

Journal of Dental Technology
November/December 2022 Regulatory Quiz
FDA QSR Update
NBC Approval #42057

1. In 2018 the FDA announced the intent to adopt quality system regulations (QSR) with rules more aligned with ISO 13485.
 - a. True
 - b. False
2. ISO 13485 is an international standard and is the most common way for medical device manufacturers to establish compliance with the Quality Management System requirements in the USA.
 - a. True
 - b. False
3. The new Quality Management System Regulation does not require full ISO certification.
 - a. True
 - b. False
4. The FDA will publish its final rule in the early half of 2023 or sooner, and will replace current QSR.
 - a. True
 - b. False
5. The new rule will be referred to as the Quality System Management Regulation (QMSR), and the FDA proposes to make it effective immediately.
 - a. True
 - b. False
6. Becoming QSMR compliant could take a dental lab a few months or more.
 - a. True
 - b. False
7. Labs looking to implement quality systems will want to focus on the old QSR.
 - a. True
 - b. False
8. Full ISO 13485 certification requirements combined with annual audits can be costly.
 - a. True
 - b. False
9. ISO 13485 serves as the basis for QMS compliance in Japan, Korea and Brazil.
 - a. True
 - b. False
10. On February 23, 2022 the FDA published a proposed rule for comment, and the comment period ended on May 24, 2022.
 - a. True
 - b. False

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