THE QUALITY SYSTEM REGULATIONS

SUBPART J - CORRECTIVE ACTION AND PREVENTIVE ACTION

October 2020

21 CFR 820.100
Corrective and preventive action

"CAPA" is an informal acronym that stands for:

*"**C**orrective **A**ction and **P**reventive **A**ction"*

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'…the objective of § 820.100 is to correct and prevent poor practices, not simply bad product… Therefore, this section [also] addresses problems within the quality system itself…"

Preamble comment 162

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'… this section applies to process and quality system nonconformities, as well as product nonconformities…"

'…this section is broader than the requirement for investigations under § 820.198, because it requires that nonconforming product discovered before or after distribution be investigated…"

Preamble comment 161

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Important Concepts:

- **Corrective Action** (CA) should include action to prevent the *recurrence* of the problem

- **Preventive action** is action taken to eliminate the cause of a *potential* non-conformity, defect, or other undesirable situation in order to prevent occurrence.

ISO 13485:2016 section 8.5.2 “When planned results are not achieved, correction and corrective action shall be taken, as appropriate.”

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Important Concepts:

- **Correction** is an ISO 8402 (now ISO 9000) definition applied by FDA and refers to repair, rework, or adjustment, and is aimed at the disposition of an existing nonconformity.

- In contrast, **Corrective Action** is action taken to eliminate the causes of an existing non-conformity, defect or other undesirable situation in order to prevent recurrence.

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Important Concepts:

Within GHTF (IMDRF) guidance document (Quality management system –Medical Devices – Guidance on corrective action and preventive action and related QMS processes; November 2010): CAPA acronym is not used "…*because the concept of corrective action and preventive action has been incorrectly interpreted to assume that a preventive action is required for every corrective action*…"

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Important Concepts:

'…FDA agrees that it is essential that the manufacturer establish procedures for implementing corrective and preventive action and has revised §820.100(a) accordingly. The procedures must include provisions for the remaining requirements in the section. These procedures must provide for control and action to be taken on devices distributed, and those not yet distributed, that are suspected of having potential nonconformities."

Preamble comment #158

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(a) Each manufacture establish and maintain procedures for implementing corrective and preventive action.

***820.3(k) Establish means define, document (in writing or electronically), and implement.**

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The procedures shall include requirements for:

(a)(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems.

- ISO 13485:2016 section 8.5.2 (Monitoring and measurement of processes)
- ISO 13485:2016 section 8.5.3 (Monitoring and measurement of product)

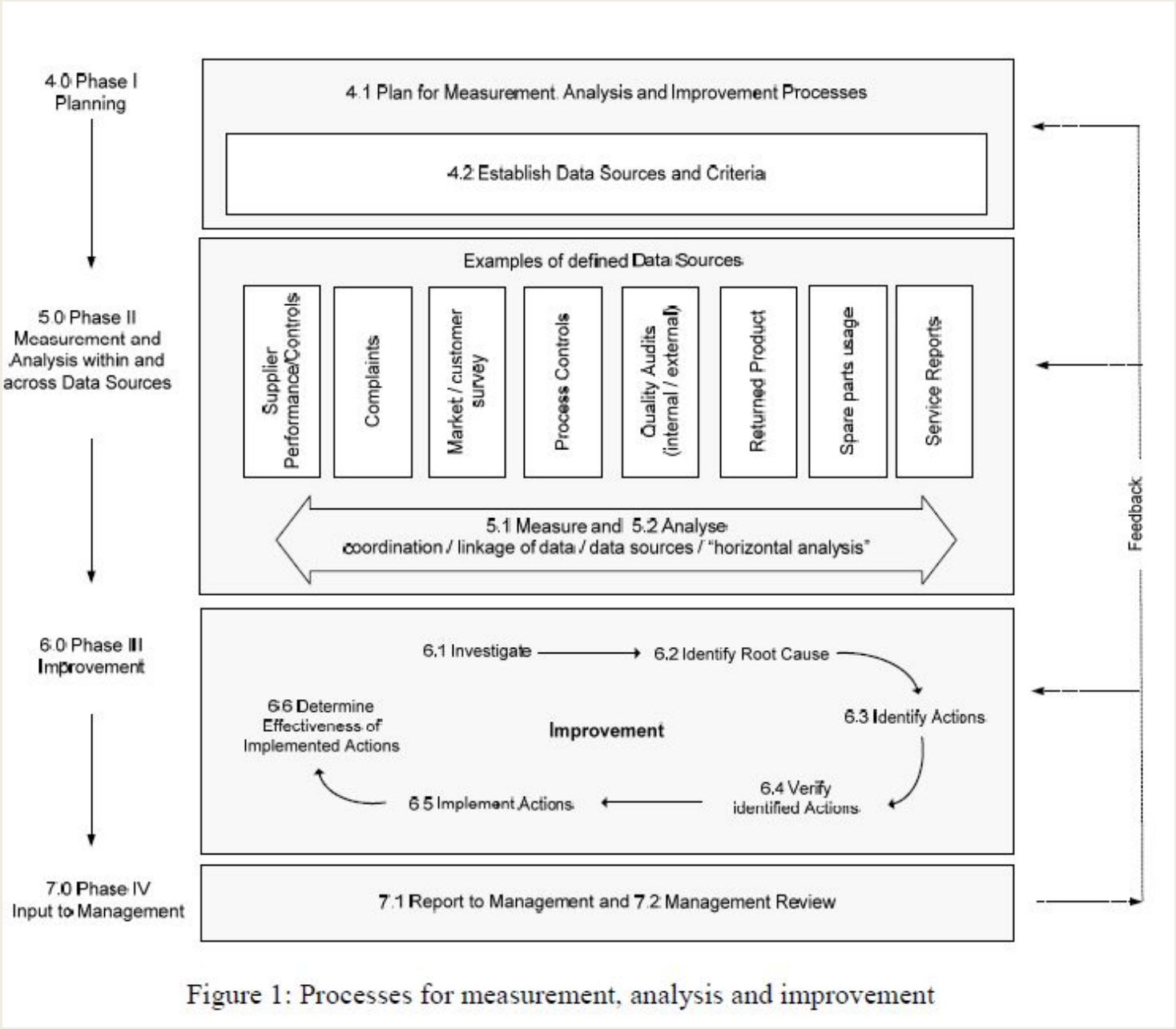

Figure 1: Processes for measurement, analysis and improvement

Guidance on corrective action and preventive action and related QMS processes; GHTF/SG3/N18:2010

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The procedures shall include requirements for:

(a)(2) Investigating the cause of nonconformities relating to product, processes, and the quality system.

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Preamble comment 161:

'…[820.00(a)(2)]…requires that nonconforming product discovered before or after distribution [as well as process and quality system nonconformities] be investigated to the degree commensurate with the significance and risk of the nonconformity. At times a very in depth investigation will be necessary, while at other times a simple investigation, followed by trend analysis or other appropriate tools will be acceptable…"

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The procedures shall include requirements for:

(a)(3) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems.

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820.100(a)(3):

> *"…FDA agrees that 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…"*

Preamble comment #159

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820.100(a)(3):

Preamble comment #159 (cont'd):

> *'…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…."*

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The procedures shall include requirements for:

(a)(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device.

ISO 13485:2016 adds, for the first time, the requirement to verify that the corrective action (section 8.5.2) and preventive action (section 8.5.3) do not have an adverse effect.

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Changes may be subject to:

-820.30(i) (design changes) and/or

-820.70(b) (production and process changes)

and their corresponding design and process verification & validation, should be completed before CAPA closure.

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820.100(a)(5) to (a)(7):

- *(a)(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;*
- *(a)(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and*
- *(a)(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.*

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(b) All activities required under this section, and their results, shall be documented.

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FDA Trends - Corrective and preventive action

- 820.100 (a & b) CAPA issues accounted for 42% of FDA observations in domestic inspections and 48% of FDA observations in foreign inspections.
- Inadequate CAPA procedures were the most frequent QS citation in 2017 Warning Letters.

https://www.fda.gov/media/111345/download

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Warning Letter Example:

Failure to establish and maintain procedures for implementing corrective and preventive actions, as required by 21 CFR 820.100(a). For example:

a. FDA reviewed 42 of your firm's Product Analysis Reports, produced between 2011 and 2014. These reports showed, in instances when your supplier's analysis provided evidence that lithium cluster bridging had prematurely drained the battery, your firm repeatedly concluded that the cause of premature depletion of XXX batteries "could not be determined." Your firm later categorized these as "unconfirmed" lithium bridges. Your firm's *Corrective Action and Preventive Action (CAPA) Procedure, (b)(4), Revision AA* states, in Section 2.0, the level of corrective action and preventive action shall be commensurate with the significance and risk of the nonconformance. Further, Section 5.0 states the risk evaluation of nonconformances is based on three factors: severity, probability, and detectability. By basing your firm's risk evaluation on "confirmed" cases and not considering the potential for "unconfirmed" cases to have been shorts, your firm underestimated the occurrence of the hazardous situation. This delayed initiation of *CAPA #XXX Titled: Lithium Clusters Shorts in M2850 Cells*, until December 18, 2013, and your firm continued to distribute devices containing this battery until October 2016.

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Warning Letter Example:

Failure to establish and maintain adequate procedures for implementing corrective and preventive action, as required by 21 CFR 820.100. For example:

A) Your firm did not follow their CAPA procedure, QP-XXX, Corrective And Preventive Actions, Revision D., Section 6.6, in that you did not analyze data sources (i.e., Complaints and non-conformances) to identify potential causes of non-conforming product or quality problems. Instead, your firm uses external audits, or feedback from suppliers to identify issues and open CAPAs if needed. There have been 277 complaints received since May 2011. In addition, communication and training of changes for affected individuals were not performed or recorded as required by section 6.6 of the CAPA procedure.

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Warning Letter Example Cont.

B) CAPAs were neither conducted nor documented in an adequate manner as evidenced by:

1. CAPA #XXX was opened to address an external audit deficiency regarding the process validation procedure needing to be verified for appropriateness. The root cause documented was "LACK OF PROCESS VALIDATIONS" and the corrective action was to validate the (b)(4) test performed during production along with conduct an external audit of the supplier of printed circuit board assemblies. However, this CAPA did not include the following: an assessment of whether there were other potential processes which were not validated, an effectiveness check, and there was no documented evidence that this CAPA was disseminated to the individuals directly responsible for assuring the quality of product and prevention of the problem.

CAPA Poll Question

QUESTIONS?