HOW TO DESIGN A WORLD-CLASS Corrective Action Preventive Action SYSTEM FOR FDA-REGULATED INDUSTRIES: A HANDBOOK FOR QUALITY ENGINEERS AND QUALITY MANAGERS

David Muchemu

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The CAPA (Corrective Action/Preventive Action) Quality subsystem is the most audited by FDA inspectors. This book is designed to help Quality management professionals in Biomedical, Pharmaceutical, Tissue, and Medical Device industries design a CAPA Quality subsystem that meets and exceeds CAPA requirements in 21CFR 820.100(J).This book accomplishes the following:· Defines CAPA· Provides cross-functional process flows· Provides requirements for a CAPA system· Provides examples for the document hierarchy needed· Provides definitions for a CAPA system· Provides examples of work instructions, and standard operating procedures for a CAPA system.

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