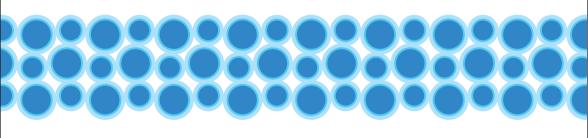
CLEANROOM CONTAMINATION PREVENTION & CONTROL

A PRACTICAL GUIDE TO THE SCIENCE



Ziva Abraham Morgan Polen Editors

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Cleanroom Contamination Prevention & Control

A Practical Guide
To the Science

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PREFACE

As the Head of Operations at Microrite, the repeat requests for investigating similar contamination issues, warning letter remediation and product failure issues made me recognize that all these scenarios have one thing in common. The commonality of these requests eluded to a basic knowledge gap in holistically addressing contamination control. Though the current regulatory thinking expects the evaluation of contamination control from a holistic perspective; the deficiency in understanding the sources of contamination and their relationship to subsequent steps in the manufacturing process was lacking.

This book is strategically arranged for evaluating contamination control holistically. As contamination control should be looked at from design, manufacturing and an operations perspective, subject matter experts, not generalists, in each area were approached to contribute to this valuable compilation of the following science based contamination control journey.

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The information in this book, which may be new to many readers will help ignite curiosity and ultimately understanding of what the sources of contamination can be and how to address contamination prevention, control and monitoring. The purpose of this book has been to create awareness and provide solutions. This book will become a contamination control audit if read, understood and applied.

Amir Abraham Vice President Microrite. Inc.