SUMMARY MINUTES

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

DEVICES GOOD MANUFACTURING PRACTICE PANEL

March 2, 2022

Via Microsoft Teams Videoconference

Attendees:

Chairperson

Yadin David, Ed.D., PE
Biomedical Engineering Consultants, LLC
Houston, TX

Members

Jeri Culbertson, DNP
Focus on Zero, LLC
Rapid City, SD

Lisa Dimmick, M.S.
U.S. Nuclear Regulatory Commission
Rockville, MD

Gordon Gillerman
National Institute of Standards and Technology
Gaithersburg, MD

Chiaoyun (Benson) Kuo, Ph.D.
University of Southern California
Los Angeles, CA

Alisha Loy, LSSBB, CRCST
University of Iowa Hospitals and Clinics
Iowa City, IA

Elise Owen, M.B.A., PMP
U.S. Environmental Protection Agency
Washington, D.C.

Industry Representatives

Robert Phillips, M.B.A., RAC
Siemens Healthineers
Malvern, PA

Scott Sardeson, RAC
3M Company, Health Care Business
St. Paul, MN

Food and Drug Administration

Keisha Thomas, M.S., M.H.S., CQIA, RAC
Acting Associate Director
Compliance and Quality

Melissa Torres, M.E., M.S., CQA
Associate Director
International Affairs

Kimberly Lewandowski-Walker, CAPT, USPHS
Senior Regulatory Officer
Medical Device Single Audit Program

Karen Masley-Joseph, M.B.A., CMQ-OE, CSSGB
Senior Advisor
Office of Medical Device and Radiological Health Operations

Anne Reid, M.S.
Deputy Program Director
Office of Medical Device and Radiological Health Operations

Jarrod Collier, M.S.
Designated Federal Officer
Office of Management

CALL TO ORDER

Panel Chairperson Yadin David, Ed.D., PE, called the meeting to order at 9:05 a.m. He noted the presence of a quorum and affirmed that the Panel members had received training in FDA device law and regulations. He announced that the Panel would be discussing and making recommendations on the alignment of current good manufacturing practice requirements for medical devices under 21 C.F.R. Part 820 with the international consensus standard used by other regulatory authorities.

PANEL INTRODUCTIONS

Chairperson David asked the Panel members and FDA staff to introduce themselves.

CONFLICT OF INTEREST STATEMENT
GENERAL ANNOUNCEMENTS

Jarrod Collier, M.S., Designated Federal Officer, read the Conflict of Interest statement and reported that no conflict of interest waivers had been issued.

He introduced Robert Phillips and Scott Sardeson as the industry representatives, and made general announcements to the public regarding transcripts and videos.

OPENING REMARKS

Ariel Seeley, J.D., welcomed the Panel members and speakers, provided background information on the Quality System Regulation for Part 820, and apprised the Panel of FDA's proposal to incorporate the provisions of ISO 13485:2016 into its quality management system requirements.

FDA PRESENTATIONS

Overview of Proposed Rule/History of Harmonization

Melissa Torres, M.E., M.S., CQA, briefly discussed the components of ISO 13485, its benefits, and the evolution of QMS requirements for medical devices. She explained the rationale for utilization of the standard, noting the Agency's longstanding interest in global harmonization efforts, standards development processes, and coordination of requirements in various programs such as the Medical Device Single Audit Program. She then focused on the goals and structure of the proposed QMSR, key considerations, and implementation activities including technology system upgrades, training, and revision of all applicable documents and regulations.

Similarities & Differences (Documentation; CAPA; Risk Management)

Keisha Thomas, M.E., M.S., CQIA, gave an overview of parallels and discrepancies in the requirements, noting that the similarities far outweigh the differences. She provided details on changes in definitions, clarification of concepts, fundamental differences, and

supplementary provisions for records management and device labeling/packaging control.

INDUSTRY PRESENTATIONS

Advanced Medical Technology Association (AdvaMed)

Jamie Wolszon, Vice President of Technology and Regulatory Affairs, discussed the importance of international voluntary consensus standards, the benefits of transitioning from QSR to ISO 13485, and points for implementation. She emphasized that voluntary standards will aid in furthering efforts to harmonize global medical technology regulations, reduce unnecessary duplication, minimize needless costs and delays in patient access to new devices, and reduce barriers to trade. Recommendations for implementation include avoidance of a "13485-plus" type approach, a transition period of at least two years, the need for a straightforward and understandable rollout, and greater emphasis on risk management.

Medical Imaging & Technology Alliance (MITA)

Diane Wurzburger, J.D., RAC, Executive of Regulatory Affairs and Quality for GE Healthcare, highlighted the advantages of the transition across the stakeholder community. She noted that it will drive consistency, efficiency, and effectiveness; that it will eliminate the need to maintain multiple quality assurance systems; and that it will reduce costs related to compliance and delays in patient access to innovative devices. She offered several suggestions for consideration including clarification on certification and inspection issues, transitional timeline, and updating of the inspection manual. She also encouraged continued development of internal training plans and educational resources.

STANDARDS PRESENTATION

ISO Technical Committee 210

Peter Linders, Chair of ISO/TC 210, explained what 13485:2016 is, noting its widespread use and similarity to 21 C.F.R. 820. He provided a brief overview of a handbook developed for implementation of the standard, expounded on the meaning of incorporation by reference, addressed the stability of the standard, and emphasized the benefits of the proposed amendment.

OPEN PUBLIC HEARING

Amanda Benedict spoke on behalf of the Association for the Advancement of Medical Instrumentation. She stated that consensus-based, uniform, and systematic approaches to quality management worldwide can improve the safety and performance of medical devices, that the intent in charge of ISO/TC 210 has been development of global requirements for quality management systems, and that the association supports efforts towards regulatory convergence.

Mark Swanson raised questions and provided clarification on several issues,

including quality planning and compliance, inspections and audits, and postmarket surveillance. He stated that it is unclear as to whether certification to 13485 will be required and if records not normally reviewed during routine inspections by FDA will become subject to audit under the new rule.

PANEL DELIBERATIONS

Robert Phillips, M.B.A., RAC, Industry Representative, proposed the following topics for further discussion going forward:

- whether certification will be required;
- length of the transition period;
- possible consideration of Annexes A and B; and
- hard coding of 13485:2016 directly within the QSR language.

Gordon Gillerman pointed out that there is considerable interest in a more voluntary consensus standards-based approach to the QSR. He further observed that it is challenging for regulators to adopt undated references to standards and that issues arise when the regulatory system lags behind current versions of frequently used global standards.

Scott Sardeson, RAC, Industry Representative, stated that a two-year transition is more adequate considering the amount of training and cultural changes that companies may have to face, and that it would be preferable to use a more consensus standard approach.

There was discussion about providing a redline document of the C.F.R. as the process continues, clarification on whether non-manufacturing entities are in or out of scope, and mapping from ISO 9001 to 13485 in addition to the new QSR. Other issues brought up by Panel members include more specificity in the development of the inspection protocol, longer periods of time for implementation, and ensuring that the requirements for risk management are met.

Chiaoyun (Benson) Kuo, Ph.D., drew the Panel's attention to the needs of device developers, noting that they do not have huge funding to advance their technologies and that the risk management requirements may impose an extra burden on them.

Mr. Phillips underscored the importance of understanding who all of the stakeholders are and of ensuring that the educational plan covers non-registered entities.

It was also suggested that the dynamics of clinical care pathways and aspects of research within the IRB process should be taken into consideration along with the preclinical stages of product development and manufacturing.

FDA QUESTIONS

Kimberly Lewandowski-Walker, CAPT, USPHS, read Question 1: Does the Panel agree with the benefits that FDA has described that would accrue as a result of the proposed amendments to 21 C.F.R. 820, and does the Panel anticipate any additional benefits to the proposed amendments that FDA has not described?

Mr. Phillips advised ascertaining whether the additional requirements will stimulate the provision of safe and effective devices to the U.S. population. He acknowledged that

industry is generally supportive of efforts to integrate the regulatory landscape.

Other members concluded that additional benefits will be seen as the technical requirements are streamlined, that the use of international standards will increase conformity while decreasing the cost of compliance to regulators, and that medical devices could become available in a more timely fashion.

Lisa Dimmick, M.S., stated that incorporation of the standard will add a higher level of regulatory clarity and **Mr. Sardeson** pointed out that it will accelerate FDA's ability to adopt best practices.

Chairperson David remarked that the overall benefit was adequately summarized and that the community of stakeholders is wider than what was initially assumed.

Captain Lewandowski-Walker read Question 2: Does the Panel envision challenges with implementing 21 C.F.R. Part 820 as proposed?

Mr. Sardeson expressed concern about the amount of work that will be required and underscored the necessity for clear guidance throughout the transition period.

Alisha Loy, LSSBB, CRCST, emphasized the need for finalization of scope, identification of all stakeholders, and multi-level education.

Other issues discussed by the Panel include:

- recognition, awareness, and understanding of changes in guidance documents and other regulations;
- alignment of these changes with 13485;
- reconvening of the Panel for review and feedback;
- availability of an open document to all stakeholders;
- costs incurred by smaller companies;
- the possibility of increased noncompliance issues;
- communicating with notified bodies; and
- the use of IOC 601 standards.

Captain Lewandowski-Walker read Question 3**:** The proposed rule includes FDA-specific requirements and provisions which clarify certain concepts used 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?

A discussion took place regarding assessment of identified gaps to determine if they need to be in the new regulation, and broadening of the gap analysis to include the whole community of stakeholders.

Mr. Phillips reemphasized the importance of redlined copies to ensure specific feedback as to whether all areas are being properly addressed.

Captain Lewandowski-Walker read Question 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 medical device firms;
b. foreign firms and firms that have foreign manufacturing sites;
c. medical and healthcare providers; and
d. patients and end users?

Mr. Sardeson recommended inclusion of service providers and other entities within the medical device supply chain.

Mr. Gillerman and **Ms. Loy** stressed the importance of including supply chain tiers and identification of all stakeholders.

Dr. Kuo encouraged the integration of research groups and organizations.

Captain Lewandowski-Walker read Question 5: FDA intends to provide additional information and educational 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?

Mr. Sardeson recommended the AAMI TIR, the ISO handbook, and the MDSAP manual, as well as relying on various organizations such as TC 210, AdvaMed, AAMI, and MITA for help with training and collaboration.

Dr. Kuo suggested using FDA guidance documents as aids in quality system development.

Mr. Phillips pointed out that stakeholders will have varying degrees of experience and familiarity with the different standards, and some might have none at all, and that this must be taken into account for training and educational activities.

There was further discussion regarding other possible venues for explaining the transition beyond instructional endeavors. Conferences, panels, continued FDA participation, and posting of testimonials on various websites were suggested, as well as the involvement of the entire community, including small companies and innovators.

Captain Lewandowski-Walker read Question 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? And does the Panel agree that the more explicitly integrated risk management expectations are essentially equivalent to the current regulation?

Ms. Loy pointed out that this is a significant change for many domestic organizations and that proactive measures should be instituted to accommodate them.

Dr. Kuo noted that research groups will need to be educated about more stringent

auditing requirements that they are not aware of which could affect their funding.

Panel members also exchanged views on outreach and resources for U.S. only manufacturers, such as the NIST Manufacturing Extension Partnership program.

Mr. Sardeson observed that further alignment and continued discussion about the expectations on risk management will benefit all stakeholders.

Captain Lewandowski-Walker read Question 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 a new inspection model?
b. What are the Panel's thoughts on the current inspection model, the Quality System Inspection Technique?

    i. In other words, what are the things that work well in the model?
    ii. What doesn't work well, or where would you want to see change?

Mr. Sardeson stated that surveillance inspections will probably be similar to MDSAP reviews and stressed the importance of understanding how FDA uses 21 C.F.R. for different kinds of inspections. He also emphasized the merits of transparency and of ensuring that investigators and auditors are knowledgeable about the new inspection model.

Mr. Phillips noted that the QSIT manual would aid industry in preparing for inspections, that it would be beneficial to exclude certain documents from review, and that some aspects of the MDSAP could be adopted.

Other topics discussed by the Panel include:

- levels of responsibility and oversight for subcontracted products or services;
- conformity assessment methodologies;
- end of life cycle issues; and
- regulatory real-world validation.

CLOSING REMARKS AND ADJOURNMENT

Ms. Thomas thanked Chairperson David and the Panel members for their feedback and recommendations, as well as those who submitted their own presentations and comments. She outlined the next steps and encouraged further comment on the proposed rule.

Chairperson David thanked each of the Panel members and all of the participants for their contributions to the meeting.

Mr. Collier expressed his appreciation to Chairperson David, Ms. Thomas, and to all of the attendees.

Chairperson David then adjourned the meeting at 2:48 p.m.

I certify that I attended this meeting on March 2, 2022 and that these minutes accurately reflect what transpired.

Jarrod W. Collier -S

Digitally signed by Jarrod W. Collier -S
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Jarrod Collier, M.S.
Designated Federal Officer

I approve the minutes of this meeting as recorded in this summary.

Yadin David

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Yadin David, Ed.D., PE
Chairperson

Summary Prepared by

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