

Journal of Dental Technology

April 2024 Regulatory Quiz

FDA Amends 21 CFR 829: Announces QMSR

NBC Approval #50427

1. On January 15, 2024, FDA issued the Quality Management System Regulation final rule.
 - a. True
 - b. False
2. The FDA is amending the title of the regulation, and establishing requirements and provisions that clarify certain expectations and concepts used in ISO 13485:2016.
 - a. True
 - b. False
3. The revised part 820 is referred to as the Quality Management System Regulation (QMSR).
 - a. True
 - b. False
4. FDA planned to align 21 CFR 820 more closely with ISO 13485:2016.
 - a. True
 - b. False
5. The effective date for compliance is three years after publication in the Federal Register.
 - a. True
 - b. False
6. The FDA states that it will begin to enforce the QMSR requirements upon the effective date which is February 2, 2026.
 - a. True
 - b. False
7. This amendment means you will need to become ISO 13485 registered.
 - a. True
 - b. False
8. Clients that subscribe to the Grand Avenue Software will already be utilizing the ISO 13485 format, but will need to ensure any necessary updates are made.
 - a. True
 - b. False
9. Safelink Consulting is here to help you navigate the new FDA regulations.
 - a. True
 - b. False
10. The author, Mary Bartlett, is an authorized trainer under OSHA's Outreach Program.
 - a. True
 - b. False

Passing quiz grades are worth ½ point documented regulatory standards credit. To earn CDT credit, once the quiz is completed, send it to the NADL at the address or fax number below or submit this quiz online at www.nadl.org/quizzes. To earn an additional ½ point professional development credit, visit www.nbccert.org to submit your time for reading the accompanying article(s) in the professional development log. Quiz credits will appear on the NBC CDT Online Education Tracking System at www.nbccert.org, which is updated weekly. This quiz is provided to test the technician's comprehension of the article's content, and does not necessarily serve as an endorsement of the content by NADL or NBC.

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