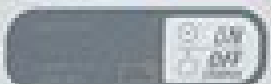
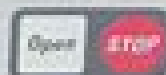
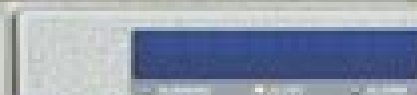




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management system or risk management principles and activities into their existing quality management system by providing practical explanations and examples The appropriate use of quality risk management can facilitate compliance with regulatory requirements such as good manufacturing practices or good laboratory practices The content of this book will provide FDA regulated manufacturers with a framework within which experience insight and judgment are applied systematically to manage the risks associated with their products Manufacturers in other industries may use it as an informative guidance in developing and maintaining a risk management system and process The two appendices add even more insight Appendix A contains general examples of risk management while Appendix B includes 10 case studies illustrating real examples of the quality risk management process across the medical product arena

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