



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-D-1279]

Qualification of Medical Device Development Tools; Guidance for Industry, Tool Developers, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled "Qualification of Medical Device Development Tools (MDDT)." This document formalizes the MDDT program and provides guidance to FDA staff, industry, healthcare providers, researchers, and patient and consumer groups on a new voluntary process within the Center for Devices and Radiological Health (CDRH) for qualification of medical device development tools (MDDT) for use in device development and evaluation programs. In addition, the guidance discusses the framework of an MDDT, including definitions of applicable terms, criteria for evaluating an MDDT for a specific context of use, considerations for qualification, and the contents of a qualification package. FDA considered comments on the draft guidance and revised the guidance as appropriate.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2013-D-1279 for "Qualification of Medical Device Development Tools." Received comments will be placed

in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled "Qualification of Medical Device Development Tools" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Kathryn O'Callaghan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5418, Silver Spring, MD 20993-0002, (301) 796-6349.

SUPPLEMENTARY INFORMATION:

I. Background

MDDT is a scientifically validated tool that aids device development and regulatory evaluation. The guidance describes the framework and process for the voluntary CDRH qualification of MDDT, including definitions of applicable terms, criteria for evaluating a MDDT for a specific context of use, the threshold for qualification, and the contents of a qualification submission.

The intent of this voluntary qualification policy is to: (1) Enable faster, more efficient development of important life-saving and health promoting medical devices, (2) promote the development of tools to facilitate more timely device evaluation, (3) provide a mechanism to better leverage advances in regulatory science, and (4) more quickly and more clearly

communicate with CDRH stakeholders about important advances in regulatory science that may be leveraged to speed device development and regulatory evaluation. CDRH expects the qualification process to expedite development of publicly available tools, which could potentially be used widely in multiple device development programs.

The intent of this voluntary MDDT program is to promote the development and use of tools to streamline device development and evaluation. Once an MDDT is submitted in accordance with the FDA guidance entitled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" (Ref. 1) and qualified for a specific context of use, it can be used by any medical device sponsor for that context of use. MDDTs can be used for the qualified context of use without the need to reconfirm the suitability and utility of the MDDT when used in a premarket submission. Qualification may contribute to acceptance and application of MDDTs across multiple medical device development programs. Qualified MDDTs can be utilized by many sponsors to aid in optimizing device development and evaluation.

As discussed in the November 14, 2013, *Federal Register* notice (78 FR 68459), FDA announced the availability of the draft of this guidance and interested persons were invited to comment by February 12, 2014. In the August 15, 2014, *Federal Register* notice (79 FR 48170), FDA began accepting nominations for participation in the voluntary MDDT Pilot Program. FDA reviewed and considered all public comments received and revised this guidance as appropriate.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on "Qualification of Medical Device Development Tools." It does not establish any rights for any person and is not

binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>. Guidance documents are also available at <https://www.regulations.gov>. Persons unable to download an electronic copy of "Qualification of Medical Device Development Tools" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number 1882 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection that is subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information under the guidance entitled "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff" have been approved under OMB control number 0910-0756.

V. Reference

The following reference is on display in the Dockets Management Staff (see ADDRESSES) and is available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; it is also available electronically at <https://www.regulations.gov>. FDA

has verified the website address, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

1. FDA Guidance, "Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff." Available at <https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf>.

Dated: August 4, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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