CORRECTIVE ACTIONS AND IMPROVEMENTS PROCEDURE

	Name	Position	Signature	Date
Author:	E. Vaiciurgis	Head of Quality		29 Sep 21
Reviewed by:	A. Dooley	QA Manager		01 Oct 21
Authorised by:	E. Vaiciurgis	Head of Quality		01 Oct 21

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1 PURPOSE

The Corrective Actions and Improvements (CAR) procedure describes the system to manage corrective actions and improvements in accordance with the cGMP.

2 SCOPE

This procedure applies to all staff operating under the Pharmaxis quality system. This procedure is to be followed when a corrective action, preventative action, or improvement has been identified through another quality system, internal reviews, or suggestions from staff and other stakeholders unless otherwise directed in a SOP.

When a change is considered to have a GMP impact, then the actions are to be captured through the Pharmaxis Change Control system in accordance with the current version of SOP-022. Note that it is not necessary to initiate a CAR for actions associated with SOP-022.

3 ASSOCIATED DOCUMENTS

- ELB-025 Corrective Actions and Improvements Log
- FM-026 Corrective Actions and Improvements Record
- FM-378 Progress Report for Raised Quality Forms
- FM-407 Effectiveness Checks

4 REFERENCED DOCUMENTS

- FM-405 Quality Metrics
- SOP-022 Change Control
- SOP-026 Internal Auditing Procedure
- SOP-098 Quality Systems Review
- SOP-141 External Auditing Procedure
- SOP-260 Quality Risk Management System
- SOP-296 Operations Department Document Archiving Procedure

5 DEFINITIONS

Term	Definition
CAR procedure	Abbreviation of the Corrective Actions and Improvements Procedure. Acronym comes from Corrective Action Record which was used on the initial version of this SOP, and will continue to be used to keep consistent with all other QA systems.
Close-out	Closure of the CAR when all appropriate actions have been successfully completed and no further actions are required.
Corrective Action	Action taken to rectify the root cause of the identified problem/issue.
Corrective Actions And Improvements Record (CAR)	A record describing the proposed and completed corrective/preventative actions and opportunities for improvement.
Effectiveness Check	A verification that the corrective / preventative action performed has eliminated the root cause of the applicable incident
Improvement Actions	Action taken to improve the Pharmaxis Quality system
Preventative Action	Action taken to prevent reoccurrence of an identified risk.
System Corrective Actions	Actions derived from internal or external audits actioned by someone outside of the department being audited.
Negligible Risk to Quality	The risk to the patient in using the finished product is considered to have close to no impact.
Minor Risk to Quality	The risk to the patient in using the finished product is considered not to have a significant impact.
Moderate Risk to Quality	The risk to the patient in using the finished product is considered to have a significant impact.
Major Risk to Quality	The risk to the patient in using the finished product is considered to have a greatly significant impact.
Severe Risk to Quality	The risk to the patient in using the finished product is considered to have a potentially catastrophic impact.

6 RESPONSIBILITIES

6.1 All Staff

- All trained staff members are responsible for initiating corrective actions and improvements record (CAR) as required as stated in section 9.1 of this SOP. Staff should notify their relevant supervisor when a CAR is being raised. Staff initiating a CAR must describe all relevant information on the form. The CAR initiator (or delegate) must also verify actions have been completed before close-out.

- Staff undertaking actions arising from a CAR are responsible for undertaking the actions to ensure that they are completed within the targeted completion date, and providing progress reports as required in this procedure

6.2 Department Supervisor/Manager

- The department Supervisor/Manager is responsible for reviewing the CAR within their department for compliance and accuracy prior to the pre-approval and, after verification that all actions have been successfully completed, the approval stages.
- Review, where applicable, effectiveness check form (FM-407) actions proposed.

6.3 QA Department

- The QA department is responsible for monitoring open CAR's as required and assisting with the overall coordination of the system
- QA staff members are responsible for filing CAR's in numeric order, maintaining the electronic Corrective Actions and Improvements Log ELB-025, and performing periodic trend analysis in accordance with SOP-098.

6.4 Quality Assurance Manager (or Delegate)

- The Quality Assurance Manager is responsible for the final approval, closeout of all CAR's.
- Initiate an effectiveness check form (FM-407) for the actions implemented if deemed required during the closure review with consultation with the applicable department supervisor(s)/manager(s).

6.5 Quality Manager (or Delegate)

- The Quality Manager is responsible for verifying the final closeout. This is a check that the CAR form has been completed compliantly and entries into ELB-025 are correct
- Will review at the end of each month CAR's that have been raised, still open, and closed during the month.

7 PROCESS FLOW

The workflow for the corrective actions and improvements procedure is described in Appendix 1 of this document.

8 SAFETY

There are no specific safety issues with this procedure. When writing actions, safety must always be considered, with any specific safety instructions included.

9 PROCEDURE

9.1 INITIATING A CORRECTIVE ACTIONS AND IMPROVEMENTS RECORD

When required a corrective actions and improvements record should be initiated and completed to the investigational stage in a timely manner. Quality metrics in handling of corrective actions and improvements records are stated in the current version of the Quality Metrics form (FM-405).

A corrective actions and improvements record (FM-026) may be initiated from;

- Issues arising from deviations, non-conformances, risk assessments or from other quality systems
- Escalation of actions associated with other quality systems
- Corrective / preventative actions from deviation forms which will take longer than one month to complete
- Further actions from non-effective previous corrective actions identified during effectiveness checks
- Actions identified not arising from any quality system (e.g. suggestions from staff)
- Corrective Actions arising from internal or external audits (in accordance with SOP-026 & SOP-141)

When a corrective action or opportunity for improvement has been identified then FM-026 must be initiated as soon as possible.

The corrective actions and improvements record FM-026 can be initiated by any trained staff member in accordance with this procedure. Staff should consult with their supervisor or team leader when raising FM-026.

Persons initiating the CAR must complete the blue section of the current Corrective Actions and Improvements Log ELB-025 located in the Logs directory of the manufacturing drive on the company server. The columns to be completed are;

- CAR Number – The next sequential CAR number is to be used.
- Date Raised – State the date the CAR record was initiated.
- Initiator – Write your name by typing first name initial and full last name. (e.g. J. Citizen).
- Initiating Department - From the dropdown menu specify the appropriate department raising the CAR.
- Affected Area(s) – From the dropdown menu specify the Operations group most affected by the CAR.
- Description of Matter to be Corrected and/or Improved on – Provide a summary of why the CAR record form is being raised.
- Risk Level Issued - From the dropdown menu specify the risk level assessed for the CAR.
- Reference(s) - Record specific document(s), deviation report numbers, OOS numbers, NCPR numbers, audit numbers, RAN's, or any other reference to a document that has required a CAR to be completed.

9.2 INITIATOR OF THE CAR– INITIAL COMPLETION OF FM-026

Where not enough space is available on the form, the use of attachments is allowed. Ensure reference is made to attachments in the relevant sections of FM-026.
Upon completion of the sections below, the CAR is to be forwarded to each of the impacted Department Manager / Supervisors for review and pre-approval.

9.2.1 Corrective/Preventative Action or Opportunity for Improvement

Ensure the relevant box is ticked.

9.2.2 CAR Number

Record the CAR number as obtained from ELB-025.

9.2.3 Reference(s)

Record specific document(s), deviation report numbers, OOS numbers, NCPR numbers, audit numbers, RAN's, or any other reference to a document that has required a CAR to be completed

9.2.4 Date Raised

Record the date the CAR was initiated.

9.2.5 Description – Section A)

Describe the issue requiring corrective/preventative or improvement actions. It should be clear and concise what the pertinent issues are. Do not include unnecessary details that do not help to clarify why the CAR has been raised.

9.2.6 Investigation – Section B)

An investigation into why the issue occurred that led to the raising of the CAR must be undertaken. If an investigation has already taken place summarise the investigation and make reference to where the investigation was performed (e.g. DR No., OOS No., RAN). The aim of the investigation is to identify a root cause that will be corrected to prevent from re-occuring.

The person investigating the issue must describe how the incident was investigated and what issues were reviewed during the investigation. Where possible the root cause of the incident should be determined. The investigation may identify a number of possible causes each of which should be considered when deciding upon a course of action.

When conducting an investigation of this issue the following should be considered;

- A review of relevant manufacturing/testing records involved in the incident
- A review of staff activities and staff training records to determine whether staff were authorised and competent to carry out relevant tasks associated with the incident
- A review of previous occurrences (if any) to determine if any similarities exist. This may assist with determining appropriate corrective/preventive actions
- A review of other activities that were taking place at the same time or in close proximity to the incident. This may be pertinent to the investigation as the incident may have detrimental consequences for concurrent

activities. Alternatively, the cause of the incident may be due to concurrent or close proximity activities.

- A review of equipment performance and calibration status of relevant equipment.
- A review of applicable SOPs and other documents describing how the activity should be undertaken or recorded. If the relevant instructions are ambiguous this could lead to confusion as to how to carry out the procedure. If instructions are not available this may lead to variation in how the procedures are performed.
- A review of materials used in the process: This will ascertain if the correct material has been used and whether the materials used were within expiry (or retest) date and are suitable for use.

As part of the investigation the risk to quality will need assessment in accordance with SOP-260, and if required the relevant RAN(s) stated. This does not have to be repeated if the quality risk has already been assessed (e.g. quality risk identified in relevant deviation report). The level of quality risk is to be stated in this section as either a negligible risk, minor risk, moderate risk, major risk, or critical risk. From this risk assessment, actions to mitigate the risk caused from the identified issue may be identified and proposed in section C) of the CAR. As a minimum justification of how this risk was assessed needs to be documented, even if a negligible risk that may seem obvious (i.e. as per SOP-260 describe the severity, probability and detectability levels used to assign the risk level).

If the risk is major or critical then the Quality Assurance Manager and relevant department Supervisor/Manager should be notified immediately and relevant actions determined and approved and acted upon without delay.

If the risk is moderate, minor or negligible then the relevant department Supervisor/Manager should be notified within one business day and relevant actions determined and approved in a timely manner with actions acted upon as appropriate.

9.2.7 Actions – Section C)

When deciding upon actions, consideration must be given to the consequences and impact the action will have upon product quality, impact on other departments, regulatory obligations and GMP requirements. The targeted completion dates for completing actions should consider the risk associated with the incident in accordance with section 9.2.6 of this procedure.

The actions may consist of multiple actions, with each individual action given its own targeted completion date. Individual actions may be assigned to the most appropriate individual or department.

Corrective actions must be directed at the root cause of the problem. Preventative actions are directed at preventing occurrences of the issue in the future and may take longer to complete than corrective actions.

If a CAR is initiated from a deviation report or an OOS investigation, all actions taken up to the raising of a CAR record are to be documented on the relevant DR report or OOS form. The CAR must reference the DR and/or OOS numbers(s).

The initiator must fill in the details of the department supervisors/managers assessed to pre-approve the actions, including the Quality Assurance Manager (or delegate) as the last entry to ensure they are the last signatory to pre-approve.

9.3 INITIAL REVIEW AND PRE-APPROVAL BY DEPARTMENT MANAGER/ SUPERVISOR

The initiator's department manager or supervisor is to review the completed sections of the CAR. If required the CAR may also need to be signed by other department managers/supervisors if the proposed action(s) impact on their department.

The review should ensure that the description of the issue that led to the CAR being initiated is accurate, that the investigation was performed considering all possibilities and identifying (if applicable) any root causes, that the risk assessment has been completed appropriately with the correct risk level assigned and applicable data (if available) is included, and the actions proposed are acceptable. The review may also identify if the actions impact another department, and if so the actions should also be signed off by the appropriate Department Manager/Supervisor to ensure all applicable heads of department have approved the proposed actions.

Once the review has been completed and the relevant Department Manager / Supervisor(s) finds the CAR proposed actions acceptable they are to sign and date section C) of the CAR to indicate they have pre-approved the actions to be taken

9.4 PRE-APPROVAL OF CORRECTIVE ACTIONS AND IMPROVEMENT RECORD

The Quality Assurance Manager (or delegate) reviews the completed sections of the CAR including the actions and if acceptable signs and dates as approved in section C). If further actions are deemed required the Quality Assurance Manager will get all previous reviewers of the actions to review, and if acceptable countersign the new action(s) to show they have been reviewed. Approval of the actions means that the actions are considered acceptable and are not expected to have an adverse effect upon quality.

The Quality Assurance Manager (or delegate) then updates the following sections of ELB-025;

- Date Actions Approved – State the date the pre-approval for corrective actions and improvements were given.
- Initial Proposed Completion Date – State the initial proposed date of completion of all actions
- Responsible Department – From the dropdown list state the department most responsible for completing the required actions.

The Quality Assurance Manager (or delegate) then files the CAR in the appropriate CAR folder located within the QA department.

9.5 COMPLETION OF ITEMISED ACTIONS

When all actions have been completed Section D) is to be completed by the initiator (or delegate) of the CAR.

Upon satisfactory successful completion of all actions the "Yes" tick box on the CAR form in section D) is to be ticked. A comment may be written if required, otherwise N/A or Not Applicable is to be written.

If all actions were not successfully completed then the "No" tick box in section D) of the CAR form is to be ticked and a comment required to describe why the actions were not completed which may include describing if any further actions required.

The further actions required tick box is required to have a yes or no response. Further actions may be proposed as an attachment to the CAR, through FM-378, or may go through another quality system (e.g. Change Request). The CAR is not to be closed out until all further actions identified have been completed.

The initiator (or delegate) is then to sign as verifying actions completed in section D) of the CAR and forwarding the document to the department manager/supervisor impacted by the actions for review and approval in accordance with section 9.7.

Where the completion of the actions has not been completed within the proposed timeframe, justification for the delay must be documented through a progress report form FM-378 in accordance with section 9.6 of this procedure. A new target completion date should be proposed. If the updated proposed completion date is not met, then a new FM-378 is to be raised with justification of the delay and new proposed timeframe stated.

Where changes to the actions are required prior to completion of the CAR, this is also to be proposed by the initiator of the CAR using FM-378 in accordance with section 9.6 of this procedure. It is to be approved by the relevant Department Managers/Supervisors impacted by the change.

9.6 PROGRESS REPORTS

Progress reports (FM-378) are to be completed by the initiator of the CAR or delegate. They are to be completed when;

- A targeted completion date is missed or going to be missed. Justification for the delay must be documented along with an updated timeframe.
- When a change to the proposed action is required. The change to the action is to be described by the initiator and signed off by the relevant Department Supervisors/Managers as acceptable.
- Further additional actions are required than those approved in section C) of the CAR.
- Recording the completion of an action with other action items ongoing
- Update in progress of actions

The progress report FM-378 is to be completed and attached to the applicable CAR as an attachment and then given to the department supervisor/manager to verify that the

progress report is correct.

When this is signed the CAR is then given to the Head of Quality (or delegate) who will update the amended proposed completion date in ELB-025 and sign section 2 of FM-378 that this action has been performed.

Multiple progress reports (FM-378) may be written as required.

9.7 REVIEW AND APPROVAL OF CAR

Relevant Department Managers/Supervisors affected by the CAR are to review the completed sections of the CAR and any relevant attachments to the CAR. The actions are to be reviewed to ensure that they have been performed in a compliant manner, that the actions' status assigned is correct, and that any further actions were appropriate. If acceptable the Department Manager/Supervisor will indicate this by signing section E of the CAR. Any comments regarding the review and approval are to be made in the comments area of section E of the CAR.

9.8 FINAL APPROVAL OF CAR

The final approval of the CAR is performed by the Quality Assurance Manager or delegate. This will be recorded in section F of the CAR. This includes reviewing if an effectiveness check of the actions is required with a tick box requiring a yes or no response to be completed. An effectiveness check is required where verification of the corrective / preventative action is required to be performed to show it has eliminated the root cause. The effectiveness check will be performed as per section 9.9.

9.9 EFFECTIVENESS CHECKS OF ACTIONS FROM CAR

If an effectiveness check is required to be performed, this will be performed through the Effectiveness Checks form (FM-407). This form requires referencing the CAR number and attachment number that it will be associated with on the top of each page of the form. It is to be attached to the applicable CAR.

FM-407 is to be initiated immediately after identified as required in section F) of the CAR form by the Quality Manager or delegate, or relevant head department manager or supervisor. Section 1 and Section 2 are to be completed.

Section 1 should be stating what root cause(s) are being looked at as having actions effectively performed to eliminate and/or control these from re-occuring, and justifying how they will be measure (if applicable).

Section 2 is to succinctly describe how the effectiveness check will be performed, including a target completion date, and the responsible department.
The effectiveness checks are may be performed (but not limited to) being performed through the following;

- Spot checks
- Auditing
- Sampling
- Monitoring / Periodic checks

- Trend analysis
- Annual report data

The timeframes for the effectiveness checks are subjective, but there must be a scientific rationale for the target completion date. This may also be dependent on how often the process being corrected occurs, and risk to patient as already risk assessed in the CAR previously. The timeframe should be small (weeks, or times process performed) if there is a high probability of detection, a high level of occurrence, is an engineered solution, or has a severe impact to patient. This is because fewer observations are required for a high degree of confidence that the root cause has been eliminated. The time frame for completion may be longer if there is a lower opportunity for occurrence, lower probability of detection, or is a training solution. In these cases more observations are needed to have a high degree of confidence the root cause has been eliminated.

Once the effectiveness checks actions have been identified and documented in section 2 of FM-407, these actions are to be reviewed and approved by the impacted stakeholders in section 3) as identified by the initiator. The signed form is then returned to the Quality Assurance Manager (or delegate) to update the Effectiveness checks columns in ELB-025 (Corrective Actions and Improvements Log). The effectiveness check actions can commence after Section 3 has been signed by all applicable stakeholders.

As the effectiveness check actions are completed, these are to be stated in section 5 of FM-407. This will be monitored by QA to ensure this is being performed. Where the completion of the actions has not been completed within the proposed timeframe, justification for the delay must be documented through a progress report form FM-378 initiated by the Quality Assurance Manager or delegate, or the effectiveness check initiator in accordance with section 9.6 of this procedure. A new target completion date should be proposed.

Upon completion of the effectiveness check actions, these are reviewed by the Quality Assurance Manager or delegate to identify if they have resolved the root cause initially being resolved in the CAR. If yes, the applicable box is ticked in section 6) of FM-407 and comments indicating how this decision reached are recorded. If no, the applicable box is ticked and comments indicating how this decision was reached are recorded. A deviation or new CAR is then raised to investigate why the effectiveness check failed and what further actions may be implemented to resolve/mitigate the root cause. This is to be raised by the Quality Assurance Manager or delegate.

The Quality Assurance Manager or delegate then completes the Effectiveness Check columns in ELB-025 and completes section 7 of FM-407. They then complete proceed to closeout the CAR form.

9.10 CLOSEOUT OF CAR

Once all relevant department manager(s)/supervisor(s) have reviewed and approved the closeout of the CAR in section E) of the CAR and, if applicable, the effectiveness check of the actions performed have been completed in FM-407, the Quality Assurance Manager will then signoff the CAR as closed. The Quality Assurance Manager will then complete the entries for the appropriate CAR number in the Corrective Actions and

Improvements Log ELB-025.

If further action has been identified as being required, through the effectiveness check unacceptable or other reason, then a reference to the new CAR or Change Request to resolve the identified issue is to be referenced here. This CAR or Change Request is to be raised at least by the day the initial CAR is closed.

If the CAR has an action identified with a supplier then the Quality Assurance Manager must fill in the supplier's name in the "Supplier Impacted" column of ELB-025, otherwise "Not Applicable" is to be written.

Upon closure of the CAR, the Quality Assurance Manager will notify by E-mail the CAR initiator and any applicable stakeholders that it has been closed.

The CAR is then sent to the Head of Quality (or delegate) to verify the documentation has been completed compliantly and that entries in ELB-026 are correct. The verification of the closeout cannot be performed by the same person performing the initial closeout. The Head of Quality (or delegate) then signs the CAR and intials the "Verified By" column in ELB-025 and files away the CAR as per 9.12.

9.11 INTERFACE WITH CHANGE REQUEST SYSTEM

Where changes are considered to have a significant GMP and/or regulatory impact then a Change Request should be initiated in accordance with the current version SOP-022. It is not necessary to initiate a CAR for actions associated with a Change Request.

9.12 STORAGE OF CARs

Original copies of CAR's are filed in the relevant CAR No. folder within the QA department. Copies of CAR's may be made by required staff whilst the CAR actions are in progress. The relevant original copy of the CAR must be annotated as actions occur.

The original CAR's may also be archived off-site in accordance with the archiving procedure SOP-296, but only when the CAR has been closed and it is not expected to be required for any upcoming audits.

9.13 MONITORING OF CARs

CARs will be monitored by the QA department to identify any trends that develop in accordance with SOP-098. This will be also be measured and reported to the Quality Committee against the quality metrics identified in FM-405.

Monthly the QA department will send to all departments a list of their open CAR's that may fall outside of their expected completion date during the month to ensure timely closure of the CAR, or to raise a progress report.

10 TRAINING REQUIREMENTS

For operations staff the training on the Corrective Actions and Improvements Procedure will be captured on the relevant induction training document.

Unless a significant update occurs to the procedure, or the associated forms or ELB then any updates require a signed confirmation that updates have been read and understood by the previously trained staff in accordance with the current version of the training procedure (SOP-041).

11 DOCUMENT CHANGE HISTORY

Version	Date Effective	Section	Description and Rationale
09	18-Oct-21	All	Change references from Quality Manager to Quality Assurance Manager in accordance with CR No.OPS-21-029 and CM-21-015-01.
		6.4	Change title to Quality Assurance Manager and update responsibilities in this procedure in accordance with CR No.OPS-21-029 and CM-21-015-01.
		6.5	Added new section describing the Head of Quality responsibilities in this procedure in accordance with CR No.OPS-21-029 and CM-21-015-01.
		9.2.6	Added a statement in accordance with CAR No.908 that "As a minimum justification of how this risk was assessed needs to be documented, even if a negligible risk that may seem obvious." This was from the 2021 TGA audit where obvious negligible risks still need to be justified.
		9.6	As per updated FM-378-05, the effectiveness check post verified by relevant department manager/supervisor is to go to the Head of Quality to update ELB-026. This is in accordance with CM-21-015-01 derived from CR No.OPS-21-026.
		9.9	Allow effectiveness check to also be initiated by relevant department manager/supervisor. Effectiveness check should not only be required to be raised by QA. Progress reports can also be raised by the initiator of the effectiveness check form.
		9.10	Update closeout section with a verification step at end by Head of Quality as a final review of the completed CAR form and ELB-025 entries for the applicable CAR. Provides further assurance all entries are correct and compliant to Pharmaxis procedures.
		Appendix One	Amend workflow with updated procedure changes as all changes above for this version of SOP-027.

Version	Date Effective	Section	Description and Rationale
08	01-Mar-21	All	Update document to new template TE-001-06 in accordance with current version of the document control procedure SOP-021.
		10	Added section 10 Training Requirements as required by new template TE-001-06.
07	01-Mar-19	9.9	Update to include instructions on how to proceed if the effectiveness check fails in accordance with CAR no.738
06	15-May-18	All	Update SOP into new template TE-001-05 in accordance with SOP-021 (Document Control Procedure)
		1	Add statement that effectiveness checks included from version 6. Effectiveness checks included in accordance with CAR No.693
		3	Added reference to the new form FM-407 for Effectiveness Checks
		4	Added reference to new form FM-405 which contains quality metrics for CAR's.
		4	Corrected title of SOP-140 to current name.
		5	Added definition for effectiveness check. Effectiveness checks introduced as per CAR No.693. Modified definition for Corrective action to include root cause.
		6	Added references to handling effectiveness checks forms introduced in this version of the SOP.
		6	Remove specific reference to QA Team Leader. Their actions covered in Department Supervisor/Manager.
		6	Rewritten "All Staff" section to make requirements clearer.
		9.1	Added that CAR may be raised from a further action from non-effective previous corrective actions identified during effectiveness checks. Effectiveness checks introduced as per CAR No.693.
		9.1	Remove "Affected site" from ELB-025 as we now only have the 20 Rodborough Road site in operation. New version of ELB with this change will be published concurrently with the effective date of this SOP.
		9.2.6	Added statement that "the aim of the investigation is to identify a root cause that will be corrected to prevent from re-occuring." This has been added to clarify investigation is looking for the root cause.
		9.2.6	Rewritten handling of negligible, minor and moderate risks for clarity.

Version	Date Effective	Section	Description and Rationale
06 (continued)	15-May-18	9.8 to 9.10	Rewritten to include how CAR form is handled during review and approval post actions being completed. this includes how to handle assessing, performing, and reporting effectiveness checks using the new form FM-407. Inclusion of effectiveness checks is in accordance with CAR No.693.
		9.13	Include statement that monitoring will also include CAR's being evaluated against the applicable quality metrics stated in FM-405.
		Appendix One	Updated workflow to include effectiveness checks
05	1-Nov-16	4, 6.3 and 9.11	Add reference to SOP-098 Quality Systems review procedure which is used by QA to look for possible trends in the CAR system (and other Quality systems).
		6.1	Rewrite to state all staff undertaking CAR actions are to do so with the targeted completion date, and they need to provide progress reports as per this procedure as required.
		9.2.7 & 9.6	Replace "completion timeframe" to targeted completion date" in accordance with FM-026-05.
		9.5	Replace "completion timeframe" to updated proposed completion date" in accordance with FM-378-02.
		9.6	Specify that the Quality Manager can also update the progress report in ELB-026 as well as currently allowed QA Team Leader. Ensures a senior Quality staff member is looking at the progress report in a timely manner.
		9.8	Add a statement that if the CAR has an action identified with a supplier then the supplier is to be identified in the "Supplier Impacted" column of ELB-025. This is in accordance with CR No.704.
04	01-Nov-14	3	Added new document FM-378 Progress Report for Raised Quality Forms to use when updating status of CAR's and allowing effective date to be modified.
		5	In line with the change in the number of risk levels from 3 to 5 in accordance with the current version of SOP-260, and in accordance with CR No.601, the negligible and critical quality risk levels were added to the definitions, and the definitions for the minor, moderate and major risks are updated
		5	Definition of preventative action updated to include "identified risk" instead of "problem/issue". Clarifies definition

Version	Date Effective	Section	Description and Rationale
04 (continued)	01-Nov-14	6.2, 6.4, and 6,5	Clarify the responsibilities required to be performed by the department supervisor/manager and the Quality Manager. Add QA Team Leader who will have final pre-approval of CAR actions and to put into ELB-025 accordingly.
		9.1	Amend to be compliant with the current version of ELB-025. This includes adding a requirement to add initiating department of the CAR, and assigning the risk level of the CAR.
		9.2.6	Update the risk levels to be assigned to negligible, minor, moderate, major, and critical in accordance with CR No.601 and the current version of SOP-260. A moderate risk is to be acted upon by the relevant department supervisor/manger and not the Quality Manager as the relevant department supervisor/manager is more able to determine appropriate actions.
		9.3	State that the initial review is also to pre-approve the proposed actions. The actions are to be pre-approved by all required department heads, and then sent to the QA Team Leader (or delegate) for final pre-approval.
		9.4	The QA Team Leader (or delegate) is to pre-approve, log initial details for pre-approval in ELB-025, and file the CAR in appropriate file instead of the Quality Manager. This will ensure that the QA team leader is aware of all CAR's raised. The Quality Manager will review all completed CAR's after the final approval stage.
		9.5 and 9.6	Added use of progress report is to be through FM-378 instead of section G). FM-378 is a new generic progress report to be used in lieu of the removed section G) from FM-026. Also included that the progress report is to be signed by the writer's department supervisor/manager to verify that the progress report is accurate, and then given to the QA team leader to log details into ELB-025. This clarifies steps, and ensures the amended completion date is entered into the new column in ELB-025 to capture the amended expected completion date.
		9.7 and 9.8	Final approval by QA Team Leader instead of Quality Manager. Quality Manager will still close-out CAR form to ensure aware of all completed actions.
		9.10	Add that CAR's may also be archived in accordance with the archiving procedure SOP-296 if they have been closed, and are not expected to be required for any upcoming audits.

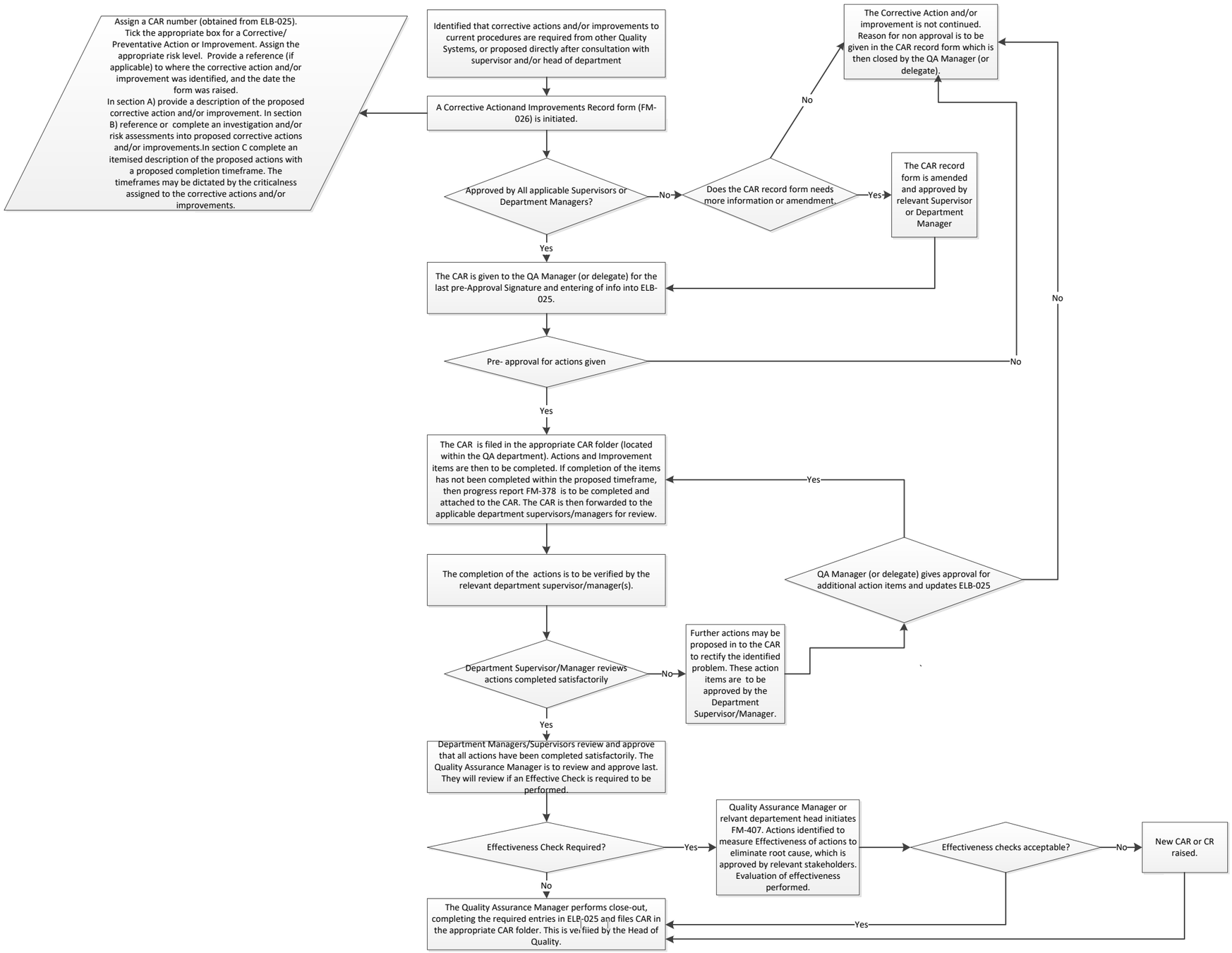
Version	Date Effective	Section	Description and Rationale
04	01-Nov-14 (Continued)	9.11	Monitoring section added that QA will review monthly to ensure CAR's are closed out, or progress report written as required.
		Appendix One	Updated to be compliant with this version of the procedure.
03	03-Aug-11	All	Updated format of SOP to be in compliance with current template TE-001-04.
		4.0, 9	Add references to Quality Risk Assessment SOP-260, and to ensure a risk assessment is performed where applicable.
		9	Rewrite of procedure to clarify and simplify how to complete the new versions of the CAR form (FM-026), and CAR log (ELB-025).
		Appendix One	Added CAR procedure workflow.
02	06-May-09	7.1	CAR system now incorporates improvement opportunities.
		7.2	Less significant issues are resolved within the Deviation Control system.
		7.2	Corrective actions arising from escalations from other systems are resolved within the Corrective Actions and Improvement Procedure.
		7.2	Internal audit "system corrective actions" are recorded on CARs.
		8.0; 8.1; 8.2; 8.3	CAR classifications and response timings section added (Critical/Major/Minor).
		9.0	Conducting investigations and root cause analysis section added
		10.0	Objective evidence of completion of actions may be required for close-out.
		11.0	Verification of effectiveness of actions section added.
		12.0	CARs should be closed out within 6 months. Justification is required for CARs kept open longer than 6 months.
		13.0	Corrective Action Request (CAR) form (FM-026-02) has been revised
		13.1	CAR owners are responsible for recording progress updates on the CAR form.
01	10-Feb-03	All	New document

12 APPENDICES

- Appendix One – Workflow for Corrective Actions and Improvements Procedure

CORRECTIVE ACTIONS AND IMPROVEMENTS PROCEDURE

APPENDIX ONE - Workflow for Corrective Actions and Improvements Procedure



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