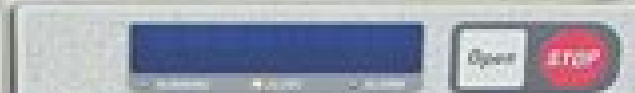




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of Critical Care Nursing Clinics of North America Shu-Fen Wung, 2018-05-11 Dr Wung is addressing an important component of critical care nursing the role of technology in patient care She has assembled top authors to provide current clinical information in the following areas Sensory overload and technology in critical care Alarm fatigue Nurse technology Interactions Safety steps to prevent Infusion errors Product design and medical devices for nurses Technologies to assess physiologic parameters hemodynamics cardio output Technologies to support hemodynamics e g balloon pump ECMO etc Interactive computer programs for application of critical thinking skills Information technology Electronic health records EHR Real time detection of clinical care deviations in ICU Medication safety technology and eICU iCARE Readers will come away with the updates they need to improve patient outcomes **Quality Risk Management in the FDA-Regulated**

Industry José Rodríguez Pérez, 2012-06-12 Risk management principles are effectively utilized in many areas of business and government including finance insurance occupational safety and public health and by agencies regulating these industries The U S Food and Drug Administration FDA and its worldwide counterparts are responsible for protecting public health by ensuring the safety and effectiveness of the drugs and medical devices Regulators must decide whether the benefits of a specific product for patients and users outweigh its risk while recognizing that absolute safety or zero risk is not achievable Every product and every process has an associated risk Although there are some examples of the use of quality risk management in the FDA regulated industry today they are limited and do not represent the full contribution that risk management has to offer The present FDA focus on risk based determination is requiring that the regulated industries improve dramatically their understanding and capability of hazard control concepts In addition the importance of quality systems has been recognized in the life sciences industry and it is becoming evident that quality risk management is a valuable component of an effective quality system The purpose of this book is to offer a systematic and very comprehensive approach to quality risk management It will assist medical and food product manufacturers with the integration of a risk

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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