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beyond the foundation level

this book explains the requirements for compliance with fda regulations and iso standards 9001 13485 for documented information controls and presents a methodology for compliance the document control system dcs or documented information control system dics is the foundation of a quality management system it is the first quality system element that must be implemented because the establishment and control of documented processes and information in a quality controlled environment is dependent on the ability to proactively manage access to documents and the movement of documents through the document life cycle a well developed document control system benefits business by improving knowledge retention and knowledge transfer within and across business units improving access to knowledge based information improving employee performance by providing standardized processes and communicating clear expectations improving customer communication and satisfaction by providing documented information from which common understanding can be achieved providing traceability of activities and documentation throughout the organization improving organization of and access to documents and data sample documents are included in the appendixes of this book to help clarify explanations and a full set of formatted procedures and document templates are available for download to get you off to an even faster start this book provides a process based approach that can be used for controlling all forms of documented information that are required to be managed under the quality management system

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