



CHANGE CONTROL FOR FDA REGULATED INDUSTRIES: A RISK ASSESSMENT APPROACH

David Muchemu

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This book accomplishes the following: .It addresses requirements for Pharmaceutical,Medical Device,Biologics,and Tissue banking change control.Defines the different phases of the change control life cycle.Establishes the relationship between risk management,cost of doing business and change control.Defines regulatory requirements for change control,including requirements for (510k) submission.Provides tools for risk assesment,and cost/benefit analysis.Helps the reader design a Change control system that meets and exceeds cGMP requirements

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