Low Endotoxin Recovery* (March 2019):

> *The reliable and sensitive detection of bacterial endotoxin is a key test underpinning patient safety in the manufacturing of parenteral drugs. The globally harmonized compendial tests linked to well-characterized reference standards have provided this assurance to industry and regulators for decades despite the complex nature of both the assays and the reference materials. This complexity has been demonstrated each time new assay approaches or reference materials have been proposed. Over the past decade, biologics manufacturing has exploded, and new products, formulations, and delivery systems continue to push the boundaries of modern manufacturing.*

Based on this, the number and quality of scientific manuscripts contributed to the *PDA Journal* on this topic should be of no surprise. This volume is intended for those in the industry who perform and/or are responsible for the quality testing and manufacture of biopharmaceutical products. For those concerned with the phenomenon of "Low Endotoxin Recovery," two articles have been published in the *PDA Journal* that cover the issue, both of which were referenced in the aforementioned *Technical Report No. 82.* This volume, plus the technical report, represent the entirety of authoritative knowledge and guidance on the subjects of endotoxin testing, risk management, and LER available from PDA.

The articles contained in this book are unedited and unaltered from their original format.

Walter Morris
Director of Publishing
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