NuVasive Response to FDA Docket: Docket (FDA-2021-N-0507)

Title: Medical Device Quality System Regulation Amendment

Comment Due: May 24, 2022

Industry Comments to Proposed Rule

Summary "The Food and Drug Administration (FDA, the Agency, or we) is proposing to amend the device current good manufacturing practice (CGMP) requirements of the Quality System (QS) Regulation to align more closely with the international consensus standard for devices by converging with the quality management system (QMS) requirements used by other regulatory authorities from other jurisdictions (*i.e.,* other countries). We propose to do so through incorporating by reference an international standard specific for device quality management systems set by the International Organization for Standardization (ISO), the 2016 edition of ISO 13485 (ISO 13485). Through this rulemaking we also propose additional requirements to align with existing requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations, and make conforming edits to the Code of Federal Regulations (CFR) to clarify the device CGMP requirements for combination products. This action, if finalized, will continue our efforts to align our regulatory framework with that used by other regulatory authorities to promote consistency in the regulation of devices and provide timelier introduction of safe, effective, high-quality devices for patients."

Response NuVasive commends the Agency (FDA) for their staunch leadership and dedicated efforts towards harmonizing with major international consensus standards. In general, we agree with your proposal to align the QSR more closely with ISO 13485. Below we submit a comment for FDA's consideration. Thank you.

Section/Line Reference	Text as Written in Proposed Rule	Proposed Re-write	Justification
D. Proposed Requirement for a Quality Management System (Proposed § 820.10)	"The current § 820.5 requires that manufacturers establish and maintain a quality management system that meets the requirements of part 820. We propose to relocate this requirement within the codified and to revise this provision to require that a quality management system that complies with ISO 13485, as modified by the proposed part 820, be documented. These requirements will serve as the minimum requirements for establishing a QMS that complies with the final version of this proposed rule. In general, when ISO 13485 refers to documenting evidence we recommend that manufacturers record quantitative data, as appropriate, because such information will assist manufacturers in monitoring the performance of their processes and effectiveness of their process controls."	"…In general, when ISO 13485 refers to documenting evidence we recommend that manufacturers record ~~quantitative~~ data, as appropriate, because such information will assist manufacturers in monitoring the performance of their processes and effectiveness of their process controls."	'Recommendations' leave too much room for interpretation. Consider replacing "record quantitative data" with "record data" to allow manufacturers to determine the type of data that may be most appropriate (e.g. qualitative vs. quantitative).