NETWORKPARTNERS

ENHANCE YOUR QMS

Corrective Action/Preventive Action

CAPA

CORRECTIVE ACTION/ PREVENTIVE ACTION

The CAPA system is a mechanism that identifies and implements any changes necessary to ensure and maintain the continued effectiveness of the Medical Device Manufacturers (MDM) Quality Management System (QMS).

ISO 13485 requires:

that the MDM shall identify any changes necessary to ensure and maintain the continued suitability, adequacy and effectiveness of the quality management system, as well as medical device safety and performance through the use of the quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective actions, preventive actions and management review.

21 CFR Part 820.100 Subpart J, a) requires:

that each MDM shall establish and maintain procedures for implementing corrective and preventive action.

Once a corrective or preventive action has been escalated to a CAPA, it is reviewed monthly in the CAPA Review Board (CRB). The CRB ensures CAPAs are being resourced and addressed in a timely manner based on key metrics.

Metrics measure the health the of the CAPA system. Typical CAPA metrics are timeliness per phase (Investigation, Implementation, and Control) and the number of CAPAs opened and closed per month.

There are various types of triggers that can warrant a CAPA, such as but not limited to:

- Production and Process Controls
- Equipment and Facility Controls
- Design and Process Validations
- Design Controls
- Audits (External and Internal)
- Non-conforming Product
- Material Controls
- Risk Management
- Complaints
- Management Review
- Corrective Action/Preventive Actions
- Supplier Corrective Action Requests (SCAR)

CAPA

DMAIC METHODOLOGY

There are three main phases that comprise a CAPA process, which follow DMAIC (Define, Measure, Analyze, Improve, Control) Methodology.

1 PHASE I - INVESTIGATION

Define

What is the problem?

The problem statement is the backbone of a successful CAPA. It should be clear and concise.

Measure

How many parts, lots, and/or model numbers are affected by the CAPA?

Measuring the extent of the non-conformity that triggered the CAPA will help to identify activities for quarantining affected lots. Having a clear problem statement will help drive the root cause analysis activities.

Analyze

How is the problem analyzed?

There are various root cause analysis tools that are available for determining the root cause.

- Fishbone Diagram
- 5-Why's
- Cause and Effect Diagram
- Is / Is-Not

The root cause analysis is key to determining the cause of the non-conformity.

The CAPA investigation typically has a maximum 30-day investigation period to identify the root cause.

CAPA

DMAIC METHODOLOGY

2 PHASE II - IMPLEMENTATION

Once the root cause has been determined, the implementation plan is developed. Individual tasks required to address the root cause such as testing, documentation updates, as well as defining what will occur in the Control Phase with clear acceptance criteria and duration.

Prior to implementing any changes, the MDM will want to verify the root cause has been addressed correctly. This can be done through but not limited to, design verification and validation, process verification and validation activities.

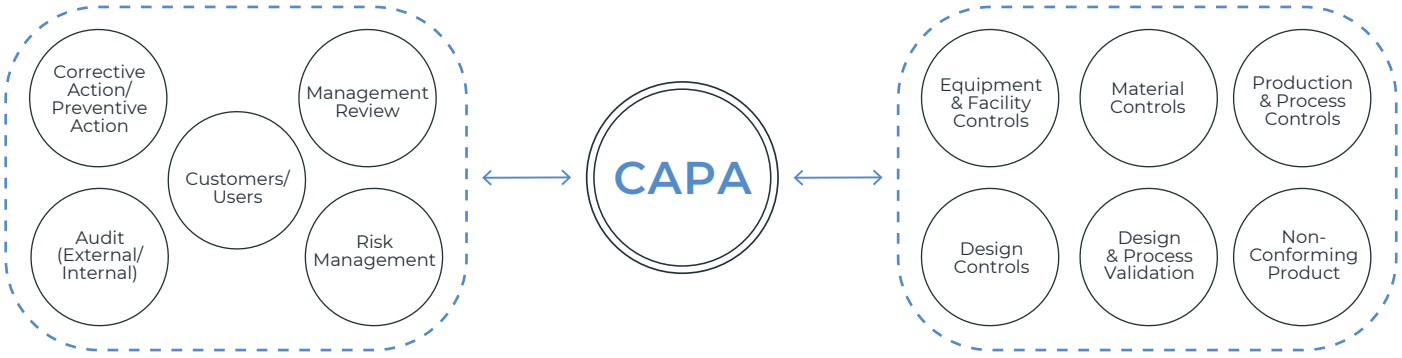
3 PHASE III - CONTROL

Once the implementation activities have successfully proven that the root cause has been addressed, the CAPA will then move to the Verification of Effectiveness (VOE) in the Control Phase.

During the control period, the implemented fix to correct the non-conformity is monitored for specified period of time to determine if the same non-conformity re-occurs.

Once all phases have been successfully completed, the CAPA is reviewed by the CAPA Review Board and closed.

The CAPA system ensures the health of the QMS and is effective for 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.



ABOUT

NETWORK PARTNERS

Network Partners is a professional services firm that helps clients complete the work necessary to provide their products to patients. We serve the medical device, pharmaceutical and biopharmaceutical industries with core competencies in Regulatory Affairs, CER, Packaging Engineering, Labeling, Quality and Project Management.

Our business model allows team leaders to turn under-resourced teams into productive groups that are better for the company and morale. This approach delivers right-sized pricing as well as quantifiable ROI on stalled projects, cost-savings initiatives and much more. We consistently deliver on time and on budget, helping clients get work done and avoid project delays.

Visit us at **networkpartners.com** to learn more.

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