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Device Validation Forum: Overview of the US FDA GMPs: Good Manufacturing Practice (GMP)/Quality System (QS) Regulation (21 CFR Part 820)

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Jan 10, 2013 5:03 pm EST

KEY POINTS Medical products are governed by a quality management system (QMS) defined by the United States Food and Drug Administration in 21 Code of Federal Regulations (CFR) 820. The current good manufacturing practice (GMP) requirements set forth in the quality system (QS) regulation are promulgated under section 520 of the Food, Drug and Cosmetic (FD&C) Act. The regulation requires specific systems and procedures documented. The current good manufacturing practices (cGMPs) allow flexibility to accomplish the objectives of the regulation. This is an advantage because it allows device manufacturers...