This document is scheduled to be published in the
Federal Register on 09/24/2025 and available online at
https://federalregister.gov/d/2025-18468, and on https://govinfo.gov

4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-D-0795]

Computer Software Assurance for Production and Quality System Software; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance entitled "Computer Software Assurance for Production and Quality System Software." FDA is issuing this guidance to provide recommendations on computer software assurance for computers and automated data processing systems used as part of medical device production or the quality system. FDA believes that these recommendations will help foster the adoption and use of innovative technologies that promote patient access to high-quality medical devices and help manufacturers to keep pace with the dynamic, rapidly changing technology landscape, while promoting compliance with laws and regulations implemented by FDA.

DATES: The announcement of the guidance is published in the *Federal Register* on [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time 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-2022-D-0795 for "Computer Software Assurance for Production and Quality System Software." 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, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 "Computer Software Assurance for Production and Quality System Software" to the Office of Policy, 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: Daniel Walter, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1526, Silver Spring, MD 20993-0002, 301-796-5587 or Phillip Kurs, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA envisions a future state where the medical device ecosystem is inherently focused on device features and manufacturing practices that promote product quality and patient safety. FDA has sought to identify and promote successful manufacturing practices and help device manufacturers raise their manufacturing quality level. In doing so, one goal is to help manufacturers produce high-quality medical devices that align with the laws and regulations implemented by FDA. Compliance with quality system obligations including those in 21 CFR Part 820 is required for manufacturers of finished medical devices to the extent they engage in operations to which those obligations apply. This guidance addresses practices relating to computers and automated data processing systems used as part of production or the quality system.

FDA recognizes the potential for advances in manufacturing technologies, including the adoption of automation, robotics, simulation, and other digital capabilities, to provide significant benefits for enhancing the quality, availability, and safety of medical devices. Medical device manufacturers have expressed a desire for greater clarity regarding the Agency's expectations for software validation for computers and automated data processing systems used as part of production or the quality system. Given the rapidly changing nature of software, manufacturers have also expressed a desire for a more iterative, agile approach for validation of computer software used as part of production or the quality system.

Traditionally, software validation has often been accomplished via software testing and other verification activities conducted at each stage of the software development life cycle.

However, software testing alone is often insufficient to establish confidence that the software is fit for its intended use. FDA believes that applying a risk-based approach to computer software used as part of production or the quality system would better focus manufacturers' assurance activities to help ensure product quality while helping to fulfill validation requirements. This guidance provides recommendations on computer software assurance for computers and automated data processing systems used as part of medical device production or the quality system. FDA believes that these recommendations will help foster the adoption and use of innovative technologies that promote patient access to high-quality medical devices and help manufacturers to keep pace with the dynamic, rapidly changing technology landscape, while promoting compliance with laws and regulations implemented by FDA.

This guidance supplements FDA's guidance entitled "General Principles of Software Validation,"[1] except this guidance supersedes Section 6 ("Validation of Automated Process Equipment and Quality System Software") of the "General Principles of Software Validation" guidance.

A notice of availability of the draft guidance appeared in the *Federal Register* of September 13, 2022 (87 FR 56059). FDA considered comments received and revised the guidance as appropriate in response to the comments, including adding a definitions section to provide clarity on commonly used terms in the guidance, updating examples of manual and automated testing, and adding examples throughout the guidance that apply the concepts in the guidance to different types of software.

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 Computer Software Assurance for Production and Quality System Software. It does not establish any rights for any

[1] Available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-principles-software-validation

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.

II. 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/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products. This guidance document is also available at https://www.regulations.gov, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics. Persons unable to download an electronic copy of "Computer Software Assurance for Production and Quality System Software" may send an email request to CDRH-Guidance@fda.hhs.gov to receive an electronic copy of the document. Please use the document number GUI00017045 and complete title to identify the guidance you are requesting.

III. Paperwork Reduction Act of 1995

While this guidance contains no new collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by OMB under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). The collections of information in the following table have been approved by OMB:

21 CFR Part; Guidance; or FDA Form	Topic	OMB Control No.
11	Electronic records; Electronic signatures	0910-0303
814, subparts A through E	Premarket approval	0910-0231
814, subpart H	Humanitarian Device Exemption	0910-0332
820	Current Good Manufacturing Practice (CGMP); Quality System (QS) Regulation	0910-0073

Grace R. Graham,
Deputy Commissioner for Policy, Legislation, and International Affairs.
[FR Doc. 2025-18468 Filed: 9/23/2025 8:45 am; Publication Date: 9/24/2025]