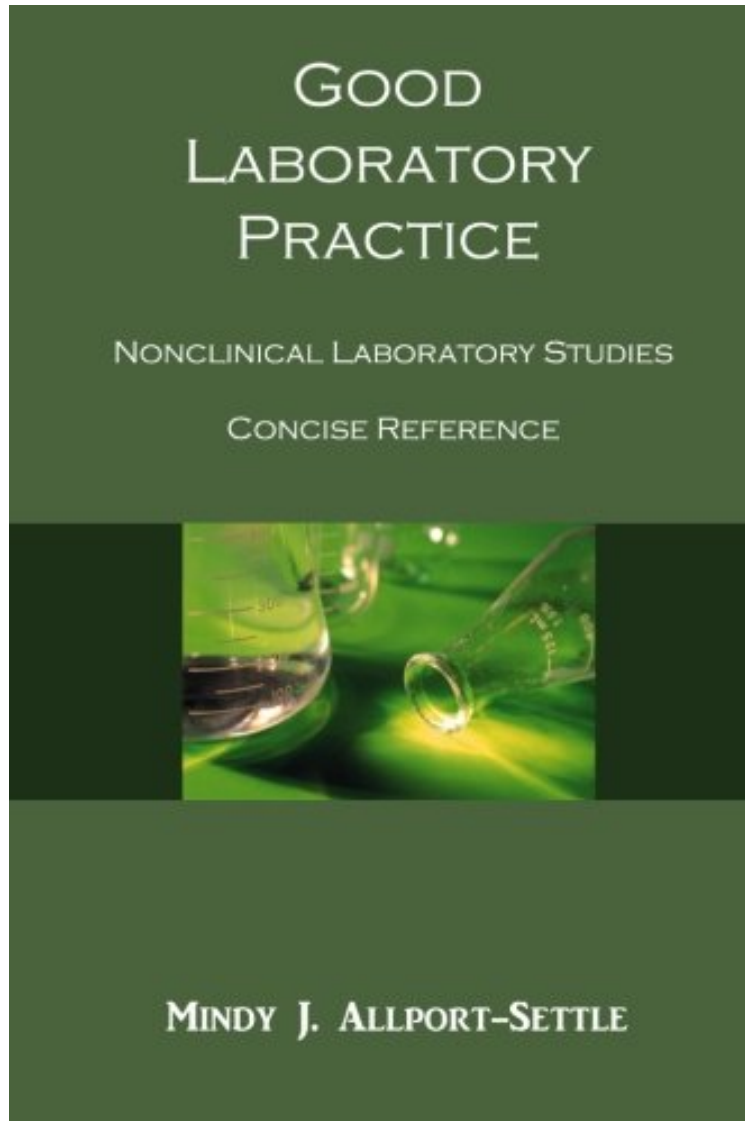


# Good Laboratory Practice: Nonclinical Laboratory Studies Concise Reference

*Mindy J. Allport-Settle*

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This book is designed to be a unified reference source for the U.S. Food and Drug Administration's Good Laboratory Practice regulations, guidance, and associated documents for pharmaceutical, biologics and medical device products nonclinical trials. Good Laboratory Practice Regulations and Guidance: \* FDA Overview and Orientation \* Overview of GCP and Introduction to GLP \* Part I: Federal Regulations Relating to Good Laboratory Practice o Parts 58: Good Laboratory Practice for Nonclinical Laboratory Studies o 1987 Final Rule - Good Laboratory Practice Regulations \* Part II: Guidance Documents o Bioresearch Monitoring Good Laboratory Practice o Good Laboratory Practices Questions and Answers \* Part III: Redbook 2000 o IV.B.1 General Guidelines for Designing and Conducting Toxicity Studies o IV.B.2 Guidelines for Reporting the Results of Toxicity Studies Reference Tools \* Part IV: Combined Glossary and Index

About the AuthorMindy Allport-Settle has served as a key executive, board member, and consultant for some of the best companies in the pharmaceutical, medical device, and biotechnology industry. She has provided guidance in regulatory compliance, corporate structuring, restructuring and turnarounds, new drug submissions, research and development and product commercialization strategies, operational, project and contract management, and new business development. Her experience and dedication have resulted in international recognition as the developer of the only FDA-recognized and benchmarked quality systems training and development business methodology. Her education includes a Bachelor's degree from the University of North Carolina, an MBA in Global Management from the University of Phoenix, and completion of the corporate governance course series in audit committees, compensation committees, and board effectiveness at Harvard Business School.