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# CAPA in the Pharmaceutical and Biotech Industries: How to Implement an Effective Nine Step Program (Woodhead Publishing Series in Biomedicine)

*J Rodriguez*

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CAPA in the Pharmaceutical and Biotech Industries: How to Implement an Effective Nine Step Program contains the most current information on how to implement, develop, and maintain an effective Corrective Action and Preventive Action (CAPA) and investigation program using a nine step closed-loop process approach for medical devices and pharmaceutical and biologic manufacturers, as well as any anyone who has to maintain a quality system.This book addresses how companies often make the mistake of fixing problems in their processes by revising procedures or, more commonly, by retraining employees that may or may not have caused the problem. This event-focused fix leads to the false assumption that the errors have been eradicated and will be prevented in the future. The reality is that the causes of the failure were never actually determined, therefore the same problem will recur over and over. CAPA is a complete system that collects information regarding existing and potential quality problems. It analyzes and investigates the issues to identify the root cause of nonconformities. It is not just a quick-fix, simple approach, it is a process and has to be understood throughout organizations.

- Provides an understanding of the principles and techniques involved in the effective implementation of a CAPA program, from the identification of the problem, to the verification of preventive action
- Emphasis is placed on the practical aspects of how to perform failure investigations and root cause analysis through the use of several types of methodologies, all explained in detail
- Provides effective methods to use with a Corrective Action system to help quality professionals identify costly issues and resolve them quickly and appropriately

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