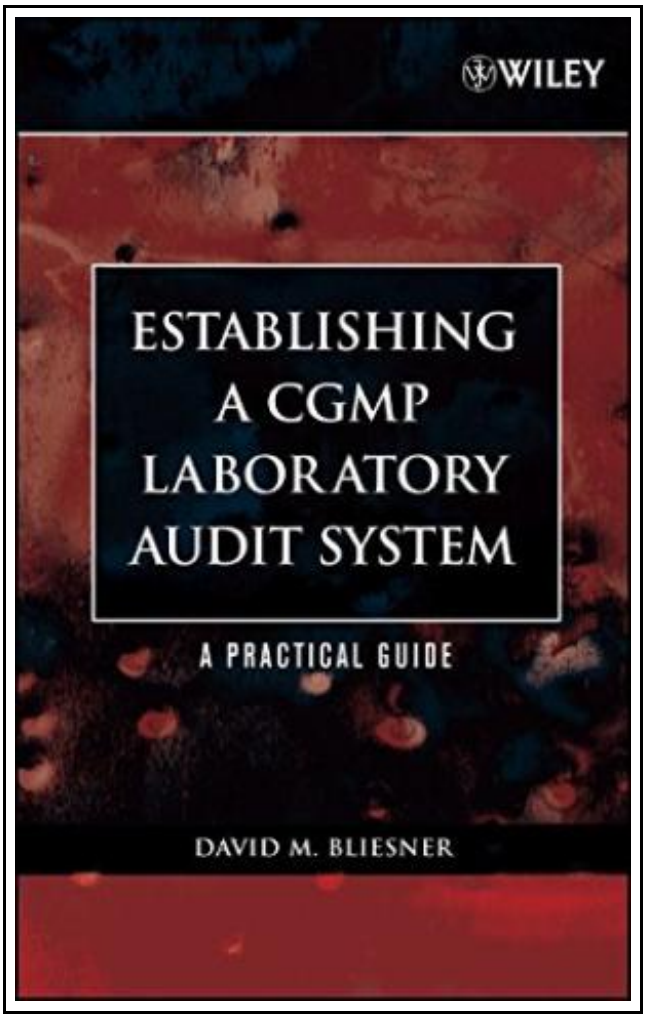
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ESTABLISHING A CGMP LABORATORY AUDIT SYSTEM: A PRACTICAL GUIDE

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John Wiley and Sons Ltd. Hardback. Book Condition: new. BRAND NEW, Establishing a CGMP Laboratory Audit System: A Practical Guide, David M. Bliesner, The first systematic, hands-on auditing guide for today's pharmaceutical laboratories In today's litigious environment, pharmaceutical laboratories are subject to ever stricter operational guidelines as mandated by the FDA, and must be able to establish and demonstrate sustainable operational practices that ensure compliance with the current good manufacturing practice (CGMP) regulations. David Bliesner's Establishing a CGMP Laboratory Audit System: A Practical Guide is designed to provide laboratory supervisors and personnel with a step-by-step, hands-on audit system that they can rely on to ensure their facility remains compliant with all current and future requirements. Focusing on a "team approach," the author uses detailed flowcharts, checklists, and descriptions of the auditing process to help readers develop a new audit system or upgrade their current system in order to: Improve current compliance Demonstrate sustainable compliance Produce data for federal inspections Avoid regulatory action Enhanced with detailed checklists and a wealth of practical and flexible auditing tools on CD-ROM, this book provides an ideal resource for new and future laboratory personnel, and an excellent means for keeping existing industry practitioners up to date on the nuances of operating a consistently compliant pharmaceutical laboratory.

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