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Effective supplier management for the medical device industry ©2013

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According to Kim Trautman, the FDA's expert on current good manufacturing practices for medical devices, poor supplier performance continues to drive a significant number of product recalls. Device manufacturers are required to evaluate and select their suppliers based on the supplier's ability to meet specified requirements, including quality. The FDA's Quality System Regulation, 21 CFR, Part 820 delineates the requirements for supplier management under $820.50 Purchasing Controls. The regulation allows for a significant amount of latitude in regards to compliance; however, compliance issues associated with $820.50 continue to be frequently cited as a Form 483 observation and in FDA warning letters.

Biography

Christopher Joseph Devine is the president of Devine Guidance International, Inc., a consulting firm specializing in providing solutions for regulatory compliance, quality control, supplier audits, internal audits, and supplier management issues facing the medical device industry. Additionally, he is the author of Devine Guidance, a weekly blog focusing on the understanding of regulations mandated by the FDA and other regulatory bodies and published by the Medical Device Summit. Furthermore, he is the author of three books on regulatory compliance. He has 34 years of experience in quality assurance, regulatory affairs, and program management. He is a senior member of the American Society for Quality (ASQ), a member of Regulatory Affairs Professionals Society (RAPS), a member of the Project Management Institute (PMI), and a member of the Society of Manufacturing Engineers (SME).

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