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FDA Issues Guidance on Qualification of Medical Device Development Tools Alert

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The U.S. Food and Drug Administration (FDA) recently issued a final guidance titled “Qualification of Medical Device Development Tools.” According to the guidance, a Medical Device Development Tool (MDDT) is “a method, material, or measurement used to assess the effectiveness, safety, or performance of a medical device. An MDDT is scientifically validated and can be qualified for use in device evaluation and to support regulatory decision-making.”

The qualification of an MDDT is limited to a specific “context of use” or statement describing “the conditions and boundaries within which the MDDT has been qualified for use,” but once the FDA has qualified an MDDT “CDRH reviewers should accept the MDDT for the qualified context of use without the need to reconfirm the suitability and utility of the MDDT when used in a CDRH regulatory submission.”

The voluntary, no-fee qualification process involves four steps; however, two are optional. In the required proposal phase, the person seeking to qualify the test submits a proposal to the FDA that includes a description of, and justification for, the MDDT.

The two optional phases are the incubator and pre-qualification phases. According to the guidance, “the goal of the incubator phase is for [Center for Devices and Radiological Health] CDRH to work with submitters to foster the development of MDDTs that have potential to significantly improve public health” and “the goal of the pre-qualification phase is for CDRH to provide feedback on the plan to collect evidence to support qualification of the tool.”

The final phase is the qualification phase. In this phase, the guidance states that the submitter must submit a complete qualification package, including at least the following:

- all descriptive elements and protocols as described in the proposal and pre-qualification sections
- statement if the tool has been previously submitted to the MDDT Program or through the Drug Development Tool Program
- MDDT description

- all of the evidence needed to support qualification
- discussion of how the strength of evidence supports qualification
- assessment of advantages and disadvantages for tool use

An appendix to the final guidance includes a more complete list of the contents of the qualification package.

The guidance and a contemporaneous summary identify three categories of MDDTs:

- **Clinical outcome assessment**: Measures of how a patient feels or functions. These could be patient-reported or clinician-reported rating scales.
    - Examples of tools that might be eligible for qualification include: patient reported outcome rating scales, such as those used to measure pain, improved mobility, symptom relief, function, or health status and heart failure-related hospitalization.
- **Biomarker test**: A lab test or instrument used to detect or measure an indicator of biologic processes or pharmacologic responses to a treatment (biomarker).
    - Examples of tools that might be eligible for qualification include: tests used as an aid in diagnosis, for patient selection, or as clinical study endpoints, such as instruments or methods for measuring blood pressure; or instruments or methods for measuring certain concentrations of serum proteins, such as an assay to detect the level of a specific hormone in a patient in order to determine enrollment eligibility for study population in a clinical trial.
- **Nonclinical assessment model**: A nonclinical test method or model (e.g., in vitro “bench,” animal, or computational model) that measures or predicts device function or performance in a living organism.
    - Examples of tools that might be eligible for qualification include: models used to measure a parameter of interest or to substitute for another generally accepted test or measurement, such as computer modeling to assess conditions typically evaluated through human, animal, or bench testing to evaluate a device instead of collecting data from human subjects; use of tissue and other material phantoms to evaluate imaging devices; or in vitro models to replace animal testing.

Companies concerned about the potential loss of trade secrets in their MDDTs should note that the FDA only intends to qualify an MDDT when the submitter will give written permission to disclose the following information:

- a brief description of the tool and its principle of operation
- the qualified context of use
- a general summary of the evidence to support qualification and a discussion of the strength of

that evidence

- a brief assessment of the advantages and disadvantages of using the MDDT for its qualified context of use
- information on how a device developer can contact the tool developer so that it may access the tool

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