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RISK MANAGEMENT PUBLIC TRAINING

Risk management has become increasingly important for medical device companies in the last few years, especially since the implementation of the revised ISO 14971 standard in 2007. ISO 14971:2007 is an integral part of a quality system and should be incorporated into the design and development process. It is recognized by the US Food and Drug Administration (FDA), Europe, Canada and Australia as the "de facto" standard for risk management.

The purpose of ISO 14971 is to establish, document and maintain a risk management process. This ISO 14971:2007 training class is conducted by a real world manufacturing experience, not professional "canned" presenters. This ensures that your team will get a high quality training session tailored to the needs of your organization.

This training will provide participants an in-depth appreciation of differences in philosophy of the risk management standard according to ISO 14971. This topic will enable participants to understand how risk management has to be performed and the common methods for risk assessment will be presented. Participants will learn the philosophy of risk management according to ISO 14971.

- Integration of risk management into an existing Quality Management System
- Regulatory and reporting requirements of the standard
- Conducting a review of the intended use of your device
- Modifying your design and development process to incorporate ISO 14971
- How to identify hazards in your product or production process, and estimating their severity
- Judging the probability that harm may occur from those hazards
- How to control those risks and monitor the effectiveness of the controls put into place
- How to comply with regulation standards