FDA Final & Draft Guidance Documents in Last 90 Days as of 30 Jan 2022

Guidance title	Issue Date	Guidance Status	Submit Comments by	Submit Comment Online Link (If Draft only)	Guidance Weblink	Comment
Principles of Premarket Pathways for Combination Products	1/26/22	Final	N/A	N/A	https://www.fda.gov/media/119958/download	Section 3038 of the 21st Century Cures Act, enacted in December 2016 (P.L. 114-255) ("Cures Act"), substantially amended section 503(g) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 USC 353(g)), the principal section of the FD&C Act expressly addressing combination products. General themes of these amendments include enhancing clarity, predictability, efficiency, and consistency of premarket regulatory expectations for combination products, including by ensuring that Agency components and staff coordinate appropriately on premarket review of these products, and that Agency thinking is aligned in conducting these reviews. FDA is publishing this guidance as part of its efforts to implement Cures Act section 3038 and in keeping with the Agency's long-standing commitment to transparency, efficiency, and regulatory consistency, to facilitate development of safe and effective combination products. This guidance looks at the pathway availability and related considerations. In that section of the guidance there are 3 paths the device-led combination product path, the drug-led combination product path and the biologic-led combination product path.
Principles for Selecting, Developing, Modifying, and Adapting Patient-Reported Outcome Instruments for Use in Medical Device Evaluation	1/26/22	Final	N/A	N/A	https://www.fda.gov/media/141565/download	FDA is issuing this guidance to describe principles that should be considered when using Patient-Reported Outcome (PRO) instruments in the evaluation of medical devices and provide recommendations about the importance of ensuring the measures are fit-for-purpose. This guidance is not meant to replace the Patient-Focused Drug Development (PFDD) guidance series.
Patient Engagement in the Design and Conduct of Medical Device Clinical Studies	1/26/22	Final	N/A	N/A	https://www.fda.gov/media/130917/download	FDA is pursuing various efforts of encouraging voluntary patient engagement in clinical studies, including guidance. FDA believes medical device clinical studies designed with patient input may help to address common challenges faced in medical device clinical studies. While FDA acknowledges that patient engagement may be beneficial across the total product lifecycle, this guidance focuses on the applications of patient engagement in the design and conduct of medical device clinical studies.
Assessing the Credibility of Computational Modeling and Simulation in Medical Device Submissions	12/23/21	Draft	3/24/22	https://www.regulations.gov/docket/FDA-2021-D-0980	https://www.fda.gov/media/154985/download	This draft guidance document provides the FDA's recommendations on a risk-based framework that can be used in the credibility assessment of computational modeling and simulation (CM&S) used in medical device regulatory submissions. This guidance applies to physics-based, mechanistic, or other first principles-based models. The recommendations are intended to promote consistency and facilitate efficient review of medical device submissions. The use of CM&S (also referred to as in silico methods) in regulatory submissions is well established and rapidly increasing.8 130 CM&S of medical devices can streamline development and reduce burdens associated with premarket device evaluation. It can also reveal important information not available from traditional in vivo or in vitro assessments, such as serious and unexpected adverse events that are undetectable within a study sample but occur frequently enough within the intended population to be of concern. As interest in medical device-related CM&S grows, it will be important to both monitor current usage and identify areas where CM&S might be more broadly leveraged to enhance public health. The appropriate and expanded use of CM&S in obtaining accurate and precise results to support regulatory submissions necessitates the development of processes and approaches that promote consistency in the way CM&S is conducted and reviewed.

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						There are several ways that CM&S can potentially be used to support a regulatory submission, including but not limited to: 1. In Silico Device Testing. 2. CM&S used within medical device software. 3. In Silico Clinical Trials. 4. CM&S-based qualified tools.
Technical Considerations for Medical Devices with Physiologic Closed-Loop Control Technology	12/23/21	Draft	2/22/22	https://www.regulations.gov/docket/FDA-2021-D-0996	https://www.fda.gov/media/154994/download	This draft guidance heavily relies on IEC 60601-1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers. 1st edition:2007 + Amendment 1:2013 + Amendment 2:2020. Searching on 60601-1-10 there are 23 references in the document. This draft guidance document provides the FDA's recommendations on design considerations, non-clinical testing, animal studies, and labeling to support premarket submissions for medical devices with physiologic closed-loop control technology. This guidance applies to the design and testing of a device incorporating physiologic closed-loop control technology. The design and testing will depend on a variety of factors, including, but not limited to, the energy or article being delivered, environment of use, level of automation, training of the user population, patient population, properties of the physiologic-measuring sensor, method of control algorithm design, and properties of the delivery system. The recommendations are intended to promote consistency and facilitate efficient review of medical devices with physiologic closed-loop control technology submissions.
Referencing the Definition of "Device" in the Federal Food, Drug, and Cosmetic Act in Guidance, Regulatory Documents, Communications, and Other Public Documents	12/16/21	Draft	2/14/21	https://www.regulations.gov/docket/FDA-2021-D-0997	https://www.fda.gov/media/154866/download	The U.S. Food and Drug Administration (FDA or the Agency) recommends the consistent use of terms and definitions of legal significance. In light of recent amendments to section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as a result of the enactment of the Safeguarding Therapeutics Act, FDA is issuing this draft guidance to promote clarity regarding references to the terms "device" and "counterfeit device." There is also discussion of software in terms of the definition of "device" and software. Refer to the Sections II. Background, & IV. Statement of Policy.
Content of Premarket Submissions for Device Software Functions	11/4/21	Draft	2/2/22	https://www.regulations.gov/docket/FDA-2021-D-0775	https://www.fda.gov/media/153781/download	This guidance document is intended to provide information regarding the recommended documentation sponsors should include in premarket submissions for FDA's evaluation of the safety and effectiveness of device software functions, which are functions that meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).1 The recommendations in this guidance document pertain to device software functions, including software in a medical device (SiMD) and software as a medical device (SaMD).2 When final, this document will replace FDA's Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices issued on May 11, 2005, and it will update FDA's thinking related to the documentation FDA recommends sponsors include for the review of device software functions in premarket submissions. This guidance identifies the software information generally necessary for evaluating the safety and effectiveness of a device in a premarket submission. The recommendations in this guidance

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						also may help facilitate FDA's premarket review. This guidance describes information that would be typically generated and documented3 during software development, verification, and design validation. The least burdensome approach was applied to identify the minimum amount of information that, based on our experience, would generally be needed to support a premarket submission for a device that uses software. During premarket review, FDA may request additional information that is needed to evaluate the submission. For example, in order to demonstrate a reasonable assurance of safety and effectiveness for devices that use software, documentation related to the requirements of the Quality System Regulation (QSR) (21 CFR Part 820) is often a necessary part of the premarket submission. As part of QSR design controls, a manufacturer must "establish and maintain procedures for validating the devices design," which "shall include software validation and risk analysis, where appropriate." (21 CFR 820.30(g)). The documentation recommended in this guidance is based on FDA's experience evaluating the safety and effectiveness of device software. However, sponsors may use alternative approaches and provide different documentation so long as their approach and documentation satisfies premarket submission requirements in applicable statutory provisions and regulations. For the current edition of the FDA-recognized consensus standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. For more information regarding use of consensus standards in regulatory submissions, please refer to the FDA guidance titled Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices and Standards Development and the Use of Standards in Regulatory Submissions Reviewed in the Center for Biologics Evaluation and Research https://www.fda.gov/regulatory-information/search-fda-guidance-documents/standards-development-and-use-standards-regulatory-submissions-reviewed-center-biologics-evaluation. 1 The term "device" is defined in 201(h) of the Federal Food, Drug, and Cosmetic (FD&C) Act to include an "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is ...intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man ... or intended to affect the structure or any function of the body of man..." and "does not include software functions excluded pursuant to section 520(o) of the FD&C Act." 2 See FDA website on "Software as a Medical Device (SaMD). https://www.fda.gov/medical-devices/digital-health-center-excellence/software-medical-device-samd" 3 As a reminder, manufacturers of device software must create and maintain software-related documentation in accordance with the requirements of the Quality System (QS) Regulation (21 CFR 820.30 Subpart C – Design Controls of the Quality System Regulation).