PREFACE

Delphi Analytical Services, Inc. has spent the last several years helping companies in the pharmaceutical industry improve their level of compliance with current good manufacturing practices (CGMPs). This involvement has included large and small companies who have already been subject to regulatory action from the U.S. Food and Drug Administration (FDA) as well as companies who are taking preventative measures to avoid regulatory action. As part of this effort, a significant amount of time has been spent reviewing the quality systems associated with analytical laboratories.

The FDA mandates that a drug firm and its laboratory be operated in a state of control by employing conditions and practices that assure compliance with the intent of the Federal Food, Drug, and Cosmetic Act and portions of the CGMP regulations that pertain to it. Specifically, a laboratory, which is in a state of control, provides services that confirm the company is producing finished drug products of sufficient quality, known strength, proper identity, and known purity.

In order to demonstrate that your firm is in control, data are need to support your position. These data are obtained by executing a well organized and systematic laboratory audit.

In addition to demonstrating current control, you must show that you will be in control in the future. Therefore, you must also demonstrate you have a system in place to continually monitor the status of compliance within your laboratory and correct deficiencies if they are discovered.

Establishing a CGMP Laboratory Audit System: A Practical Guide is a systematic approach for auditing your laboratory to demonstrate to your
organization and, ultimately, to the FDA, that you are in control of your laboratory system. In addition, this guide helps you accomplish the goal of establishing sustainable compliance within your laboratory. This text is a “how to” book—how to establish a current good manufacturing practices (CGMP) laboratory audit system. The intended purpose of the book is to instruct through detailed flowcharts, checklists, and descriptions, the process of establishing a CGMP laboratory audit system from scratch or to upgrade existing systems to comply with current industry practices. Moreover, this process is an excellent means to teach or refresh laboratory personnel on the nuances of operating a modern pharmaceutical laboratory under CGMPs.

Specifically designed for laboratories regulated by the U.S. government, this guide is useful for:

- Facilities operating under current good manufacturing practices (CGMPs)
- Facilities operating under current good laboratory practices (CGLPs)
- Facilities operating under ISO standards.

However, any laboratory can benefit from the level of control obtained by the guide and the corresponding incremental gains in efficiency and productivity from implementing such a system.

This guide is not an academic treatise, but a collection of real-world tools, that can be applied immediately and directly to your laboratory. Some unique and special features presented include:

- Detailed audit checklists corresponding to the seven subelements which compose the laboratory control system
- A real-world audit summary report example template
- The current FDA guidance document on the subject of drug manufacturer inspections
- Audit tools and templates, such as suggested meeting agendas, audit routines, audit calendars, and data capture forms.

All of these tools and others are provided on a CD-ROM, which accompanies this book, for easy application by the end users in their own laboratories. Moreover, these tools and templates are provided in readily modifiable formats so that they maybe tailored to fit the needs of the individual organization. The inclusion of these practical tools makes this guide unique. It would require untold personnel hours to develop these checklists and example templates individually. In fact in smaller organizations, the time, talent, and experience to create such tools is most likely outside their capabilities.
To my knowledge no such detailed instructional text for implementing CGMP laboratory quality systems (including detailed example templates of critical end-user documents) exists in the marketplace. I hope you find *Establishing a CGMP Laboratory Audit System: A Practical Guide* useful and wish you the best in your continuing quest to attain compliance and improve quality.

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