

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

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