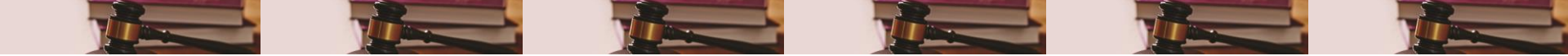

Medical Devices:
Do I Need to Open a CAPA?

Adrienne Franco Busby, Partner, Faegre Baker Daniels LLP
Anne Miller, Principal Regulatory Counsel, Medtronic
Marta L. Villarraga, Principal, Exponent, Inc.

Moderated by **Dennis Gucciardo**, Senior Associate, Hogan Lovells US LLP

FDLI

21 C.F.R. § 820.100

- **What does the regulation require?**

"Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action."

- **What must the procedure(s) do?**

Analyze the following sources "to identify existing and potential causes of nonconforming product, or other quality problems."

- Processes
- Work operations
- Concessions
- Quality audit reports
- Quality records
- Service records
- Complaints
- Returned product
- "Other sources of quality data"

Preamble to 21 C.F.R. Part 820*

- "…the objective of § 820.100 is to correct and prevent poor practices, not simply bad product. Correction and prevention of unacceptable quality system practices should result in fewer nonconformities related to product. **Therefore, this section addresses problems within the quality system itself.** For example, it should identify and correct improper personnel training, the failure to follow procedures, and inadequate procedures, among other things."

- "…the **degree** of corrective and preventive action taken to eliminate or minimize actual or potential nonconformities must be appropriate to the **magnitude of the problem and commensurate with the risks encountered**."

- "FDA cannot dictate in a regulation the degree of action that should be taken because each circumstance will be different, but FDA does expect the manufacturer to develop procedures for assessing the risk, the actions that need to be taken for different levels of risk, and how to correct or prevent the problem from recurring, depending on that risk assessment."

* 61 Fed. Reg. 52602, 52633-52634 (Oct. 7, 1996) (codified at 21 C.F.R. Part 820)

Any more FDA guidance?

- From FDA's Website "Quality System (QS) Regulation/Medical Device Good Manufacturing Practices.*"
  - "Manufacturers should use good judgment when developing their quality system…"
  - "The regulation provides the framework that all manufacturers must follow by requiring that manufacturers develop and follow procedures and fill in the details that are appropriate to a given device according to the current state-of-the-art manufacturing for that specific device."
  - "It is left to manufacturers to determine the necessity for, or extent of, some quality elements and to develop and implement specific procedures tailored to their particular processes and devices."
- From FDA's Guidance Document "Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff" (February 3, 2003)
  - "Your procedure(s) should explain how your CAPA system is tied to your risk management program."
  - "Your procedure(s) should define how your CAPA system will address nonconforming practices as well as nonconforming product."

* https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm (last visited November 29, 2017)

Consequences of Decision Making

- **Common Warning Letter Citation**: "Procedures for corrective and preventive actions have not been adequately established, as required by 21 CFR 820.100.(a). "
  - "since release of [PRODUCT], your firm has received 18 complaints regarding burns, potential burns, or [PRODUCT] that were "too hot"; **(b)(4)** of these complaints resulted in patient injury … . ***A Corrective and Preventive Action (CAPA) was not initiated***, in spite of 1) patient … injuries, 2) complaint trending codes …, and 3) the total number of complaints regarding the temperature of the device."
  - "your firm identified that **(b)(4)** of all **(b)(4)** complaints for laparoscopic devices are related to insulation damages and cracking issues and **(b)(4)** of all **(b)(4)** complaints are related to sterilization/cleaning issues. However, your ***firm did not initiate a corrective action to reduce re-occurrence of either issue***."
  - "during pre-production testing for lot **(b)(4)** of [COMPONENT] powder, your firm discovered quality issues with the sulfur you received from your supplier. However, you ***failed*** to document the steps taken to investigate, determine a root cause, and to ***initiate corrective and preventative actions***."

* https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm (last visited November 29, 2017)