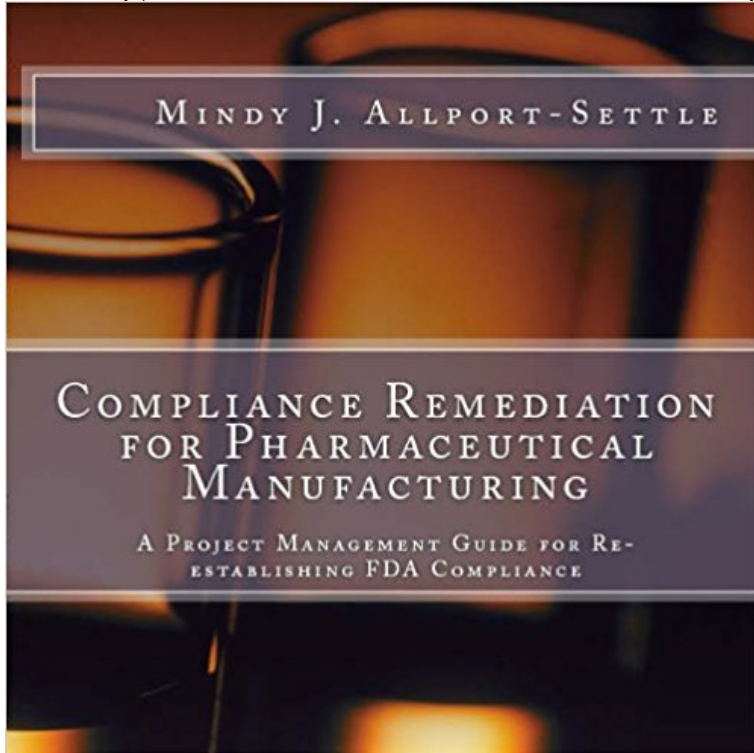


Compliance Remediation for Pharmaceutical Manufacturing: A Project Management Guide for Re-establishing FDA Compliance



Manage regulatory commitments, meet key deliverable dates, generate supporting data reports, support the financial forecasting process. This remediation project management guide provides a systematic approach to managing and tracking the multiple projects typically required to re-establish cGMP compliance. It emphasizes up-front planning for every aspect of site remediation and compliance upgrade by focusing on managing activities to a series of targeted milestones. Data-driven reports and documentation facilitate communication between the company and regulatory agencies on the path to quality compliance. This system is the benchmark process for leading regulatory compliance efforts and its successful implementation will create a platform for profitability for the company. Includes FDA reference documents.

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