CAPA in the Pharmaceutical and Biotech Industries. Woodhead Publishing Series in Biomedicine

Description:  
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 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

Contents:  
Step-by-step basics on how to build a comprehensive CAPA program
How to use a nine step CAPA process to effectively handle any product or quality system failures
How to effectively use failure investigations and CAPA in order to handle, and process complaints investigations in a timely manner
How to effectively use risk management concepts to assign a risk level to failure investigations in order to prioritize based on risk
How to use Failure Mode and Effect Analysis to identify potential failure modes
How to review data from post production, and post market in order to determine the need for changes as well as new mitigations activities
Responding effectively to non-conformances, failures, deviations and complaints by identifying root causes and implementing corrective and preventative actions
Efficient use of root cause analysis tools
Optimizing CAPA and RCA documentation procedures
Essential SOPs and other documentation
Review areas of common FDA’s 483 inspection observations
How to effectively identify and track deviations and non-conformances
Learning to analyze and trend data to identify existing and potential causes of non-conformance
Gathering, organizing and managing the correct data required to conduct an effective Root Cause Investigation
Review the elements of a good investigation
Integrating RCA and CAPA with other systems such as: Internal auditing, deviations, Out Of Specification (OOS) and complaint handling
Performing trend analysis and using effective RCA tools
How to use of statistical methodologies when performing Root Cause Analysis
CAPA and the linkage to effective management review and annual product reviews
Step-by-step basics on how to build your own comprehensive CAPA program
Most important: Review of the real benefits of an effective CAPA system

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