

1. New technology in dental laboratory manufacturing is introducing many advantages such as streamlining and automating processes.
  - a. True
  - b. False
2. This technology does not place requirements on the user to ensure that the software is validated for accuracy.
  - a. True
  - b. False
3. Validation can decrease failure rates, recalls and corrective actions, ensure less risk to patients and users, and reduce liability to device manufacturers.
  - a. True
  - b. False
4. Validation requirements apply to only software used as components in medical devices.
  - a. True
  - b. False
5. When scanners, printers, milling machines, or other CAD/CAM equipment are a part of the manufacture of dental devices, FDA requires that the software used in the hardware is validated.
  - a. True
  - b. False
6. When complaints from customers are handled within software, then that software must be validated as well.
  - a. True
  - b. False
7. Part of a purchaser's due diligence when determining which software to purchase is to verify that the software is validated for the intended purpose.
  - a. True
  - b. False
8. Any software used to automate any part of the device production process or any part of the quality system does not need to be validated for its intended use.
  - a. True
  - b. False
9. The developer of the software is usually not responsible for validation which includes testing.
  - a. True
  - b. False
10. If a business uses "off-the-shelf" software as a part of the manufacturing process, then the user will be responsible for the validation, so it is best to purchase hardware and software together so validation has been conducted.
  - a. True
  - b. False

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