

# AGE OF REGULATION

SANDY WEINBERG

*Fast Trak BioDefense, GE Healthcare  
Atlantic, Georgia*

GERALD J. WHARTENBY

*Regulatory Consultant for GE Healthcare  
Philadelphia, Pennsylvania*

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## 1 INTRODUCTION

In examining regulations, often it is easy to become inundated with the complexity of existing rules and regulations. Like being in a maze, we travel through the twist and turns of current Food and Drug Administration (FDA) regulations often leading us in directions where a clear path is difficult to find. The number, import, and intricacy of the U.S. FDA regulations, requirements, guidelines, and draft documents are often so overwhelming as to make it difficult to see the underlying ideology that directs so many FDA measures.

As we travel this maze of regulations, there are three underlying precepts that together provide a foundation for and an understanding of all the myriad