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Dockets Management Staff (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. FDA-2021-N-0507; *Medical Devices; Quality System Regulation Amendments; Notice of Proposed Rule*

Dear Sir or Madam:

We submit these comments on behalf of Cook Group Inc. ("Cook"). Cook is a family owned group of domestic and international corporations engaged in the manufacture of diagnostic and therapeutic products for use in various medical specialties including interventional radiology, cardiology, vascular surgery, critical care, gastroenterology, urology, reproductive health, wound care and surgery. We invent, manufacture, and deliver a unique portfolio of medical devices to healthcare systems of the world that includes more than 14,000 different product variations. Our company employs about 12,000 people around the world. Eight thousand of those employees are based in the United States and while more than 56 percent of our sales are used outside the United States, more than 70 percent of our products are manufactured in this country.

We thank the Food and Drug Administration (FDA) for the opportunity to provide comments on the proposed rule *Medical Devices; Quality System Regulation Amendments* dated February 23, 2022. This proposed rule intends to amend the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) Regulation by incorporating by reference the device quality management system set by the International Organization for Standardization (ISO) with the 2016 edition of ISO 13485.

Cook commends FDA for its work in harmonizing the regulation of devices with an internationally recognized standard designed to promote a systems approach to quality management. As noted in the proposed rule, the agency's efforts will help to provide consistent, safe and effective devices and facilitate timelier access to patients as well. This "more flexible approach to quality, based on risk management, found within ISO 13485 will meet the needs of patients to have access to quality devices in consonance with the progress of science and technology." [1, 2]

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[1] International Medical Device Regulators Forum, http://www.imdrf.org/

[2] Medical Devices; Quality System Regulation Amendments, Vol. 87 FR 10119, pg. 10119-10134, (23 February 2022). Federal Register website. https://www.federalregister.gov/documents/2022/02/23/2022-03227/medical-devices-quality-system-regulation-amendments

We fully support the agency's proposed rule outlining incorporation of requirements of the ISO standard by reference and provide several additional comments. FDA has stated that the purpose of the proposed rule is to "converge QS regulation with the QMS requirements of ISO 13485, while continuing to provide the same level of assurance of safety and effectiveness…. (page 10120 of the Federal Register notice). Thus, our comments focus on areas where the proposed rule creates greater requirements than exist currently under QS regulations or ISO 13485.

Proposed Definition of Customer

In proposed 820.3, *Definitions*, "customer" is defined as ... "persons or organizations, including users, that could or do receive a product or a service that is intended for or required by this person or organization. A customer can be internal or external to the organization."

The proposed rule makes the definition much wider than ISO 13485. The reference to "internal to the organization" is exceptionally broad and far beyond the requirements of ISO 13485. While it is a laudable goal to focus on customers internal to an organization, it would create an exceptional amount of paperwork to document compliance with such a requirement, with limited benefit.

We suggest deleting the last sentence:

"A customer can be internal or external to the organization."

Proposed change in Definition of Product

Proposed 820.3(b) supersedes the ISO 13485 definition of "product" ("result of a process") with "components, process agents, in-process devices, finished devices, and returned devices". ISO 13485 includes a note indicating that "services" can also be considered products under the definition of "product", but "services" are not included in the QSMR definition. In the preamble to the proposed rule, FDA notes:

> "[C]onsistent with the clarification in [ISO 13485] clause 0.2, which specifies that 'when the term "product" is used, it can also mean "service",' for the requirements of clause 7.4 Purchasing we expect that when ensuring purchased products conform to requirements, oversight for purchased services are also included."

However, other types of "services" are included in the current QSR, including current 820.170, *Installation*, and 820.200, *Servicing,* and have equivalent section in ISO 13845 (Section 7.5.3, *Installation activities* and Section 7.5.4, *Servicing activities*). Thus, the reason for changing the definition is not clear.

We propose the following definition of "product":

"*Product* means the result of a process and can include components, process agents, in-process devices, finished devices, and returned devices. Products can include hardware, software, and services."

Review of Management Review, Internal Audit and Supplier Audit Records

Organizations with effective quality management systems have long utilized their internal management review activities, internal audit systems, and supplier audit systems as a "management tool for corrective action, quality improvement, and overall assurance of component and service quality."[3]

Under FDA's Quality System Inspection Technique (QSIT) guide of August, 1999, FDA has published its general policy that "during routine inspections conducted at any regulated entity that has a written quality assurance program, FDA will not review or copy reports and records that result from audits and inspections of the written quality assurance program . . . FDA may seek written certification that such audits and inspections have been implemented, performed and documented and that any required corrective action has been taken."[4] The current QSR regulations also included an exception to FDA's inspectional authority for management review, and internal audit and supplier audit records.

> **We agree with this inspectional policy and believe the following information should be added to the proposed rule at Line 315:**
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> **Add the following:**
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> **"(e) *Inspection of records.* (1) All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available for review and copying by FDA employee(s).**
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> **(2) Records required by Clause 5.6, Management review, of ISO 13485 and Clause 8.2.4, Internal audit, of ISO 13485 and supplier audit records used to meet the requirements of Clause 7.4.1, Purchasing process, of ISO 13485, are not subject to inspection by employees of FDA, but the procedures established under these provisions are subject to inspection. Upon request of a designated employee of FDA, an employee in top management shall certify in writing that the management reviews, quality audits required under this part, and supplier audits where applicable, have been performed and documented, the dates on which they were performed, and that any required corrective action has been undertaken."**

This proposed text follows FDA's current policy stated in 21 CFR 820.180, with appropriate updates to align with the rest of the proposed QMSR regulation.

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[3] Medical Devices; Current Good Manufacturing Practice (CGMP) Final Rule; Quality System Regulation, Vol. 61 No. 195 Fed. Reg. 52,625 (7 October 1996). Federal Register website. https://www.govinfo.gov/content/pkg/FR-1996-10-07/pdf/96-25720.pdf.

[4] Compliance Policy Guide. (June 2007). CPG Sec. 130.300 FDA Access to Results of Quality Assurance Program Audits and Inspections. FDA website. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-130300-fda-access-results-quality-assurance-program-audits-and-inspections.

Transition Timeline

The magnitude of change required to upgrade a quality system from the current 21 CFR 820 QSR or an earlier version of an ISO quality standard will vary considerably between organizations. Firms will need to perform gap analyses comparing their current operational system requirements to the requirements of ISO 13485:2016 to determine where it may be necessary to revise system requirements, document new procedures, install new processes, train personnel and document compliance. Small U.S.-based companies may have never been audited to ISO 13485 and may not be able to create such a system in 12 months, creating a competitive disadvantage with OUS companies that already comply with ISO 13485. While Cook is confident that it can update its systems in 12 months, a longer transition time may be warranted for cases such as these.

Cook remains concerned that the time required to update FDA QSIT Program, train field staff, update Compliance Policy Guides, train necessary internal staff, fully train regulated industry to the final requirements of the QSR Amendments will require more time than proposed. We offer two alternative solutions:

> **Cook recommends that the transition period be implemented in phases to become effective at 36 months after the date of publication of the final rule in the Federal Register.**
>
> **Alternatively, Cook recommends that FDA retain the 12-month effective date for the QMSR but allow companies to comply with either QSR or QMSR for a period of 36 months following publication of the final QMSR rule.**

Quality System Inspectional Technique (QSIT), Inspector Training and Transparency

FDA has identified the need to update the current Quality System Inspectional Technique (QSIT) and inspector training in order to achieve successful implementation of the proposed rule. FDA raised a question regarding specific regulatory considerations to be considered in developing the new inspection model at the Device Good Manufacturing Practice Advisory Committee on March 2, 2022. Panel members responded with several suggestions[5] including:

Consider use of techniques employed in the Medical Device Single Audit Program (MDSAP) so as to build on the information already known and not 'reinvent the wheel'.

- Utilize an International Medical Device Regulatory Forum (IMDRF) working group to help shape a globally uniform system that will cover the needed elements of an inspection depending on the scope of the audit activity being conducted.

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[5]Brief Summary of the Device Good Manufacturing Practice Advisory Committee Meeting. March 2022. 21 CFR 820 Quality System Regulation Amendment Proposed Rule. FDA website. https://www.fda.gov/media/156939/download

- Be aware that this change in regulatory requirements will need to be well supported by experienced and knowledgeable trainers with a substantial training program in order to implement change management during the front-line audit activity.

Cook agrees with these general suggestions and supports transparency and training for all stakeholders, including industry, preferably in parallel with training of FDA staff.

Thank you for issuing the proposed rule on this topic and for providing an opportunity to comment on this important public health matter.

Respectfully,

Stephen L. Ferguson
Chairman of the Board