DEVIATION CONTROL

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1 PURPOSE

This procedure describes the procedure for documenting and actioning deviations within Pharmaxis Ltd. in accordance with cGMP requirements.

2 SCOPE

This procedure applies to all deviations and non-conformances to Pharmaxis operating procedures and other required regulatory standards.

3 ASSOCIATED DOCUMENTS

- FM-016 Deviation Report
- ELB-026 Deviation Log

4 REFERENCED DOCUMENTS

- FM-013 Non-Conforming Product and Material Disposition Form
- FM-026 Corrective Actions and Improvements Record
- FM-031 Out of Specification Report Form
- FM-378 Progress Report for Raised Quality Forms
- FM-405 Quality Metrics
- FM-407 Effectiveness Checks
- SOP-022 Change Control
- SOP-025 Control of Non-Conforming Product
- SOP-027 Corrective Actions and Improvements Procedure
- SOP-098 Quality Systems Review
- SOP-260 Quality Risk Management System
- SOP-296 Operations Department Document Archiving Procedure

5 DEFINITIONS

Term	Definition
Deviation	A failure to meet or comply with documented procedures and cGMP requirements.
Conditional Approval	Approval has been given for the deviation to be allowed to occur, but with specific conditions and/or criteria that need to be met to allow final approval.
Final Approval	Approval that the deviation has been reviewed and formally accepted.
Closeout	A deviation is closed when the deviation report form has been approved and all specified and/or appropriate actions have been undertaken.

Term	Definition
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.
Corrective Action	Actions taken to rectify the immediate problem.
Preventative Action	Actions taken to prevent recurrence of the problem in the future.
Effectiveness Check	A verification that the corrective / preventative action performed has eliminated the root cause of the applicable incident

6 RESPONSIBILITIES

All Staff

- All staff members are responsible for raising deviation reports when deviations occur. Staff should notify their relevant supervisor when a deviation report is being raised. Staff raising deviation reports must describe all relevant information on the deviation report form. Staff undertaking actions arising from deviation reports are responsible for undertaking the actions within the agreed completion time-frame. Any amendment to the completion time frame is to be justified and a new expected completion date identified using FM-378.

Department Supervisor / Team Leader (or delegate)

- In consultation with their direct report, are responsible for proposing any corrective and/or preventive actions stemming from the deviation report and ensuring that any actions are undertaken in a timely manner.

Department Manager / Supervisor (or delegate)

- Approval of deviations, if relevant to their area, by reviewing the deviation report for compliance and accuracy. This includes conditional approval, review of proposed corrective or preventative actions, completion of the further actions and effectiveness checks
- Initiating effectiveness check forms (FM-407) for the actions implemented if deemed required during the review of completion of any further actions

Quality Assurance Manager (or delegate)

- Responsible for reviewing, approval and and closure of all deviation reports.
- Initiating effectiveness check forms (FM-407) for the actions implemented if deemed required during the initial closure review with consultation with the applicable department supervisor(s)/manager(s).

Head of Quality (or delegate)

- Responsible for final closure all deviation reports, including verifying entries correct for the deviation in the Deviaiton Log ELB-026.
- Reviewing at the end of each month deviation reports that have been raised, still open, closed and requiring effectiveness checks during the month. This includes reviewing the quality metrics for deviations from FM-405

QA Department

- Shall ensure that any deviation reports which affect batch release are approved prior to release.
- Responsible for filing deviation reports in numeric order, maintaining the electronic Deviation Log ELB-026, and performing periodic trend analysis in accordance with SOP-098.

7 PROCESS FLOW

The workflow for handling deviations are described in Appendix One of this procedure.

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 Raising a Deviation

When a deviation has been identified FM-016 (Deviation Report form) must be initiated as soon as possible. Where an incident might lead to a recall situation the Head of Quality must be notified immediately. Deviation report forms may also be raised as required in accordance with specific instructions from other Standard Operating Procedures.

The deviation report form FM-016 can be initiated by any trained staff member in accordance with this procedure. Staff should consult their supervisor or team leader when raising deviations.

Note if the incident is very minor in nature and has no GMP impact, it may be appropriate to record relevant information directly on the applicable documentation without the need to raise a deviation report. If unsure, consult the Quality Assurance Manager

Persons initiating a deviation report form must complete the blue section of the Deviation Log ELB-026 on the company server. ELB-026 is the source of the deviation report (DR) numbers. The columns to be completed are;

- Deviation Number – The next sequential DR number is to be used.
- Date of Occurrence – State the date the deviation occurred. If the deviation

occurs over several days, then state the initial date the deviation occurred.

- Date of Discovery – State the date that the deviation was first identified
- Date Raised – State the date the deviation report form was initiated.
- Initiated By – Write your name by typing first name initial and full last name. (e.g. J. Citizen).
- Initiating Department –Write the department you are initiating the deviation report for.
- Affected Product / Items – Describe all products affected by the deviation including batch numbers (or equivalent). If the deviation is not product related then a description of the item affected is to be recorded (e.g. equipment name with I.D. number).
- Affected Controlled Documents – Record the specific document(s) which are being deviated from including the version number.
- Affected Site – From the dropdown menu specify the appropriate site affected by the deviation.
- Affected Department – specify the Operations group(s) most affected by the deviation.
- Description of Deviation – Provide a summary of the deviation being raised.
- Initial Assigned Risk Level Issued – From the dropdown menu specify the identified risk to the quality of the product.

The Quality Assurance department will complete the log when the deviation report form is approved and closed. The close-out section (green-headed section) is password protected and restricted to the QA department.

9.2 Initiator of Deviation – Completion of Relevant Sections of the Deviation Report

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-016.

When required the initiator may allow more relevant staff to complete any of sections A, B, C, D and E of FM-016.

Upon completion of the sections below, the deviation report is to be forwarded to the relevant impacted Department Manager / Supervisor for review.

9.2.1 Deviation Number

Record the Deviation Number as obtained from the Deviation Log ELB-026.

9.2.2 Product(s) / Items(s) Affected

Record all products affected by the deviation. If the deviation is not product related then a description of the item affected is to be recorded along with any identifiers (e.g. equipment name and I.D. number)

9.2.3 Batches Affected

Record the relevant affected lot numbers of product affected. If no lot numbers are affected than state “Not Applicable” or “N/A”.

9.2.4 Reference(s)

Record the specific document(s) which are being deviated from including the version number. If the deviation is required to be raised from another quality system (eg. audit or OOS or NCPR etc.) then also include the relevant references to this document.

9.2.5 Date(s) of Occurrence

Record the date that the deviating event occurred. If the event occurred over multiple days record all days affected.

9.2.6 Date of Discovery

Record the date that the deviation was first identified.

9.2.7 Description of Deviation - Section A)

Describe the deviation. It should be clear from this section what the pertinent facts of the incident are. Do not include unnecessary details that do not help to clarify the deviation. Record all relevant batch, material or test information.

9.2.8 Investigation / Cause – Section B)

An investigation into why the deviation occurred must be undertaken. If an investigation has already taken place summarise the investigation and make reference to where the investigation was performed (e.g. OOS No., RAN). Describe the investigation and/or cause of the deviation. Details recorded in the investigation should not re-iterate the description of the event.

The person investigating the deviation must describe how the incident was investigated and what issues were reviewed during the investigation. Where possible the root cause of the deviation should be determined. Examples of root causes are:

- Failure to comply with or follow the stated procedure (SOP's etc.)
- Human error / oversight (further root cause analysis may be possible)
- Equipment operational / performance failure
- Equipment or process validation deficiency
- Documentation ambiguous - not clearly described
- Training not effective, competence deficiency

9.2.9 Immediate Action Taken – Section C)

Describe in detail all immediate actions taken after the deviation incident. All actions are be documented clearly and concisely, with accompanying evidence of completion of actions where applicable attached to the deviation report.

If immediate actions encompasses other departments – discuss the immediate actions with the impacted department and ensure that the actions are appropriate.

9.2.10 Risk Assessment – Section D)

The risk assessment for every deviation is to be justified. This can be handled through;

- a formal quality risk assessment performed in accordance with the current version of SOP-260. The applicable RAN must be referred to in this section.
- A previously perfomed risk assessment. The applicable RAN must be reference in this section.
- The severity, probability and detectability levels identified as per section 8.2.3 of the current version of SOP-260. How the severity, probability and detectability levels were assigned is to be documented. From this data, the risk is assigned from the table shown in this section of FM-016.

The level of risk to the quality of the product initially identified is to be stated in this section as either a negligible risk, minor risk, moderate risk, major risk, or severe risk.

9.2.11 Effect Upon Quality / Justification – Section E)

Describe the evaluation of the effect / impact upon quality of the relevant batches affected by the deviation. The justification for approving the deviation should be recorded, including references to any supporting data.

9.2.12 Proposed Further Actions – Section F)

Record any proposed further corrective or preventative actions that will limit reoccurrence of the deviation as per section 9.3 of this SOP.

9.3 Further Actions

Any corrective or preventative actions to ensure that the deviation does not reoccur, or to allow conditional release are to be proposed in section F) of FM-016, either by the initiator (or delegate) or the department manager / supervisor impacted by the deviation or the Quality Assurance Manager.

- If there are no further actions then this section is to be left blank. This will allow any actions deemed necessary by the department manager / supervisor or Quality Assurance Manager to be recorded.
- If actions are expected to take less than three months to complete, then the actions to be taken are to be recorded including who will perform the action and the expected time to complete.
- If the actions are expected to take longer than three months to complete, then a Corrective Actions and Improvements Record (FM-026) is to be initiated in accordance with SOP-027. The CAR No. is to be recorded.

In general, corrective and/or preventive actions should reflect the significance of the deviation. Issues with a higher quality risk to product should receive a higher priority for implementing any identified corrective and/or preventive actions.

Any proposed further action(s) are to be approved by the department manager/supervisor impacted by the deviation, and reviewed by the Quality Assurance Manager as acceptable when performing conditional or final approval.

The completion of the further actions is recorded in section I) of FM-016. Once the actions are completed this section is to be completed and signed as verified by the

initiator (or delegate) of the deviation report . If any further actions are required then a Corrective Actions and Improvements Record (FM-026) shall be raised in accordance with SOP-027. The report is then sent to the relevant department manager / supervisor to sign that the actions items have been performed and documented in a correct manner. The report is then sent to the Quality Assurance Manager (or delegate) to perform a final review of the deviation report, and to close out the deviation report form.

If the further action required is to address specific training deficiencies, records of re-training (or equivalent) are to be attached and specified in section I).

Where an event is considered to be a one-off or a random event, it may not be necessary to implement any corrective and/or preventive actions. In this case the action to correct the immediate problem may be deemed sufficient.

9.3.1 Progress Reports

Progress reports (FM-378) are to be completed by the initiator or delegate of the deviation report when;

- A proposed timeframe is 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 already approved

The progress report FM-378 is to be completed and attached to the applicable deviation report as an attachment and then given to the relevant Department Supervisor/manager to verify that the progress report is correct.

When this is signed the deviation report is then given to the Head of Quality who will update the amended proposed completion date in ELB-026 and sign section 2 of FM-378 that this action has been performed.

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

9.4 Approval of the Deviation Report Form (FM-016)

The initiator's department manager or supervisor is to review the completed sections of the deviation report prior to sending to the Quality Assurance Manager. The review should ensure that the description of the deviation is accurate, that the investigation was performed considering all possibilities and identifying (if applicable) any root causes, that the justification/rationale is appropriate and includes applicable data (if available), that the risk level of the deviation is appropriate, and any corrective and/or preventative actions or conditional approval requirements are appropriate.

Once the review has been completed and the Department Manager / Supervisor finds the deviation acceptable they sign the appropriate conditional approval or final approval section and send to the Quality Assurance Manager for approval.

The Quality Assurance Manager (or delegate) reviews the completed sections of the

deviation report, and if acceptable signs the appropriate conditional approval or final approval section. Approval of the deviation means that the deviation is considered acceptable and is not expected to have an adverse effect upon quality.

The Quality Assurance Manager will determine if the justification/rationale is adequate for the deviation report to be approved.

9.4.1 Conditional Approval (Section G)

An assessment of whether conditional approval (and not final approval) is required to be determined. If conditional approval is required then the yes box is to be ticked and the required preapproval conditions recorded, including the criteria to allow for a final approval. The applicable Department Manager / Supervisor and the Quality Assurance Manager then sign to indicate conditional approval is given.

Where a batch/product/material has not been fully tested, or test results have to be repeated, or required steps for release have not been completed, the batch may be further manufactured under deviation provided all tests/steps will eventually be completed. The Department Manager / Supervisor and Quality Assurance Manager shall authorise the conditional approval to proceed with conditions that all tests/steps are completed before the batch is released. The Quality Assurance Manager will inform the initiator that the deviation has been conditionally approved with the specific conditions required to be met before final approval of the deviation can be obtained.

If no conditional approval is required then the N/A box is ticked, and the deviation will have final approval assessed.

9.4.2 Final Approval (Section H)

The relevant department manager, in consultation as applicable with the Quality Assurance Manager and Regulatory Affairs, shall determine if the Regulatory Affairs department needs to review the deviation. If regulatory department approval is required for a deviation, then the deviation report form is forwarded to the regulatory department for review and signing. If no regulatory department review is required then the N/A box is ticked.

If there were any conditional approval conditions to be met, the stated criteria must be met and verified before the deviation can have final approval. If the conditions have not been met then the No box is to be ticked. If there is insufficient justification for not meeting the conditional approval the deviation may not be approved. The deviation form may then be closed if no further actions are required.

The Quality Assurance Manager or relevant Department Manager / Supervisor summarises the rationale for approving or not approving the deviation including impact on final product (or item if no product involved). This rationale is then approved by the relevant Department Managers / Supervisors and the Quality Assurance Manager or delegate). Note approval must be sigend off by 2 different

managers / supervisors. If the deviation report is not approved the initiator should discuss with the relevant Department Manager / Supervisor and the Quality Assurance Manager for appropriate alternatives.

After conditional and/or final approval the Quality Assurance Manager (or delegate) will update the green section of the Deviation log ELB-026.

Where product release is affected by a deviation report the deviation report must be approved prior to release. (Note: It is not necessary for the DR to be closed prior to release as there may be associated further actions or effectiveness checks being carried out that do not impact the release of the batch.)

9.5 Initial Closeout of the Deviation Report

The initial closout of the Deviation Report is performed by the Quality Assurance Manager or delegate when the deviation report;

- The deviation has been through all the approval steps

and

- All applicable/appropriate actions have been completed (or a CAR raised) if required

This will be recorded in section I) of the Deviation Report. 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. If a further action is required and no effectiveness check is deemed required this must be justified.The effectiveness check will be performed as per section 9.6.

The Quality Assurance Manager then completes the applicable entries for the deviation report number in the Deviation Log ELB-026.

If the deviation had a root cause or other issue identified with a supplier then the Quality Manager must fill in the suppliers name in the “Supplier Impacted” column of ELB-026, otherwise “Not Applicable” is to be written.

9.6 Effectiveness Checks of Actions

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 DR 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 Deviation Report.

FM-407 is to be initiated immediately after identified as required in section I) or J) of the Deviation Report form by the Department Manager/Supervisor or the Quality Assurance Manager or delegate. Section 1 and Section 2 are to be completed.

Section 1 of FM-407 should be stating what root cause(s) are being looked at as having actions effectively performed to eliminate and/or control these from re-occurring, and justifying how they will be measure (if applicable).

Section 2 of FM-407 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 assigned risk to patient as already risk assessed in the deviation report 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 of the effectiveness check form. The signed form is then returned to the Quality Assurance Manager to update the Effectiveness checks columns in ELB-026 (Deviations 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 in accordance with section 9.3.1 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 Deviation Report. 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. In cases where the effectiveness check has failed this is to be investigated further in a new deviation or CAR which will be raised by the Quality Assurance Manager – the current deviation can be closed with reference to the new deviation or CAR number.

The Quality Assurance Manager then completes the Effectiveness Check columns in ELB-026 and completes section 7 of FM-407. They then proceed to final effectiveness check closeout of the deviation Report.

9.7 Final Closeout of the Deviation Report

The final closeout of the Deviation Report is performed by the Quality Assurance Manager or delegate when the initial closeout has been completed and no effectiveness checks were identified, or after the effective checks have been completed in FM-407. This will be recorded in section K) of the Deviation Report.

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 9.6.

If further action has been identified as being required through the effectiveness check being 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 on the day the deviation has final closure.

The Quality Assurance Manager then completes all remaining entries for the deviation report number in the Deviation Log ELB-026.They then pass on to the Head of Quality to verify the deviation has been completed correctly and ELB-026 has been filled in correctly.

9.8 Interface with Other Quality Systems

9.8.1 QC Lab Events

Where a QC laboratory event is not recorded on an OOS report (FM-031) the investigation and subsequent follow-up and/or corrective action may be recorded on a deviation report. Out of trend events may be captured on a deviation report.

9.8.2 Non-Conforming Product System

Where a deviation leads to rejection or disposal of products/materials a deviation report and a “Non-Conforming Product and Material Disposition Form” (FM-013) must be generated. To reduce duplication, the investigations and actions taken information, as recorded on the deviation report, may be referenced onto the “Non-Conforming Product and Material Disposition Form” (FM-013). Refer to “Control of Non-conforming Product” (SOP-025) for further details.

9.8.3 Product and Material Release

The QA department shall check batch documentation to determine if any deviation reports have been raised which impact the release of the batch /material. Where batch release is affected, the deviation must be approved before the batch can be released.

9.9 Storage of Deviation Report Forms

Original copies of deviation report forms are filed in the relevant DR files in the QA area. Copies of deviation forms may be made by stakeholders whilst the deviation is in progress. The relevant original copy of the deviation report must be annotated as actions occur.

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

9.10 Monitoring Deviations

Deviations will be monitored by the QA department to identify any trends that develop in accordance with SOP-098

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

10 TRAINING REQUIREMENTS

For operations staff the training on the Deviation Control 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
14	31-Oct-22	9.2.9	Updated immediate action as per DR#3666
13	08-Aug-22	5, 7, 9 and Appendix One	Removed references to planned and unplanned deviations in accordance with CR No.OPS-21-039. Planned deviations are being replaced by “temporary changes” as already documented in current version of the Change Control Procedure SOP-022.
		6	Added to Head of Quality that review monthly devation to quality metrics as per the current version of FM-405. No reference to quality mterics in previous version.
		7.2	Update row to “Iniital” risk Level Assigned. This allows the risk level at closure to be differentiated.
12	01-Feb-22	Page 12 Header	Corrected version number and expiry on page 12 to match rest of document. Error in previous version corrected.
11	04-Jan-22	6	In accordance with CR No.OPS-21-026, Quality Manager responsibilities role split into the responsibilities of the QA Manager and Head of Quality.
		6	The responsibilities of the Department Manager / Supervisor has been updated to include allowance to raise effectiveness check forms. They are in best position to identify if required, and how will be measured which will improve the procedure.

Version	Date Effective	Section	Description and Rationale
11 (Continued)	04-Jan-22	8.1, 9	References to the Quality Manager changed to the Quality Assurance Manager or Head of Quality in accordance with OPS-21-026.
		9.1	ELB-026 Heading changed from "Initial Risk Level Issued" to "Assigned Risk Level Issued". As per CAR No.908, the risk assessment requirement has strengthened in the form, and the intial risk assessment will be only risk assessment documented as all devaitions will need how risk assigned justified.
		9.2 & 9.3	Sections updated to match updated Deviation Report Form FM-016-10 which is being published concurrently with this procedure.
		9.2.11	Added a specific section on how risk assessments are to be performed on every deviation in accordance with CAR No.908.
		Appendix One	Updated in accordance to current version of this procedure.
10	01-Mar-21	All	Update document to new template TE-001-06 in accordance with current version fo the document control procedure SOP-021.
		10	Added section 10 Training Requirements as required by new template TE-001-06.
9	01-Mar-19	9.6	Update to include instructions on how to handle situation where effective check to correct actions fails. Required in accordance with CAR No.738.
8	01-Nov-18	All	Update format to comply with new version of template TE-001 (TE-001-05) in accordance with the current version of SOP-021
		4 & 9	Make reference to new Quality Metrics form which states target times for completing deviations
		4 & 9.6	Add Effectiveness Check form and how to complete in accordance with CAR No.693.
		6	Responsibilities for reviewing trending moved from department supervisor/team leader to the QA department. This is due to QA Department trending deviation periodically in accordance with the current version of SOP-098.
		6	Added to Quality Manager responsibilities that they initiate effectiveness check forms, and review at the end of the month deviation reports.
		9.1 & 9.2.7	Added requirement that date of discovery is required to be added to the deviation report and deviation log in accordance with CAR No.693.

Version	Date Effective	Section	Description and Rationale
8 (Continued)	01-Nov-18	9.1	Update "Risk Level Issued" to "Initial Risk Level Issued" in accordance with the deviation report FM-016-08 being made effective concurrently with this procedure. This is changed to allow on approval a revised risk level.
		9.2.11 & 9.3	"Proposed Further Action" section changed from G) to E) in line with change to deviation report form (in FM-016-08) being made effective concurrently with this procedure. This is to make form easier to use from Operations staff feedback. Further Action instructions moved earlier within section 9 of this procedure as per flow of the new deviation report.
		9.3.1	"Conditional Approval" Section on deviation form changed from E) to F) so this has been changed in this procedure. . This is to make deviation report easier to use from Operations staff feedback. Verbiage changed to reflect this change.
		9.3.2	"Final Approval" Section on deviation form changed from F) to G) so this has been changed in this procedure. This is to make deviation report easier to use from Operations staff feedback. Verbiage changed to reflect this change.
		9.5 and 9.7	Added that two closeouts now required for a deviation report – an initial closeout and a final closeout. This allows for any effectiveness checks to be performed between the initial closeout and the final closeout. The deviation report is considered closed once all corrective and/ore preventative actions have been completed as was in all earlier versions of this procedure. Effectiveness check required as per CAR No.693.
		Appendix One	Updated workflow in accordance with updated deviation record completion process
7	01-Nov-16	4 & 11	Add reference to SOP-098 Quality Systems review procedure which is used by QA to look for possible trends in the deviation system (and other Quality systems).
		9.4	Add a statement that if the root cause of the deviation was a training deficiency then records of re-training (or equivalent), including an evaluation of the re-training effectiveness, must be attached to the deviation. This was in accordance with CAR No.598.

		9.4.1	Specify that 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.

Version	Date Effective	Section	Description and Rationale
7 (Continued)	01-Nov-16	9.5	Add statement in accordance with CR No.704 that if a supplier is identified as the root cause of the deviation, or has impacted the deviation in any way they are to be identified in the "Supplier Impacted" column of ELB-026.
		4 , 6	Add reference to the FM-378 (Progress Report for Raised Quality Forms) which is to be used if an amendment to the completion date for actions from the deviation are required.
		5, 9.2.10	Update definitions to specify the five levels of risk (from previous three) in accordance with the updated version of SOP-260 and CR No.601.
		6	Update responsibility for Department Managers / Supervisors to give conditional approval and final approval for deviations that impact their area.
		9 & 9.5	Specify that planned deviations are to remain open until the planned deviation is no longer required. It is then able to be closed out.
		9.1	The completion of the deviation log ELB-026 has been updated to be in compliance with the updated version of the log.
		9.2.11	Proposed Further Actions reference is now section G in FM-016. Changed to be in compliance with the updated version FM-016.
		9.3	Update to state that the relevant Department Manager / Supervisor is to approve the deviation at the conditional approval stage (if applicable) and at the final approval stage. This ensures that the relevant Department Manager / Supervisor is approving the rationale for the deviation's approval.
6	01-Nov-14	9.3.2	The assessment of requirement for regulatory approval, acceptance of conditional approval, and rationale for approving deviation may now be performed by the relevant department manager/supervisor. The final approval is to be given by the relevant department manager/supervisor and the Quality Manager. Previous version had this all performed by the Quality Manager. This update will ensure relevant manager/supervisor has reviewed and agrees with rationale for approving deviation.
		9.4	Update reference to sections to comply with the updated versions of FM-016.

		9.4.1	Added new section to describe how to use new form FM-378. This form created to ensure that actions are reviewed and progress reported in a timely manner.

Version	Date Effective	Section	Description and Rationale
6 (Continued)	01-Nov-14	9.5	Remove reference to stating risk level. This has been captured already as part of the approval process.
		10	Add that deviation reports 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.
		11	Monitoring section included that QA will review monthly to ensure deviation reports are closed out, or progress report written as required.
		Appendix One	Updated to comply with updated procedure.
5	15-Jul-12	All	Update format to comply with TE-001-04 in accordance with the current version of SOP-021.
		5, 9.2.10, and 9.6	Definitions of three types of deviation, and risk changed from “minor, major, and critical” to “minor, moderate, and major” in harmonise with the current version of the Quality Risk Management procedure SOP-260
		9.5	State that action “expected” to take less than two months to complete are to be actioned through further actions, otherwise a CAR form is to be initiated. Any further actions through the deviation report are to have the expected completion date described.
4	16-May-11	All	All references to QA Manager changed to Quality Manager in line with job title name change since previous version.
		All	Any reference to Deviations logs now refers to ELB-026 which is the controlled deviation log.
		4.0, 5.0, 8.2.10 & 8.5	Add reference to SOP-260 Quality Risk Management System and risk assessments to allow use in justifying acceptance of the deviation, and to prioritise any further actions arising from the deviation.
		5.0	Update definition of an unplanned deviation for clarification. Included definitions for Conditional Approval and Final Approval for clarification
		6.0 & 8.3	Added section for responsibility of Department Manager / Supervisor to ensure they review their area’s deviation reports and agree to any further required actions.
		7.0 and Appendix One	Added workflow process section referring to workflow diagram shown in Appendix One. This clarifies workflow of deviation reports, and was used to rewrite

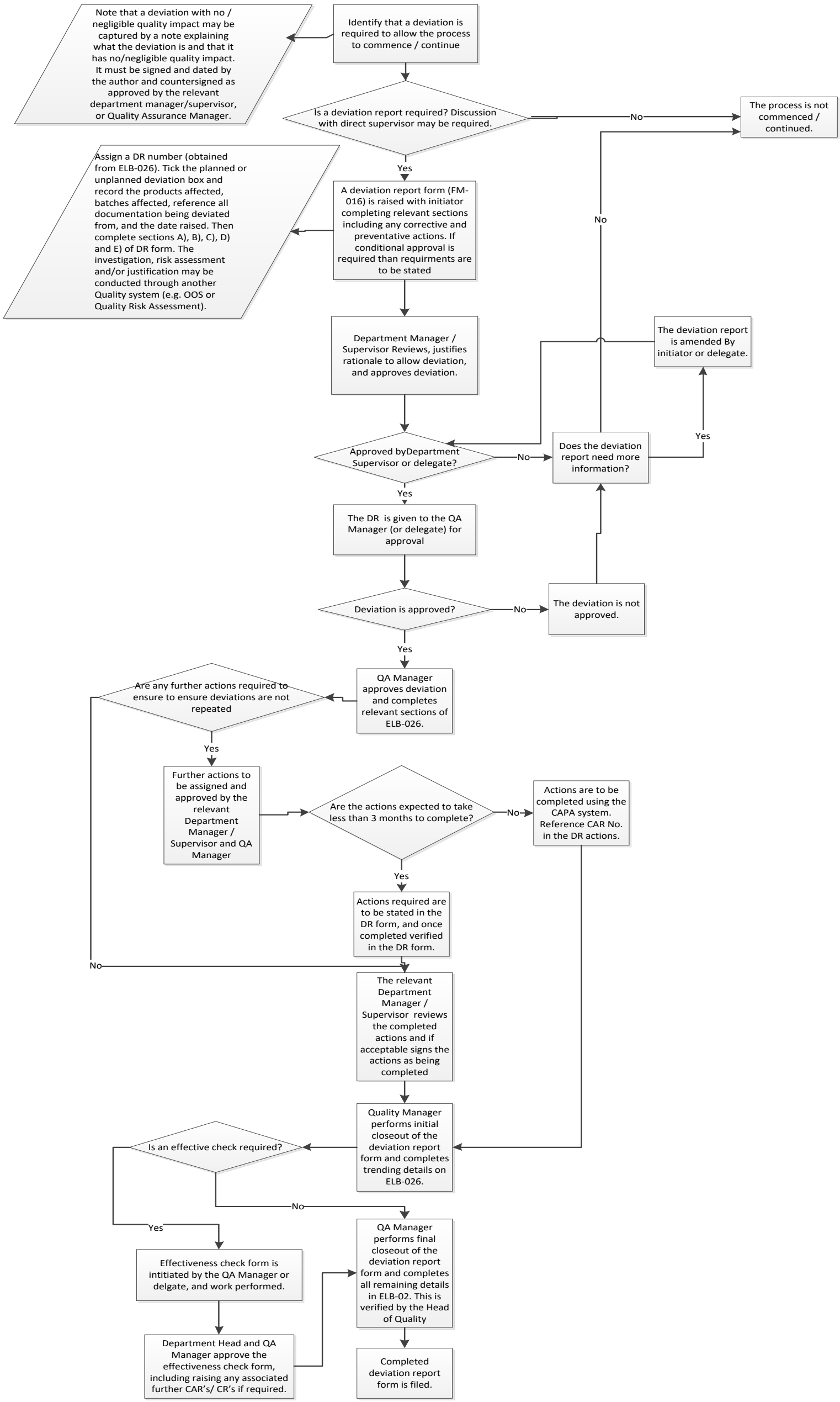
			the deviation report procedure to clarify the process.

Version	Date Effective	Section	Description and Rationale
4 (Continued)	16-May-11	8.0	Rewrite deviation report procedure. Sections 7 to 12 from previous version are captured in section 8.0 in this version. Rewrite enables procedure to be followed more easily. It clarifies how to handle further actions and that any actions which will take longer than 1 month to complete are to be handled through the Corrective Action and Improvement system described in SOP-027. Removed section on Environmental / Equipment /Facility Management as relevant SOP's state when to raise a deviation report, which is allowed in accordance with section 8.1. Removed requirement that justification required if a deviation report is open for longer than three months, this been changed to "from expected completion time".
3	09-Mar-09	8	Deviation Report (FM-016) revised to account for changes to this SOP.
		10.1	Regulatory review of DRs may be required.
		10.2	Pre-approval step required to determine if there are conditions or actions required for approval.
		10.3	Release of product requires DR approval. Approved DRs can remain open whilst further actions are undertaken prior to close-out.
		11	The deviation system now includes provision for corrective action. Critical deviations/events are escalated to a CAR.
		12	Deviations open longer than 3 months may require justification to remain OPEN.
		13	DRs are categorised according to severity and impact upon quality - Critical, Major, Minor.
		14	Interface with other systems clarified.

12 APPENDICES

- Appendix One – Workflow Deviations

Appendix One – Workflow Deviations



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