Challenge Questions

Software Precertification Program

FDA proposes the following challenge questions for public input.

0.1   FDA recognizes stakeholder perspectives and priorities as important inputs into the development of the Precertification Program. How should anticipated stakeholder benefits in Table 1 in the program Working Model be revised, and what additional stakeholder perspectives should be included?

0.2   As a stakeholder, what would you want to know about the organizations that have been precertified and about the SaMD products that they manufacture?

Excellence Appraisal

FDA proposes the following challenge questions for public input. Although these questions are specific to excellence appraisal models and precertification status, they should be considered in coordination with the other aspects of the Precertification Program. The questions should also be considered with the objectives of establishing an excellence appraisal model, including identifying the evidence SaMD manufacturers can provide that ensure product safety and effectiveness, harmonizing FDA regulatory review with SaMD manufacturer timelines, and creating clear and straightforward FDA requirements.

1.1.   How might an existing excellence or maturity appraisal framework used by a SaMD manufacturer be leveraged to demonstrate an organization's performance and success as outlined by the five excellence principles?

1.2.   How might the appraisal process consider the track record demonstrated through an organization's objective Key Performance Indicators (KPIs) as part of the evaluation?

1.3.   Does it matter if the track record is in medical device products or in consumer products and why? How long, and how detailed of a track record would be needed to demonstrate an organization's sustainable performance? Why?

1.4.   When looking at past performance, how should negative events be evaluated to provide an accurate assessment of responsiveness, responsibility, and improvement?

1.5.   FDA is anticipating establishing two levels of precertification. Please advise whether and why the same appraisal model should be used to assess all organizations applying for precertification, or whether separate appraisal models should be used for each level of precertification and why?

1.6.   How might an appraisal framework reconcile the requirement for precertified organizations to demonstrate a consistent threshold of excellence with the recognition that different organizations are likely to use performance measures specific to their operations and product lines?

1.7. How might an excellence or maturity assessment balance the FDA's "least burdensome" approach with the obligation to assure stakeholders that SaMD are safe and effective?

1.8. When considering large organizations that are multinational or include multiple business units, what defines a "unit" for purposes of FDA precertification? If FDA precertifies a "unit" within a corporation or multinational, how should FDA factor in corporate processes during appraisal?

1.9. Should there be two levels of Pre-Cert? What should be the differentiating factors between Pre-Cert levels?

1.10. Are there specific approaches to developing SaMD, such as machine learning and artificial intelligence, that raise different considerations with respect to the excellence principles, e.g., such that the appraisal would be different and/or precertification for the company based on processes/culture using one technology should not apply to other SaMD development methods? Why or why not?

Review Pathway Determination

FDA proposes the following challenge questions for public input. Although these questions are specific to the review pathway determination, they should be considered in coordination with the other aspects of the Precertification Program. The questions should also be considered with the objectives of establishing the review pathway determination component of the Software Precertification Program, including developing a risk-based framework to determine the need for premarket review and clearly communicating to stakeholders how different premarket and postmarket requirements apply to each category of SaMD products.

2.1 Given the definition of SaMD, what additional information is needed to help stakeholders clearly differentiate between software as medical device (SaMD), software in a medical device (SiMD), and other types of software and hardware?

2.2 The IMDRF definition statement is intended to provide a structure towards defining intended use. Should other components be included, and if so, what, or should the current components be modified to provide clarity around the function of the SaMD and if so, how?

2.3 The IMDRF risk categorization framework uses and defines "inform," "drive," and "diagnose/treat" to identify the "significance of information provided by SaMD" of how the SaMD is intended to be used. What additional clarity or modifications are necessary within these definitions that will enhance the use of this risk categorization framework?

2.4 The IMDRF risk categorization framework uses and defines "non-serious," "serious," and "critical" to identify the "state of health care situation and condition" where the SaMD is intended to be used. What additional clarity or modifications are necessary within these definitions that will enhance the use of this risk categorization framework?

2.5 How should FDA think about a major change versus a minor change for SaMD, and about how these changes should be handled?

2.6   Should the current software modifications guidance be enhanced with the added assurance of a precertified organization and if so, what are some proposed enhancements and what concepts should be considered for the guidance?

2.7   Should FDA be informed about new products, major changes, and minor changes from precertified organizations that do not undergo premarket review, and if so, how?

2.8   Cybersecurity issues often circumvent intended use. How can/should this be considered when determining risk level?

Streamlined Review

FDA proposes the following challenge questions for public input. Although these questions are specific to the streamlined premarket review process, they should be considered in coordination with the other aspects of the Precertification Program. The questions should also be considered with the objectives of establishing the scope of the review of a precertified company's SaMD, what information will be reviewed, how modifications affect marketing authorization, and how to leverage existing SaMD community standards.

3.1   Given that one goal of this program is to significantly reduce the average premarket review timeline, what would be the best way for precertified companies to share product review information with us? Specifically:

   3.1.1.   What specific elements of review could be shifted to the company-specific excellence appraisal (as opposed to the product-specific review)?

   3.1.2.   What are the features of a SaMD product that need to be assessed during device review?

   3.1.3.   What product-specific content would be expected to be reviewed premarket?

   3.1.4.   What specific postmarket real world data could be collected to support the assurance of safety and effectiveness for each product if an element is not reviewed premarket?

   3.1.5.   What updates should FDA require, and at what interval, to provide continuous assurance of safety and effectiveness?

   3.1.6.   Should there be a phased market authorization, where some elements are reviewed premarket and other elements are gathered through real world evidence to support full market authorization? What should happen to products that receive "preliminary" market authorization but fail to provide adequate evidence in the agreed upon timeframe?

3.2.   Beyond number of days, what are additional key factors important for a successful streamlined review?

3.3.   Once a review decision is made:

   3.3.1.   How should the FDA share that information with the company? With the public?

   3.3.2.   Should the public know that a product comes from a precertified company and if so, what is the best way to share that information?

3.4. Imagining that there is an initial, automated part of the review – what information can be provided so an initial automated review can add value?

3.5. A key element for streamlined review will be the communication between precertified companies and FDA. What technologies can be leveraged to support bi-directional communication?

3.6. How should FDA handle an organization that submits an unsuccessful submission for premarket review? Should there be a limit on the number of unsuccessful submissions a precertified organization can submit before their precertification status is affected?

3.7. Could FDA conduct a premarket review without requiring a premarket submission and if so, how, e.g., by accessing and interactively reviewing information internal to the precertified organization about the SaMD?

   3.7.1. What are possible methods to facilitate FDA access to necessary information?

   3.7.2. Is there information other than risk management, technical evaluation, and clinical evaluation necessary for such a review to assure safety and effectiveness of the SaMD?

   3.7.3. How should the reviewed information relevant to the marketing authorization decision be documented for administrative purposes?

3.8. Is premarket clinical performance necessary to assess SaMD safety and effectiveness? Please explain your answer and provide your rationale.

3.9. Should FDA be informed about new products, major changes, and minor changes from precertified organizations that do not undergo premarket review, and how?

Real World Performance

FDA proposes the following challenge questions for public input. Although these questions are specific to real world performance, they should be considered in coordination with the other aspects of the Precertification Program. The questions should also be considered with the objectives of establishing the real-world performance component of the program, including developing elements, metrics, and methodology of real world performance data (RWPD) and analysis needed for Pre-Cert Program activities and defining RWPD requirements for each component of the program.

4.1 As FDA conducts a landscape assessment of existing RWPD frameworks and use cases, what are important sources of information and stakeholders to include?

4.2 How can RWPD surveillance best be designed to support existing standards of safety and effectiveness?

4.3 What are critical RWPD elements to be monitored by SaMD manufacturers?

4.4 Are the definitions for data types underlying RWPD accurate and comprehensive or do the terms used in this section need to be modified or revised and if the latter, how?

4.5 From the perspective of a precertified organization, how does RWPD differ from real world evidence (RWE) in supporting pre-launch product clearance and post-launch modification product claims?

4.6 Since the methodology of analyzing RWPD is still evolving, how can we strike a balance between ensuring the scientific rigor in analytic methods and encouraging innovation in collecting and analyzing RWPD for regulatory considerations?

4.7 RWPD can come in different shapes and sizes. Should RWPD requirements depend on the risk level of the intended product claim or modification in claims?

4.8 How can precertified organizations best leverage existing RWPD processes to reduce the submission burden for pre-launch product clearance and post-launch modification product claims?

4.9 How can FDA and SaMD manufacturers ensure that least burdensome principles are applied in collecting real world data? That is, what is the minimum amount of RWPD necessary to adequately determine precertification through the most efficient manner at the right time?

4.10 How can we ensure that the patient or end-user expectations about safety and effectiveness of SaMD are met by the process developed to review and evaluate the use of RWPD in precertification?

4.11 Should an organization that meets a higher level of precertification have the same requirements for RWPD monitoring as an organization at a lower level of precertification and why?

4.12 How can we ensure the methods to review and evaluate RWPD for precertification are robust, applicable, and understandable across different types of organizations?

4.13 With what frequency should FDA assess RWPD as an input into precertification maintenance?

4.14 What RWPD elements should be the most critical inputs for assessing whether precertification status should be maintained or modified?

4.15 What would be an appropriate risk matrix for FDA to use in determining which adverse outcomes should result in a loss of precertification status?

4.16 How can FDA use RWPD surveillance to support SaMD manufacturers in continuous product improvement and maintenance of precertification status?