Corrective And Preventive Action (CAPA) Methodology

Current Good Manufacturing Practices for Medical Devices (CGMP) subpart J – Sec.820.100 Corrective and Preventive Action states; *each manufacturer shall establish and maintain procedures for implementing corrective and preventive action.* Based on this requirement, Medical Device and Pharmaceutical companies have created a CAPA system to provide a uniform and consistent process to conduct and document external and internal problem investigations and subsequent corrective and preventive actions.

Business Excellence Professional Consulting (BEPC) provides a framework and a systematic methodology for identifying, documenting, analyzing, and preventing occurrence or recurrence of problems associated with products, processes, and/or systems.

The CAPA methodology is outlined below in 5 phases using the 6 sigma DMAIIC process.

DMAIIC Phase	CAPA Phase
Define	1. Inputs and Triggers 2. CAPA Request 3. Open CAPA File for Documenting Investigation and other actions
Measure	1. Perform an Investigation of the incident 2. Document the investigation
Analyze	1. Results of the investigation are analyzed to identify the root cause and corrective and preventive actions 2. The Failure Investigation Report and the implementation Plans are reviewed and approved
Innovative improvement	1. Verification and Validation is performed on possible corrective actions 2. Corrective and Preventive Actions are Implemented
Control	1. Effectiveness of the Corrective Actions is Monitored

The BEPC Advantage

Why should our clients choose BEPC?

- Each client receives dedicated attention and a customized solution for their specific needs
- Flexibility to contract short or long term, fulltime or part time services
- Competitive negotiated rates with Volume Discounts
- Our network of consultants covers the US East, Central and West Coasts, as well as Mexico, minimizing our clients' costs
- High quality consultants ensures high quality results; our consultants are:
  - Highly skilled and qualified
  - Professional and committed
  - Experienced with short learning curves

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