



Work **Smarter,**



Not Harder

Make your CAPA verification of effectiveness SMART | by Mark Durivage

As an auditor, I frequently write findings for corrective and preventive actions without an adequate—or even well thought out—verification of effectiveness (VOE) that demonstrates effectivity.

The purpose of a VOE is to ensure that the actions taken yield the expected result and that there are not unintended consequences as a result of the corrective action. Despite their good intentions, many VOEs frequently fall short of adequately or thoroughly assessing CAPA effectiveness.

The CAPA process generally consists of eight distinct phases (see Figure 1, p. 42): problem identification, impact assessment, correction and containment, investigation and root cause analysis (RCA), corrective action, implementation, VOE and closure. The VOE phase is also called effectivity.

Regulations and standards

U.S. Food and Drug Administration (FDA) regulatory requirements and many International Organization for Standardization (ISO) standards require a review of the effectiveness of implemented CAPAs. These regulatory requirements and standards, however,

Just the Facts

The specific, measurable, achievable, relevant and time bound (SMART) method can ensure an organization's corrective and preventive actions (CAPA) are truly effective.

The method requires asking five basic questions that can help quality practitioners improve the effectiveness of their CAPA programs and demonstrate compliance with regulations, standards and expectations.

provide little, if any, guidance on what constitutes an acceptable VOE.

The VOE requirements for quality system regulation, which can be found in the FDA's Code of Federal Regulation (Title 21, Part 820.100 Corrective and preventive action), says: "Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for ... verifying or validating the [CAPA] to ensure that such action is effective and does not adversely affect the finished device."¹

The requirements pertaining to VOE in ISO 9001:2008 are: "The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered. A documented procedure shall be established to define requirements for ... reviewing the corrective action taken and its effectiveness."²

ISO 9001:2008 states: "The organization shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects

of the potential problems. A documented procedure shall be established to define requirements for ... reviewing preventive action taken and its effectiveness.”³

ISO 9001:2015 addresses VOE requirements: “When a nonconformity occurs, including any arising from complaints, the organization shall ... review the effectiveness of any corrective action taken.”⁴

In the recently released ISO 13485:2016, VOE requirements are explained: “The organization shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions shall be taken without undue delay. Corrective actions shall be proportionate to the effects of the nonconformities encountered ... reviewing the effectiveness of corrective action taken.”⁵

After reviewing these requirements, the question you must ask is, “How do

I ensure a CAPA is truly effective?” This raises several additional questions:

- + Do I re-execute the process validation?
- + Do I see whether the issue reappears in 90 days?
- + Do I analyze the next three production lots?
- + Do I analyze the next three shipments from the supplier?

While each of these questions may be valid, their answers may not fully verify the effectiveness of implemented corrective actions. This is where the application of specific, measurable, achievable, relevant and time-bound (SMART) goals method can be applied to CAPA and VOE processes.

Make CAPAs SMART

The SMART method sets goals that can be directly applied to a good VOE using five questions:

- 1. Specific**—Is the VOE unambiguous, clear and focused?
- 2. Measurable**—Are quantifiable data being used to assess the VOE?
- 3. Achievable**—Is the VOE feasible or practical?
- 4. Relevant**—Is the VOE appropriate for the level of risk?
- 5. Time bound**—Does the VOE have a realistic deadline?

VOE example

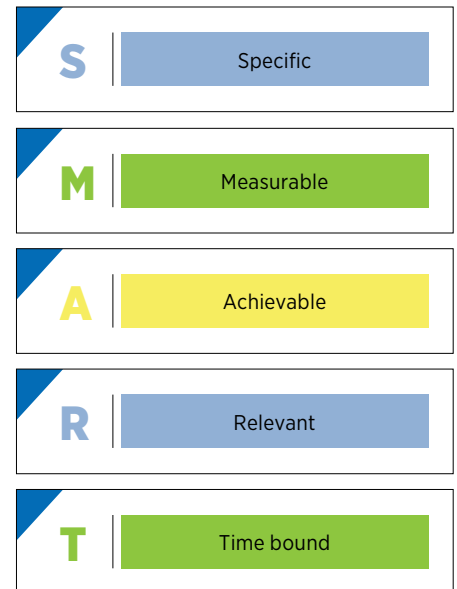
Consider this example of VOE (names of the product and organization and the team’s results were changed for confidentiality). Recently, a long-running stable process on Acme Press 112, which produces Adapter 1674, revision C, began producing parts that were out of specification on critical characteristic No. 3. Acme Press 112 is used only to produce Adapter 1674. A typical production lot can be produced in a 10-hour shift, which is a normal workday for the facility.

A CAPA was opened as a result of the nonconforming product being produced. An impact assessment and containment

FIGURE 2

Applying SMART criteria

Verification of effectiveness checks



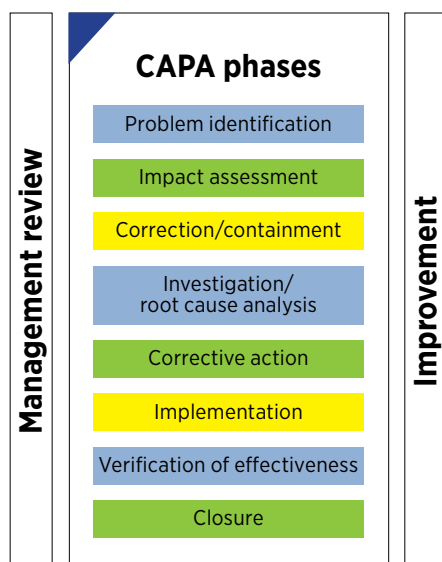
action were performed, production records for the previous five lots were reviewed, a root cause investigation was conducted, and a corrective action was implemented.

During a review of the batch records, the CAPA team’s investigation revealed machine settings were set outside the validated parameters due to new, inexperienced operators. The team concluded this was the likely root cause of nonconforming product.

The CAPA team decided to address the root cause by changing the programmable logic controller user access permissions, which would restrict an operator’s ability to select parameters that were outside the validated settings. Additionally, operators were retrained to ensure validated

FIGURE 1

The 8 phases of the CAPA process



CAPA = corrective and preventive action



machine parameters were set per procedure and that the validated settings would be recorded in the device history record (DHR), also known as a batch record.

The CAPA owner, in conjunction with the CAPA team, used the SMART method to develop the VOE check, and they decided on the following VOE:

Adapter 1674 Revision C critical characteristic No. 3 produced on Acme Press 112 will be monitored for conformance to specifications over three consecutive days of production (three lots) using a tightened level of inspection per the sampling procedure.

The CAPA will be deemed effective if critical characteristic No. 3 is within specification for three consecutive days of production (three lots), the operators are unable to select parameters outside of the validated range, the operators were retrained, and the proper validated settings are recorded in the batch record.

Evaluating the VOE

The next step is to evaluate the VOE and determine whether it's SMART.

Specific—Is the VOE unambiguous, clear and focused? Yes:

- + Adapter 1674 revision C critical characteristic No. 3 produced on Acme Press 112 will be monitored for conformance.
- + Operators are unable to select parameters outside the validated range.
- + Operators will be retrained to ensure validated machine parameters are set per procedure.
- + The validated settings are recorded in the DHR.

Measurable—Are quantifiable data being used to assess the VOE? Yes:

- + Critical characteristic No. 3 will be monitored for conformance to specifications for three consecutive days of production (three lots) using a tightened level of inspection per the sampling procedure.

- + Training records will be reviewed to ensure the operators were retrained.
- + Batch records will be reviewed to ensure the proper validated settings were recorded and used.

Achievable—Is the VOE feasible or practical? Yes:

- + There will be monitoring for conformance to specifications for three consecutive days of production (three lots) using a tightened level of inspection per the sampling procedure.

Relevant—Is the VOE appropriate for the level of risk? Yes:

- + Tightened level of inspection per sampling procedure will be used to monitor critical characteristic No. 3.
- + Time bound—Does the VOE have a deadline? Yes:
- + The VOE will occur over three consecutive days of production (three lots).

Results

Acme Press 112 produced Adapter 1674 revision C for three consecutive days (three lots). Critical characteristic No. 3 was verified using the tightened inspection plan. All inspected manufactured product was found to be in conformance.

It was confirmed that the operators were able to set parameters only within the validated range. The training records indicated the operators were retrained. Additionally, the batch records were reviewed to ensure the proper validated settings were recorded and used. The

CAPA team decided the CAPA was complete and effective. The team also shared its success with other departments so similar actions could be implemented.

The example demonstrates the appropriate use of the SMART method to verify CAPA effectiveness and ultimately provide CAPA closure. Adapting the SMART method can help improve the effectiveness of your CAPA program and demonstrate compliance with regulations, standards and expectations. **QP**

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2. International Organization for Standardization (ISO), *ISO 9001:2008—Quality management systems—Requirements*, subclause 8.5.2.
3. Ibid., subclause 8.5.3.
4. ISO, *ISO 9001:2015, Quality management systems—Requirements*, subclause 10.2.1.
5. ISO, *ISO 13485:2016, Medical devices—Quality management systems—Requirements*, subclause 8.5.2.

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