



Conformity Assessment to ISO 14971 A Key to the Kingdom

Charles Sidebottom

Secretary, ISO/IEC Joint Working Group on
Application of risk management to medical devices





Conformity Assessment to ISO 14971

✘ ISO 14971 is a management system standard that describes a life-cycle process that:

- ✦ begins with a concept and continues throughout the use of the device including decommissioning and disposal; and
- ✦ can exist as a stand-alone system; or
- ✦ can be integrated into a manufacturer's formal quality management system.



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✘ Beginning with a concept, risk management continues throughout the life cycle of the device:

- ✚ Planning
- ✚ Design and development
- ✚ Design and development verification
- ✚ Design and development validation
- ✚ Production and post-production monitoring



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- ✘ When implemented as a stand-alone system, ISO 14971:
 - ✚ Sets out the necessary top management responsibilities
 - ✚ Outlines the material to be included in a risk management file
 - ✚ Provides a fully auditable process suitable for either a supplier's declaration of conformity or a third party assessment



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- ✘ When implemented within the framework of a quality management system, ISO 14971:
 - ✚ Acknowledges the potential for, and even the desirability of, integrating risk management into a manufacturer's quality management system
 - ✚ Identifies activities that are outside a traditional view of quality management



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✘ Examples of challenges when integrating with a manufacturer's formal quality management system: :

✚ Management responsibilities:

- Establish a policy for determining criteria for risk acceptability

✚ Design and Development Planning:

- criteria for risk acceptability based on the manufacturer's policy



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✘ Examples of challenges when integrating with a manufacturer's formal quality management system:

✚ Measurement, analysis and improvement

- publicly available information about similar medical devices on the market
- new or revised standards



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✘ Example of mapping of the risk management requirements in ISO 14971 onto the requirement of ISO 13485:

		ISO 14971:2007				
		3.1 Risk management process	3.2 Management responsibilities	3.3 Qualification of personnel	3.4 Risk Management Plan	3.5 Risk Management File
ISO 13485:2003	4.1 General requirement	X				
	4.2 Documentation requirements					X
	5.1 Management commitment		X			
	5.3 Quality policy					
	5.4 Planning				X	
	5.5 Responsibilities, authority and communication				X	
	5.6 Management review		X			
	6.2 Human resources			X		





Thank you for your attention

