

## QSR/cGMP vs. ISO 13485: Considerations in Achieving ISO 13485 Certification



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**ABSTRACT** Both good manufacturing practice (GMP) and International Organization for Standardization (ISO) are quality systems. However, there are differences between quality system regulation (QSR)/current good manufacturing practice (cGMP) compliance and ISO certification. The GMPs are a regulatory requirement mandated by law. ISO is a voluntary certification obtained by a company when they determine that the certification is beneficial to their operations and/or marketing strategies. The revised GMP includes design review, management review, vendor qualification, process validations, and comprehensive...

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