Product Risk Management Under ISO 14971:2007

By **John E. Lincoln**

May 15, 2013 7:51 am EDT

ISO 14971:2007 requires the manufacturer of medical devices to make judgments relating to safety of the medical device, including the acceptability of risks, and provides a format and suggested tools to use in the identification of the hazards The risk management process includes the development of a company risk management plan. The risk management plan comprises senior management commitment, high-level strategic considerations, and product level considerations. The risk management process includes risk analysis, purpose, hazards, and risk estimation. These activities are addressed and...