Journal of Dental Technology
August/September 2024 Regulatory Quiz
US Food and Drug Administration (FDA) Moves Forward with Transition to ISO 13485
NBC Approval #50428

1. The FDA believes that global harmonization of medical device regulation can contribute to public health by providing quicker patient access to high-quality devices.
    a. True
    b. False

2. The harmonization of regulations is meant to add more regulatory requirements to the process of bringing medical devices to market.
    a. True
    b. False

3. FDA historically used the terms "safety and performance" while ISO 13485 uses the terms "safety and efficacy".
    a. True
    b. False

4. According to the article, rework as defined by the FDA is anything you do to a product after it has been distributed.
    a. True
    b. False

5. Medical device reporting and complaint handling are new requirements introduced in the FDA's QMSR transition.
    a. True
    b. False

6. The new QMSR requirements according to ISO 13485 will be enforced starting February 2026.
    a. True
    b. False

7. Domestic dental laboratories exempt from FDA registration are also exempt from FDA inspections under the new QMSR requirements.
    a. True
    b. False

8. The transition to the new QMSR will require dental laboratories to have well-organized documents for FDA inspections.
    a. True
    b. False

9. FDA inspectors under the new standard will have the authority to review internal audit records, supplier audit records, internal audit documents and management review minutes.
    a. True
    b. False

10. The final rule that transitions the old Quality Management System Regulation (QMSR) to existing requirements under ISO 13485:2016 was published by the US FDA in February 2024.
    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 https://www.nadl.org/jdt-quiz-submissions. 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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