PrimusGFS General Regulations

Appendix 3

Guidance for the Closure of Non-Conformances & Corrective Actions

Used in conjunction with the PrimusGFS v3.2

This document will be effective on April 11, 2023

PrimusGFS (owned by Azzule Systems, LLC)

Contact Us:
PrimusGFS@azzule.com

Santa Maria, California, U.S.A. +1-805-862-4219
Culiacán, Sinaloa, México +52-667-716-5037
Viña del Mar, Chile +56-32-332-5045

PrimusGFS v3.2 General Regulations

12 Non-conformances & Corrective Actions (excerpt, see General Regulations for the complete Section 12)

a. In order for the audit to move to the certification phase, all identified non-conformances must have corrective actions verified and closed out by the certification body.
b. The corrective actions must be submitted into the PrimusGFS database within 30 calendar days from the original audit date.
c. The submission of corrective actions does not guarantee that the score will increase but should demonstrate that the organization has taken or will take the corrective actions and/or preventive measures to control the identified non-conformance.
f. If a corrective action is not able to be completed during the 30-day corrective action timeframe, the organization should submit a corrective action plan, with the evidence of intent to complete, and a timeframe for completion and/or a written risk assessment with the identified mitigation measures in place that show the identified root cause of the non-conformance is controlled.

GFSI Corrective Action Requirements

5.24 Management of Certification - Evidence of corrections or corrective actions shall be returned, completed, and verified by the Certification Bodies, within a timescale defined with the Certification Programme Owner, before certification can be awarded.

In order to be certified, it is necessary for all corrective actions to be closed out by the certification body. Closure of corrective actions can be accomplished by submitting corrective actions or corrective action plans if applicable.

Corrective Action – actions taken to correct the root cause and the observed deficiency identified during an audit.

The corrective action must be written, and objective evidence must be presented to verify its implementation. The written submission of corrective action shall include:

a. a determination of the root cause,
b. actions taken to mitigate any immediate issues due to the deficiency (e.g., placing product and/or field on hold, recall, etc.),
c. the corrective actions taken
d. and preventive actions to avoid recurrence.

See Reference and Guidance Information section below for additional assistance with corrective action response and root cause analysis.

Corrective Action Plan – the written plan of actions taken to correct the root cause and the observed deficiency identified during an audit"

A corrective action plan is submitted only when the necessary corrective actions (for a justified reason) will require more than the thirty (30) calendar days from the end of the audit for complete implementation. It is not to be used to delay the implementation of corrective actions.

The corrective action plan must be well documented and shall contain:

a. actions taken to mitigate any immediate issues due to the deficiency (e.g., repairs, training, placing product and/or field on hold, recall, etc.),
b. a determination of the root cause,
c. actions to be taken to correct the root cause and the observed deficiency,
d. evidence of the intent to complete (e.g., purchase orders, service requests, etc.) the corrective actions,
e. the expected timeframe and responsible person for completion of the corrective actions.

Risk Assessment - a written risk assessment with evidence of mitigation measures in place which show that the identified non-conformance is controlled is expected to be submitted in support of the corrective actions and corrective action plans.

See Reference and Guidance Information section below for additional assistance with corrective action response, root cause analysis and risk assessments for GAP and GMP operations.

Corrective Action Evidence – objective evidence that shows the non-conformance has been adequately addressed MAY BE in the form of:

a. documents such as Standard Operating Procedures, Work Instructions, etc.,
b. records such as inspections reports, completed logs with actual data/information
c. photographs showing the before and after conditions

NOTE: Blank forms such as logs for recording operating data, system pre-operational or operational conditions, maintenance logs, etc. are not acceptable as evidence of corrective actions for deficiencies related to recordkeeping.

Closure of Identified Deficiencies and Corrective Actions/Corrective Action Plans

The closure of the deficiencies and their associated corrective actions or corrective action plans shall be handled through the guidance for each category as stated below.

1. Automatic Failure Level Questions

    a. The status of the corrective action will be shown on the Corrective Action report as "CA Accepted - Yes or No"
    b. Corrective action will be designated as "Closed" in a RED box whether the CA was accepted or not, until a new on-site audit of the entire operation by the CB can be completed.
    c. Please note that corrective actions must be submitted and accepted by the CB before the on-site re-audit can be conducted.

    Note: There are a number of questions that result in an automatic failure of the audit if and ONLY if the question is scored as NC – 0 points. These questions are notated with the following statement, **A ZERO POINT DOWN SCORE IN THIS QUESTION RESULTS IN AN AUTOMATIC FAILURE OF THE AUDIT.**

    a. **If scored as 0 points:** questions shall be handled as shown above for Automatic Failure Questions.
    b. If scored with a Major or Minor Deficiency: questions shall be addresses as described below.

2. All other scored questions (Essential or General questions)

    All Non-conformances

    a. The CB and/or auditor will review the evidence submitted as corrective actions and/or corrective action plans submitted.
        i. If the CB/auditor accept the evidence as submitted, it will be indicated on the Corrective Action report as "CA Accepted – Yes"
        ii. the corrective action will be designated as "Closed" in a GREEN box.
        iii. The CB and/or auditor's acceptance of the corrective actions taken will upgrade the question score as appropriate and award the additional points that coincide with the upgraded score.

    b. If the CB and/or auditor determines that the **SUBMITTED CORRECTIVE ACTIONS ARE UNACCEPTABLE OR THAT THE AUDITEE CHOSE NOT TO SUBMIT A CORRECTIVE ACTION**

        i. This will be indicated on the Corrective Action report as "CA Accepted – No"
        ii. The corrective action will be designated as "Closed" in a RED box.
        iii. **THIS WILL RESULT IN THE AUDIT NOT BEING CERTIFIED**.

    NOTE: During the next audit the auditor must verify that all of the corrective actions/corrective action plans implemented/submitted have adequately addressed the deficiencies identified during the audit and that

these actions were effective. When the corrective action/corrective action plan has been found to be ineffective or not have adequately addressed the issues, question 1.03.03 should be evaluated by the auditor to determine if a deficiency should be raised during that audit.

3. Information Gathering Questions

   Used only for gathering information and no points are awarded for these questions. Corrective actions or corrective action plans are not required for this category.

Reference and Guidance Information

The PrimusGFS website (www.primusgfs.com) has reference and guidance documents that are available for your use. They are located the v3.2 documents page under "Additional References"

1. Corrective Action Response Form - You may use this form or an alternate, if you use an alternate it must have all of the information included on the PrimusGFS form (TK-F-027)

2. PrimusGFS Guidance for Root Cause Analysis PGFS-R-076

3. Guidance for GAP Risk Assessments PGFS-R-074

4. Guidance for GMP Risk Assessments PGFS-R-075

Document Revision History

Date	Rev. No.	Description
9/24/2021	0	Initial
02/01/2023	1	Simplified the closure process for Essential and General Level Questions, deleted reference to “Pending Verification Next Audit” status, deleted confusing example scenarios, deleted question type descriptions. Reformatted the document structure, revised the requirements of corrective actions and corrective action plans. Added reference to and a description of risk assessments, added a link to the PrimusGFS web site and references to the Corrective Action Response form, and guidance documents for Root Cause Analysis, GAP and GMP Risk Assessments.

Appendix 3 Corrective Actions Closure

Question Category (level)	Deficiencies	Accepted (CB/auditor decision)	Closure (for the audit)	Certification considerations
Automatic Failure, AF	Non-Conformance 0 points	Yes / No		NOT CERTIFIED
All other questions (General, Essential, AF accepting major/minor)	Major/Minor Non-Conformance	Yes		Additional points could be applicable.
		No		NOT CERTIFIED

NOTE: During the next audit the auditor must verify that all of the corrective actions/corrective action plans implemented/submitted have adequately addressed the deficiencies identified during the audit and that these actions were effective. When the corrective action/corrective action plan has been found to be ineffective or not have adequately addressed the issues, question 1.03.03 should be evaluated by the auditor to determine if a deficiency should be raised during that audit.