



### Written Committees Audit Plan (GAP) Evaluation Checklist

Item	Date of closing meeting	Date GAP Received
Timescales for GAP fulfillment		
Y    N    NS		

For a Y/N, the GAP must be received within 30 days of the exit interview (unless extension has been given).

For a critical NC, the GAP must be received within 24 hours (unless extension has been given).

This is the first or last time the GAP has been submitted.

An exemption was requested and granted. If yes, new submission deadline:

### Comments from Assessment Report (GAP) (element 3 - Corrective Action Standard)

Item	Description of the non-conformity	Details of how non-conformity (NOC) is recommended to be addressed	Details of how NOC is acceptable
1	A description of the non-conformity (NOC) is recommended.	In immediate corrective action:	NS/Non GAP is acceptable.
2	Details on identification, segregation, evaluation and any action taken on non-compliant product (pulling, reworking, re-cooling, re-reporting or destroying).	If critical non-conformity or potential safety in all areas, related production and distribution, considered ready and no later than CI-A.	
3	Immediate CA taken on deficiencies which may cause production of non-compliant product.	Immediate CA taken on deficiencies which may cause production of non-compliant product.	
4	Root Cause of the Non-conformity		
5	Details on the process and results of the review analysis to determine the root cause of the NOC. Analysis is not focused on the deficiencies (objectionable) identified in the GAP, but on the system based resolution that allowed the NOC to occur.		
6	Details of the "control system(s)" which will address the root cause and prevent reoccurrence.		
7	The system changes that will be taken to prevent the NOC from reoccurring.		
8	The Person(s) or Position(s) responsible for these changes.		
9	The Date(s) these changes will be completed.		
10	Inform Control Measures (if applicable)		
11	The interim control measures and monitoring procedures to be put in place where system changes can not be completed immediately (long term corrective action).		
12	The Person(s) or Position(s) responsible for these control measures.		
13	The Date these changes will be completed.		
14	Verification of implementation and effectiveness (one fine regulated party will determine that the corrective action or control measure was effective).		
15	The actions that will be taken to verify that the measures taken to correct the system weaknesses identified in the NOC were completed and effective.		
16	The Person(s) or Position(s) responsible for completing the verification.		
17	The Date the verification is completed.		
18	The steps that will be taken to correct deficiencies (objectionable) identified.		
19	The actions that will be taken to correct the deficiencies identified.		
20	The Person(s) or Position(s) responsible for these actions.		
21	The Date these changes will be completed.		
22	Inform Control Measures (if applicable)		
23	The interim control measures and monitoring procedures to be put in place where system changes can not be completed immediately (long term corrective action).		
24	The Person(s) or Position(s) responsible for these control measures.		
25	The Date these changes will be completed.		
26	Verification of implementation and effectiveness (one fine regulated party will determine that the corrective action or control measure was effective).		
27	The actions that will be taken to verify that the measures taken to correct the system weaknesses identified in the NOC were completed and effective.		
28	The Person(s) or Position(s) responsible for completing the verification.		
29	The Date the verification is completed.		

Y    N    NS    Commitment to complete self-assessment and self-correction within 30 days.

If a Schedule I & 1 compliance level "A" or "B" was obtained the GAP includes a commitment to correct deficiencies in both the establishment and the QM within 30 days after the GAP is accepted and to conduct a self-assessment and self-correction using the "Thorough Self-Evaluation Form" and submit it to the CMA within the 30 day deadline. (See Schedule I & 1 Regulatory Verification Process).

If a Schedule I compliance level "C" was obtained, the GAP includes a commitment to correct deficiencies in both the establishment and the QM within 30 days after the GAP is accepted and to conduct a self-assessment and self-correction using the "Thorough Self-Evaluation Form" (Stated, if a 1 compliance level "C" must be corrected prior to exit meeting. Final will be listed as per "Y").

If a Schedule I & 1 compliance level "D" was obtained, the GAP includes a commitment to correct deficiencies in both the establishment and the QM prior to resuming operations and to conduct a self-assessment and self-correction using the "Thorough Self-Evaluation Form" (Stated, if a 1 compliance level "D" must be corrected prior to exit meeting. Final will be listed as per "Y").

Details of how non-conformity

### Comments

Company	Evaluation	Date of Resolution