Device Quality Management Systems (QMS): Similarities, Differences, and Ramifications

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Knowing which QMS is operable, under what circumstances, and in which markets, is critical to compliance and to the accuracy of subsequent documentation in meetingregulatory requirements. Understanding that though ISO 13485 and 21 CFR 820 QMS requirements have many similarities, they are different documents with different requirements and different regulatory oversight. Understanding these differences will prevent errors and omissions, insure a common ground for discussion, and ensure the necessary compliance as proven by the documentation.