

FDA DGMP Panel Questions

Under 520(f), before promulgating any regulation related to GMPs, an advisory committee will be assembled to submit recommendations and hold an oral hearing, ensuring such regulation conforms to the extent practicable, with international recognized standards defining quality systems, or parts of the standards, for medical devices. Given this charge, FDA has the following questions for the panel to consider regarding the proposed amendments to 21 CFR 820:

1. What benefits does the panel see from FDA primarily incorporating ISO 13485 as its foundational requirements for its QMS requirements for medical devices?
2. Does the panel envision challenges to FDA primarily incorporating ISO 13485, in whole, as its foundational requirements for its QMS requirements for medical devices?
3. The proposed rule includes FDA-specific requirements and provisions that clarify certain concepts used in the standard that will ensure the incorporation by reference of ISO 13485 does not create inconsistencies with other applicable FDA requirements. As it relates to the FDA-specific requirements outlined in the proposed rule:
 - a. Does the panel believe FDA has identified all areas that may require further requirements?
 - b. Does the panel believe FDA should consider other specific requirements?
4. FDA would like the panel's thoughts on the potential impacts of the proposed rule to the following groups of stakeholders:
 - a. Domestic-only device firms
 - b. Foreign firms/firms that have foreign manufacturing sites
 - c. Medical/Healthcare providers
 - d. Patients/end users
5. FDA recognizes there may be a need to provide additional information and education for manufacturers for this change. Does the panel have any recommendations on how the agency can support industry in preparation to meet the requirements outlined in the proposed rule?
6. FDA has explained its thinking related to current risk management expectations in the QS regulation and outlined the proposed expectations for risk management activities in the proposed rule. What are the panel's thoughts on the equivalence of the more explicitly integrated risk management expectations in the proposed rule to the current regulation?
7. As mentioned in the proposed rule, FDA would need to create a new inspection model, if a regulation based on this proposal is finalized. We are interested in the panel's thoughts on the following:
 - a. What are specific regulatory considerations the panel thinks FDA should consider in the development of the new inspection model?
 - b. What are the panel's thoughts on the current inspection model, Quality System Inspection Technique (QSIT): <https://www.fda.gov/files/Guide-to-Inspections-of-Quality-Systems.pdf>
 - i. What are the things that work well in the model?
 - ii. What does not work well? Where would you want to see change?