Integration of SOPs with CAPA - BPX shares insights

Here are the key business objectives for integrating SOPs with the CAPA process framework:

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DUBAI, October 3, 2022 /EINPresswire.com/ -- Widely used in the business world, CAPA or Corrective and Preventive Action are essentially actions taken by an organization or business for correcting non-compliance with regulations, non-conformity with the best codes of practice, or any other sub-optimal workplace situation. Thus, they are processes for identifying, documenting, and addressing defects, deficiencies, and non-conformities. Often termed as the organization's immune system or defense mechanism, CAPA helps to identify deviations or quality events, investigate them, and implement corrective and preventive action as a process improvement or remedy. CAPA can be applied in various key disciplines, i.e.

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>
> *Nikhil Agarwal*

Manufacturing
Product Design
Use-Applications
Testing, Verification, and Validation
Distribution, Shipping, Transport, and Packaging

The difference between corrective action and preventive action can be explained through their functionalities:

Corrective action is an extension of root cause analysis. The primary objective of corrective action is to ascertain the root cause, event, or error that came before the problem. The second goal is to take action directed at the root cause or error and to remedy a situation that has already occurred. Preventive action is the lesson learned by an organization, and its primary

goal is to keep an organization informed and aware of the problem and prevent it from recurring or returning to other facilities, or product lines.

The difference between corrective action and preventive action can be further highlighted, in that corrective action eliminates the causes of an existing nonconformity or undesirable situation to prevent its recurrence after it has already taken place. Preventive action, on the other hand, forecasts or predicts that a nonconformity is likely to occur and takes pre-emptive action to stop it from repeating itself. It thus identifies and eliminates the cause(s) of such potential events to prevent their future occurrence.

Why define CAPA

The corrective and preventive action report format defines a set of actions, laws, and regulations requiring an organization to take in manufacturing, documentation, procedures, or systems to rectify and eliminate recurring or repeated non-conformance, which is identified after systematic evaluation and analysis of the root cause. This report is prepared by a team consisting of quality assurance personnel and people observing non-conformance and must be standardized, enforced, and observed to eliminate the further occurrence of such events. Non-conformance may be a market-driven or customer complaint, examples being the failure of machinery, quality management system, or misinterpretation of written instructions to carry out work.

The Eight Disciplines Problem Solving (8D) methodology can be effectively used to structure the CAPA framework. This is a technique applied to solve problems and is suited to determine the problem's root cause, provide a short-term solution, and administer a long-term remedy to prevent recurring problems. The various steps in the 8D plan are:

D0: Plan
D1: Form Your Team
D2: Define the Problem
D3: Contain the Problem
D4: Identify the Root Cause
D5: Analyze and Select Corrective Actions
D6: Implement and Validate Corrective Actions
D7: Implement Preventive Actions
D8: Recognize Your Team

Key Business Objectives for defining and integrating SOPs with the CAPA process

Standard Operating Procedure (SOPs), i.e. a set of guidelines or tools to standardize an organization's operational roadmap can be effectively introduced for various investigative tools to determine the root cause that enables the CAPA process mechanism. SOPs can document the process of identification, evaluation, implementation, effective monitoring, and closure for the corrective and preventive action report format.

Describe the procedure governing various investigative tools to find the root causes that facilitate the identification of corrective or preventive actions
Identify quality and GMP (Good Manufacturing Practice) issues and monitor the implementation of CAPA.

Define a corrective and preventive action report format for tracking the identification of corrective or preventive actions through well-defined quality systems such as (but not limited to):
Deviations, event and incident investigation
External Audit observations
Out of specification (OOS) results
Out of trend (OOT) results
Non-Conformance
Product recall
Product Quality review
Failure investigation
Returned products
Market complaints
Self-inspection
Risk management assessments
Change control and planned modification
Internal/External audit observations
Regulatory issues and recommendations
Management reviews and sources of quality/data trends
Issues necessitating mid and long-term CAPA with a tracking and documentation process, recommendations of validations carried out, etc.

Approaches and Responsibilities for executing the CAPA framework

Here are the various approaches used for successfully carrying out the CAPA process:

To identify and analyze quality system data and information for existing or potential causes which may lead to non-conformance.
To undertake investigations to find out the root cause.
Identify CAPA as applicable, based on the cause<
Monitoring and tracking CAPA
Effective verification of the quality impacting the implemented actions

The responsibility for implementing CAPA lies in the hands of the following key personnel:

Lead Investigator: He is supported by a cross-functional team, and reviews and assesses deficiencies and recommendations for CAPA.

Investigation team: They identify the root cause and plans for CAPA, in case the cause is not identified at the start.
Quality Assurance team: They issue CAPA numbers and maintain the corrective and preventive action report format and documents.
Head-Quality Assurance/Designee: He maintains the CAPA tracking log and ensures the implementation of the identified CAPAs.

About BPX

Based out of Pune, India, Business Process Xperts (BPX) is a leading management consulting firm specializing in the development of digital SOPs and custom-built Corrective and Preventive Action (CAPA) process roadmaps for its distinguished clientele. A division of Mind-A-Mend Consultancy Private Limited, along with its sister organizations YRC and YFC, the firm has been developing innovative, paperless SOPs for companies belonging to diverse industry sectors, ranging from automobile to engineering companies, and banks to financial institutions. BPX has proven expertise in business process management, process consulting and process outsourcing services, acting as a key enabler facilitating organization transformational journeys, helping them to become process-oriented and organized, and achieve operational efficiencies with a core business focus.

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