

Journal of Dental Technology
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Validated Workflows
NBC Approval #43431

1. The validated workflow is tied to many SOPs and recording documents of those activities for confirmation of operating at the highest efficiency of production to maintain device quality.
 - a. True
 - b. False
2. In a digital workflow, they will need to regularly test and document different cases prior to their delivery to the dentist. This ensures that the entire workflow is working to meet the specifications in the dentist RX.
 - a. True
 - b. False
3. The best documentation for the validated workflow is to have generalized SOP that is supported with work instructions that detail each digital manufacturing method including a work instruction for the subtractive and another for the additive process.
 - a. True
 - b. False
4. SOPs and related documents are easier to change than work instructions.
 - a. True
 - b. False
5. The FDA is working to better understand the following: assuring devices 3D printed at the PoC are safe and effective, assuring appropriate control of devices 3D printed at the PoC, clarifying the responsibility entity, PoC training and capabilities.
 - a. True
 - b. False
6. This is not the first look by the FDA at in-house labs at hospitals, clinics, or private practices.
 - a. True
 - b. False
7. In-house labs at hospitals, clinics or private practices are operating under an exemption, that the FDA may need to modify.
 - a. True
 - b. False
8. The FDA is recognizing there are situations of potential higher risk to patients when devices are manufactured in HCFs, and FDA regulations exist for traditional manufacturers (dental labs).
 - a. True
 - b. False
9. The regulations could have been cause for dentists, clinics, and DSOs to reconsider having in-house manufacturing capabilities when required to be registered with the FDA and operate under QMS.
 - a. True
 - b. False
10. A single action validates a workflow.
 - a. True
 - b. False

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