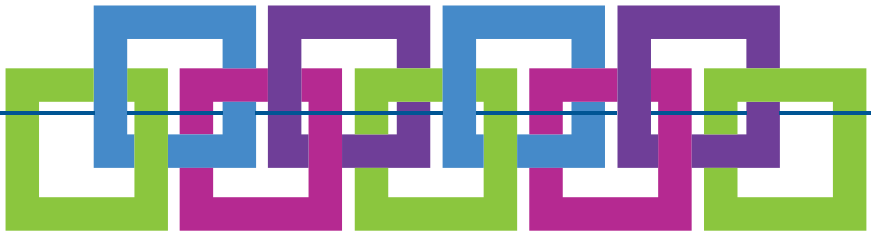
Recent Warning Letters

Review for Preparation of a Non-Sterile Processing Inspection

Volume 2



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Review for Preparation of a Non-Sterile Processing Inspection

Volume 2

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DHI Publishing, LLC
River Grove, IL, USA

10 9 8 7 6 5 4 3 2 1

ISBN: 1-933722-47-9

This book is printed on sustainable resource paper approved by the Forest Stewardship Council. The printer, Gasch Printing, is a member of the Green Press Initiative and all paper used is from SFI (Sustainable Forest Initiative) certified mills.

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4350 East West Highway
Suite 200
Bethesda, MD 20814
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Davis Healthcare International Publishing, LLC
2636 West Street
River Grove
IL 60171
United States
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ACKNOWLEDGEMENTS

Special thanks to Mr. John Kirchner whose request for a presentation on this topic lead to the research for this book series.

Thanks also to Mr. J. Edgar Guerzon who provided specific research contributions for this book series.

INTRODUCTION

Notice that a scheduled regulatory inspection can create a hectic environment, with many levels of management concerned with how well the site will perform during the inspection. Prior to 2000, it was common for the inspections to be focused around the products currently close to decision on approvability at the main Food and Drug Administration (FDA) headquarters. If there had been recent recalls these products would also be the focus of the inspection. Knowing this information typically resulted in many activities to ensure that the documentation related to these products was as "perfect" as possible for the inspection. In some cases, there may have been problems in other areas of the facility that may not have been covered in the inspection.

FDA published its initial draft compliance policy guidance on S*ystems Based Inspections of Pharmaceutical Facilities* (FDA, 2002). This new program changed how FDA conducted and evaluated the performance of manufacturing sites. The six systems review approach evaluated as a whole whether the site was operating in a state of control. With this type of inspection, any one of the six systems being out of control is indicative of the site not operating in a state of control. It is more difficult to prepare for this type of inspection since there is a lack of knowledge on the products which will be the focus of the inspector, many companies do not use a systematic approach when establishing their systems, too many different products are manufactured at the site to ensure that all are checked and prepared for the inspection, and so forth. This guidance was subsequently formally issued.

A good way to prepare for inspections is to look at the difficulties others have had during inspections. The FDA publishes Warning Letters in its Electronic Reading Room available on its website (*www.fda.gov*). Review of the available Warning Letters observations allows you to identify areas of focus and interest for investigators, some of the types of issues deemed important by the investigator, and potential issues that may be applicable at one's own site. This book provides an overview of some of the issues in recent Warning Letters issued by FDA for non-sterile pharmaceutical processes. Included are Warning Letters issued during the time period from 2000 through mid-2010.