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	CAPA Description	Root Cause	Date Root Cause Analysis Completed	Action (Corrective / Preventive)	Date Actions Defined	Potentially Adverse Implications	Date of Verification	Verification	Effectiveness Evaluation	Date Closed
Usability feedback	1	01-01-2022	No contact details provided as part of product information	Missing Test Case for Product Information	02-01-2022	New product release incl. contact details; 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	