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The ISO 9000 family of quality management systems (QMS) is a set of standards that helps organizations ensure they meet customer and other stakeholder needs within statutory and regulatory requirements related to a product or service. ISO 9000 deals with the fundamentals of QMS, including the

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seven quality management principles that underlie the family of standards.

ISO 9000 - Wikipedia

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ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes is an International Organization for Standardization (ISO) standard published for the first time in 1996; it represents the requirements for a comprehensive quality management system for the design and manufacture of medical

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