Journal of Dental Technology
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Validated Workflows Part 2
NBC Approval #43432

1. The Quality System Inspection Technique (QSIT) is a manual for FDA inspectors outlining what they and cannot do, and what the owners' rights are.
    a. True
    b. False

2. The FDA inspection begins with reviewing Corrective or Preventative Action Forms.
    a. True
    b. False

3. The FDA feels that through auditing the CAPA documents, it exposes the management's level of awareness of the deficiencies and nonconformities within their organization.
    a. True
    b. False

4. The greatest amount of FDA citations come from two CFR 820 sections.
    a. True
    b. False

5. After auditing the CAPA documents, they will continue the inspection by moving to areas they have identified through the audit as quality weakness. This could be items such as equipment maintenance, receiving inspection or approved suppliers.
    a. True
    b. False

6. The eQMS cannot be customized for each lab. It cannot accommodate state regulations or DAMAS standards.
    a. True
    b. False

7. Having a good production management program working in sync with the eQMS has tremendous potential benefits, including higher efficiency, better reporting, and shared data to bring it all together in one platform.
    a. True
    b. False

8. The FDA defines the Ti Base as an "unfinished device", and it is not a "finished device" until the dental lab has completed the restoration, and it has been delivered to the dentist.
    a. True
    b. False

9. The dental lab completing the restoration on the Ti Base is considered the device manufacturer and is responsible to operate under a QMS, but they are not required to be registered with the FDA as a Validated Milling Center/Contract Manufacturer for the 501(k) holder of the Ti Base manufacturer.
    a. True
    b. False

10. The evo820 eQMS is a subscription service with a fee for the development of a complete FDA compliant QS customized to each dental laboratory.
    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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