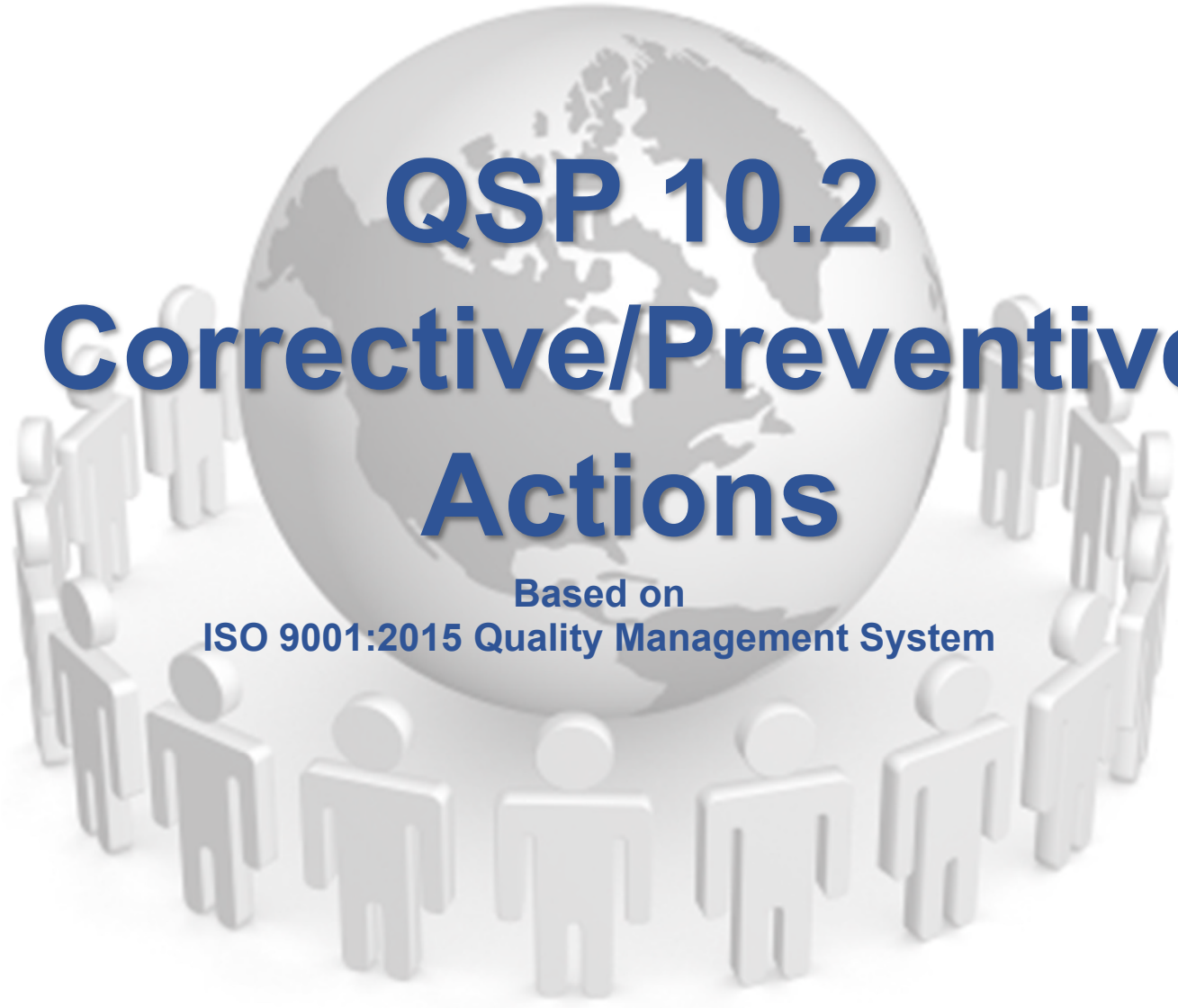
SYGNETICS

Success Through Synergy



QSP 10.2 Corrective/Preventive Actions

Based on
ISO 9001:2015 Quality Management System

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Revision Status

REV #	DETAILS OF CHANGE	DATE
0	Initial Release	1 Dec 2014
1	Changes were caused from Stage 1 Audit findings. Major rewrite. Refer to Stage 1 Audit Forms – 0411 dated December 22, 2014	5 Jan 2015
2	Updated to conform to 9001:2015 standard	1 Nov 2017

1 Purpose

1.1 This procedure establishes the process to correct the cause(s) of nonconformances or potential nonconformances in products, processes, the Quality System, and/or services at Sygnetics, Inc. in accordance with the Quality Manual.

2 Scope

2.1 This procedure is applicable to all organizations providing products and services governed by the requirements specified within the Sygnetics Quality System.

3 Responsibilities

3.1 Process Owner - Quality Manager

The Quality Manager is responsible for the following activities:

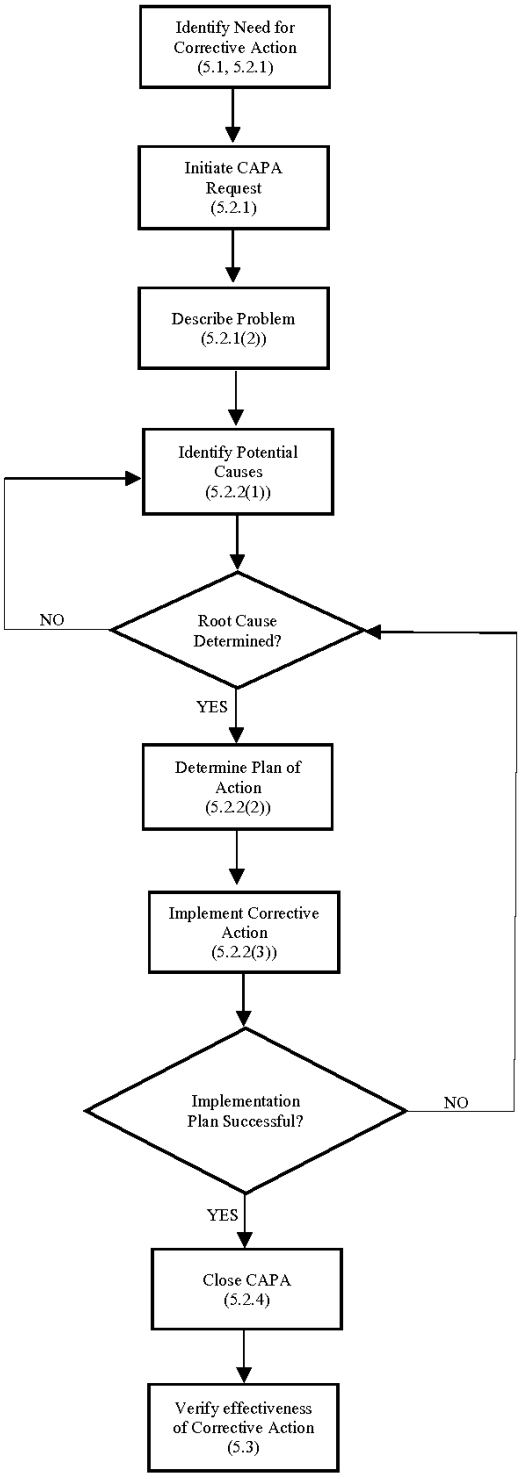
- initiating CAPA when a need for corrective or preventive action is identified
- assigning CAPA number and updating master CAPA log
- reviewing CAPA for clarity and completeness
- reviewing and assigning CAPA to responsible Program/Project Manager
- monitoring CAPA status to ensure complete and timely response
- filing completed CAPA and updating log
- tracking CAPA completion dates
- developing, maintaining, and reporting metrics as defined in the Metrics section of this document
- providing corrective or preventive action metrics to the Quality System Management Representative
- filing copies of objective evidence which support verification and validation of CAPA closure

3.2 Program/Project Manager

The Program/Project Managers are responsible for the following activities:

- investigating and determining root cause(s) of nonconformance
- identifying and implementing timely corrective or preventive action
- reviewing corrective or preventive action to verify implementation

4 Flowchart


Identify Need for Corrective Action (5.1, 5.2.1)
Initiate CAPA Request (5.2.1)
Describe Problem (5.2.1(2))
Identify Potential Causes (5.2.2(1))
Root Cause Determined?
NO
YES
Determine Plan of Action (5.2.2(2))
Implement Corrective Action (5.2.2(3))
Implementation Plan Successful?
NO
YES
Close CAPA (5.2.4)
Verify effectiveness of Corrective Action (5.3)

5 Procedure

5.1 Establishment of Need

The CAPA process shall be initiated whenever a condition warrants an investigation to determine if corrective or preventive action is required.

5.1.1 Corrective action shall be documented using the CAPA Request Form and processed electronically in accordance with this document. Corrective action shall be initiated as a result of, but not limited to, the following:

- Nonconformances identified during audits
- Action items from executive management reviews of Quality System effectiveness
- Customer complaints
- Process or product problems identified by employees
- Review of trends or significant discrepancies discovered by analysis of Nonconformance Reports

5.1.2 Preventive action shall be documented using the CAPA Request Form and processed electronically in accordance with this document. Preventive action shall be determined from the analysis of appropriate data to detect trends and identify causes that may result in future nonconformances. Data sources may include, but are not limited to, the following:

- Internal and external audit reports
- Corrective or preventive action data
- Customer comments

5.2 Process

A CAPA is processed using an electronic version of the CAPA Request Form. All fields must be filled out for the form to be complete. The Quality Manager will keep a copy of each completed form as a Quality Record.

5.2.1 The Quality Manager will:

1. Identify a need for corrective or preventive action.
2. Obtain a CAPA Request Form and completely describe the problem. Site objective evidence when possible. (*Problem Statement*)
3. Assign an identification number to the CAPA request and enter it into the CAPA Request Log.
4. Forward the CAPA form to the responsible manager.

5.2.2 The responsible Program/Project Manager will:

1. Investigate and determine the root cause(s) of the nonconformance and document the root cause(s) in the CAPA request form. (*Most Likely Cause*)

2. Determine a plan to eliminate the root cause(s) of the nonconformance, taking into consideration the magnitude of the problem and the risk involved, and document the plan in the CAPA request form. (*Implemented Solution*)
3. Execute the plan to eliminate the root cause(s) of the nonconformance, using appropriate change control procedures for all changes to processes, procedures, and other documentation.

5.2.3 If the corrective or preventive action taken is complete and acceptable, the Responsible Manager signs and forwards a copy of the CAPA form to the Quality Manager, indicating concurrence with closure of the CAPA. (within 10 working days of the CAPA being assigned)

5.2.4 The Quality Manager will review the CAPA form for clarity and completeness, close the CAPA, process and file the form, and update the CAPA Log. If the CAPA form is not complete, the Quality Manager will return the form to the Responsible Manager for completion before the CAPA form is processed and filed.

5.3 Verification

Internal auditors will verify effectiveness of action taken in accordance with QSP 9.2 Internal Quality Audit.

6 Metrics

Patterns and trends in corrective and preventive action data shall be analyzed, reported and reviewed by appropriate levels of management in order to:

- Monitor the timeliness and adequacy of corrective and preventive actions.
- Identify additional opportunities for improvement of processes, products and the quality management system.

7 Quality Records

The following Quality Records shall be generated and managed in accordance with Record Control.

Required Record	Custodian
Completed CAPA Form	Quality Manager

8 Forms

Forms related to this documents are:

Title
Sygnetics CAPA Request Form