

Brief Summary of the Device Good Manufacturing Practice Advisory Committee Meeting March 2, 2022

21 CFR 820 Quality System Regulation Amendment Proposed Rule

Introduction:

The Device Good Manufacturing Practice Advisory Committee of the Food and Drug Administration met on March 2, 2022, to discuss and make recommendations on the current good manufacturing practice requirements for medical devices under 21 CFR part 820, the Quality System regulation, to align more closely with an international consensus standard for medical devices used by other regulatory authorities.

Panel Deliberations/FDA Questions:

1. Does the panel agree with the benefits that FDA has described would accrue as a result of the proposed amendments to 21 CFR 820?
 - a. Does the panel anticipate any additional benefits to the proposed amendments that FDA has not described?
 - **Robert Phillips (Siemens): Industry generally agrees and is supportive of harmonization. There could be significant costs for some in industry, but in the long run the closer we get to harmonized reg footprint, the better for industry**
 - **Gordon Gillerman (NIST): Agree with benefits. In addition, as the technical requirements that underpin and the demonstration of conformity, will become more harmonized with global alignment, which will eventually allow future alternative uses for employees.**
 - **Elise Owen (EPA): When there are global use of standards, this increases overall compliance as a potential benefit.**
 - **Robert Phillips (Siemens): Increased focus on compliance and conformance will support ultimate focus on safety and efficacy.**
 - **Yadin David (Biomedical Engineering Consultants): Do you believe CMDCA outcomes can support this gap analysis effectively?**

- **Robert Phillips:** Those learnings should be considered. Conformance is very important to any regulation, but there needs to be a gap analysis for bridging gaps.
 - **Alisha Loy (University of Iowa):** Additional benefit – dynamic use of consensus standards in regulation for other jurisdictions. Opportunity for international convergence.
 - **Jeri Culbertson (Focus on Zero):** Less regulatory burden and time to market potential benefit.
 - **Scott Sardeson (3M):** If it’s done correctly, it will allow for best practices adoption more quickly. There are more robust ways to look at things.
 - **Lisa Dimmick (NRC):** Adds a level of regulatory clarity and transparency of requirements.
 - **Yadin David (Biomedical Engineering Consultants):** Generally, agree with the benefits proposed. There is a need to look at the gaps and the additional requirements to effectively address the needs of compliance. Global convergence and ease of use for global manufacturers is an additional value. The breadth of stakeholders (e.g., 3rd party Servicers, Researchers) needs to be adequately addressed.
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2. Does the panel envision challenges with implementing 21 CFR part 820, as proposed?
- **Scott Sardeson:** Most of challenges have been identified. Time for transition is a particular area to pay attention to. Clear guidance on new ways of thinking. Good transition planning timeframe. “Devil in the detail as you start to implement”
 - **Alisha Loy:** In addition, ensuring that the scope of what is in and what is out? Clinical care pathways and linkages to other standards, regulations, guidance documents. Identification and education of all stakeholders.
 - **Robert Phillips:** It is not only the QSR, but the guidance documents, other regulations, or touch points. Education is critical for stakeholders – registered and unregistered. Process changes and evidence to comply particularly for those that are not presently engaged in the ISO13485. Redlined QS regulation document to be released (details on specific changes). There is a need to understand the totality of the landscape that is impacted by the change.
 - **Chiaoyun (Benson) Kuo (USC):** With current QSR we address all devices. Unclear on implication on lower risk companies, small companies etc. All stakeholders need to be addressed. Cost implication on small, low risk companies. Risk of increased non-compliances? Audit implications? Linkages and leverage of NB’s (specifically EU). What is the relationship between notified bodies and investigators?
 - **Gordon Gillerman:** Mentioned the linkage and alignment with many standards (ISO 14971, IEC 60601 standards and many others). Need a

more organized approach to education in NIST, small business association, and FDA.

- **As previously mentioned, concerns regarding the challenge of hard codifying the specific edition of ISO 13485 (2016), opposed to referencing the incorporation of whatever the current edition of ISO 13485.**
3. The proposed rule includes FDA-specific requirements and provisions, which clarify certain concepts used in in the standard. These requirements and provisions are intended to ensure that incorporating ISO 13485 by reference 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?
- **Scott Sardeson: Feels comfortable that the extensive analysis done with AAMI on TIR 102 - - most of this was done. Believes all issues were identified, but part of standardization is alignment. Do we need these things in the future is a question? Work toward accessing are they best practices and necessary for patient safety or are they legacy.**
 - **Yadin David: What are the outcomes? What is the implication in patient safety, defects and failures identified?**
 - **Gordon Gillerman: IEC 60601 standard adoption into the US and adoption of national requirements. Are we just looking at what is different or what is needed to be addressed (a true patient safety focus)? Are they actually necessary?**
 - **Alisha Loy: Gap analysis should be broader than just the document. Dynamic to the responsibilities of defect management. How is the sufficient testing addressed? All clinical pathways of care – research, clinician innovation, sterilization, etc. Need to address risk management significantly more. Are we partnering effectively where we have real world application of devices that is ensuring safe devices?**
 - **Robert Phillips: Gap analysis of 820 and ISO13485 as documents was good. Would like to actually see the superset of red line not just the documents. Needs to address what is changing across the TPLC and not just the 820 parts. All the guidance documents etc.**
 - **Scott Sardeson - AAMI work group undertook the mapping of 13485 to 820; and 820 to 13485. TIR 102 is the AAMI document that reflects detailed mapping of requirements. Also, the ISO Handbook is very useful as well – FDA’s voice was quite strong in the development of those documents, and they would be very useful to industry to understand the specific detailed requirement by requirements alignment.**

4. FDA has considered and addressed the impact of the proposed rule on the following groups of stakeholders. Does the panel believe that FDA should consider any additional impacts not addressed in the proposed rule on:
 - a. Domestic-only device firms
 - b. Foreign firms/firms that have foreign manufacturing sites
 - c. Medical/Healthcare providers
 - d. Patients/end users
 - **Yadin David: Consider additional stakeholders (e.g. researchers, all registered sites).**
 - **Scott Sardeson: Look at all the players in the supply chain--the various kinds of manufacturers, service providers (ex. contract sterilizer). The current list is about user and traditional manufacturer.**
 - **Gordon Gillerman: Important that we consider the supply chain. Information needed to address risk management of the medical devices does have linkages with suppliers. There will be a press to component and subassembly manufacturers on necessary info; make sure we prepare the supply chain tiers for participation in this change (not only those subject to the requirements of 820).**
 - **Kuo: NIH grant awardees, Researchers, Small business grant recipients etc.**
 - **Alisha Loy: consider clinical pathway groups**

5. FDA intends to provide additional information and education opportunities, including guidance and/or compliance guides, for manufacturers that are not as familiar with ISO 13485. Does the panel have further recommendations of resources FDA might consider to support manufacturers in preparing to meet the requirements outlined in the proposed rule?
 - **Scott S: AAMI TIR 102, ISO Handbook/Practical guide and MDSAP audit module to support way of working. Consider relying on all the industry groups (AdvaMed, MITA, AAMI, TC210) to support the training and collaboration.**
 - **Kuo: FDA guidance document might be supportive, especially for low-risk devices.**
 - **Robert Phillips: Many different types of stakeholders in need of QS training experience with shift to ISO 13485, Global to ISO 13485, ISO 9001 to ISO 13485 (multi- starting points) --As well as stakeholder types.**
 - **Alisha Loy: Broad stakeholder support to partner and bring in perspective relatable to their own roles.**
 - **Scott S: US specific industry will need to have more PR work to support industry. Promote the value. All the stakeholders need to be a part of the process. Robust communication, campaign, road shows and outreach— not just training videos**

- **Elise Owen:** Emphasis on continued engagement with FDA on TC210 work.
 - **Gordon Gillerman:** Engagement by all stakeholders in ISO 13485, ISO 14971 and more. US industry and FDA are active, but let's expand the level of engagement. Need to bring everyone's views to the table. We need to figure out how to increase engagement. NIST is looking into this more broadly. Encourage voices of small innovators.
 - **Yadin D:** Dilemma of getting small manufacturers engaged, however, there are cost implications.
 - **Kuo:** Does not feel impact of this on large companies. FDA needs to ensure the public how the agency embraces.
 - **Lisa D:** Testimonials might support PR.
6. FDA has explained its thinking about current risk management expectations in the QS regulation and outlined its proposed expectations for risk management activities in the proposed rule. Does the panel agree with the description of the risk management expectations in the proposed rule? Does the panel agree that the more explicitly integrated risk management expectations are, essentially, equivalent to the current regulation?
- **Alisha Loy:** Excited about the implementation of risk management. The spirit in existing language is present for this to be equivalent, but it's not in practice everywhere so the disconnect is the FDA feels it was in the preamble; but in reality, it is really different. There needs to be lots of potential education and clarity in responsibilities. FDA is working under the premise that this isn't a significant change, but it will be a lift for the level of detail we are asking for.
 - **Scott S:** Where this will be a big challenge, US only manufacturers due to the lack of experience globally. Global companies already have ISO14971 heavily engaged.
 - **Yadin D:** From innovators/researchers is this a big delta or standard way of working.
 - **Kuo:** If not exposed to QMS then it's a big delta. Risk management concepts have been a part of their work. Auditing has never been a focus for them.
 - **Robert Phillips:** US only manufacturers with US only markets. This will be a significant delta particularly in risk management.
 - **Elise Owen:** US manufacturers with US only markets, should consider benefit in the potential to lower barriers for them to export--expand OUS. Commerce department engagement.
 - **Gordon Gillerman:** NIST manufacturers extension program opportunity to expand into new markets or new areas.

- **Yadin D: Example - WHO production of medical technology in low resource regions. Many were aware of the EU CE Mark process, but not of US processes.**
 - **Scott S: If the companies are small and are kept aware, they can be made aware. Low risk isn't as low a risk as was historically believed (e.g., gowns, face masks). This will be better for the users to know alignment and consistency in management and utilizing the risk management tools.**
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 works well in the model?
 - ii. What doesn't work well or where you would want to see change?
- **Scott S: New inspection model needs to help address the different kinds of inspections. Surveillance Inspections – MDSAP can be used. Other types of inspections – premarket (PMA). Will be useful to have clarity on changes in inspections.**
 - **Robert Phillips: Need to understand different categories of inspections. Current QSIT manual is out there and transparent for industry to know the scope of activities. Scope of activities within or not (e.g., Internal Audits, Management Reviews – to support self-policing) --would like FDA to continue not reviewing these. Look at what is already covered under/by MDSAP, don't re-invent the wheel. Identify the national requirements focus areas.**
 - **Alisha: Dynamic of contract management activities. Where do they get oversight and inspections by the FD? If we subcontract a service, we are obligated via supplier management and corrective action. Who is the most appropriate for different levels of oversight in this community?**
 - **Gordon Gillerman: As we look at harmonizing, we accrue many benefits. We also will need to focus on conformity assessment and on supplier management. IMDRF should help to shape the global comprehensive system. All integrated and aligned.**
 - **Jeri Culbertson: Who owns devices at the end of the lifecycle? What do we do with it? This is all a part of the life cycle of the device. Real world validation of devices – testing in-house vs. actual way it is done in the field. Surveillance scope and reprocessing of devices and how it aligns with patient safety**
 - **Scott S: Does not want comment on content of QSIT per se. When QSIT was launched, there wasn't a clear understanding of how to use QSIT by**

even FDA investigators. Do not underestimate the front-end change management, it's important to ensure they are knowledgeable and don't recede back to the old way of working.

- **Yadin D: It was hard to describe to newcomers how these inspections were to be handled. Method of communicating issues is a challenge.**
- **Scott S: Transparency of QSIT is valuable. MDSAP and QSIT having focus on areas of risk and product/patient safety. Experience level is very key. Where is the biggest risk in the quality management system?**

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