

List of CAPAs

ISO 13485:2016 Section	Document Section
8.5.2	(All)
8.5.3	(All)

Summary

This list contains all of our Corrective and Preventive Actions (CAPAs).

List of CAPAs

- “*Adverse Implications*”: Verifying that the corrective / preventive action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device.
- “*Verification*”: Documenting proof of implementation of actions taken.
- “*Effectiveness*”: Review of the effectiveness of corrective / preventive actions taken.
- “*Root Cause*”: Analyzing the underlying cause that led to the event. Different methodologies can be used, e.g. *5 Why’s* (asking 5 times Why? in a row) or *Ishakawa/Fishbone Diagram* (identifying cause categories and sub-causes in a diagram).

Input Category	CAPA ID	Date Created	Description	Root Cause	Completed	Date (Corrective / Preventive)	Action	Date Defined	Potentially Adverse Implications	Date of Verification	Effectiveness Evaluation	Date Closed
Usability feedback	01-01-2022	No CAPA	Missed Test Case for Product Information	01-01-2022		New product release incl. contact tails; update test cases		03-01-2022		Release of product version and test case update	Number of future complaints related to this issue; review of technical information by Notified Body for completeness	

Template Copyright openregulatory.com. See template license.

Please don't remove this notice even if you've modified contents of this template.