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This is a focused and well-organized book with in-depth interpretation of ISO 13485 (EN 46000) requirements. It identifies and explains 99 distinct, auditable requirements that must be implemented to pass the certification audit.

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ISO 13485 Medical devices -- Quality management systems -- Requirements for regulatory purposes is an International Organization for Standardization 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 devices. This standard supersedes earlier documents such as EN 46001 and EN 46002, the previously published ISO 13485, and ISO 13488. The current ISO 13485 edition was published on 1

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ISO 13485 - Wikipedia

ISO 13485:2016 can also be used by suppliers or external parties that provide product, including quality management system-related services to such organizations. Requirements of ISO 13485:2016 are applicable to organizations regardless of their size and regardless of their type except where explicitly stated.

ISO - ISO 13485:2016 - Medical devices — Quality ...

Book Summary: The title of this book is ISO 13485 (EN 46000) Requirements, 99 Requirements Checklist and Compliance Guide and it was written by Jack Kanholm, Lynette Howard. This particular edition is in a Hardcover format. This books publish date

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Abstract. ISO 13485:2003 specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory

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requirements applicable to medical devices and related services.

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The workbook is intended for distribution to all personnel for self study or group training, and it includes a short multiple-choice test and a certificate of completion. This course satisfies ISO 13485 (EN 46000) requirements for training personnel in understanding and operating the quality management system.

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