Pediatric Blood and Marrow Transplant
Adult Blood and Marrow Transplant
Stem Cell Laboratory

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Deviations and Investigations

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COMM-PAS-013
Deviations and Investigations

1 PURPOSE

1.1 To describe the procedure for reporting, documenting, approving, and tracking events occurring outside of Standard Operating Procedure (SOP), current Good Manufacturing Practices (cGMP), and/or Good Tissue Practices (GTP) for the Adult and Pediatric Blood and Marrow Transplant Program (APBMT) and Stem Cell Laboratory (STCL).

2 INTRODUCTION

2.1 An event management system is necessary to promptly alert the APBMT Clinical Quality Program (CQP) and applicable parties of an event, document details of the event, including root cause, risk assessment, investigation, and action(s) taken, and to facilitate the timely closure of events.

2.2 Deviations from approved SOPs must not negatively affect the safety of the donor, recipient, or the HPC product. If applicable, exceptional release measures are in place; refer to the APBMT-COMM-001 *Donor Selection, Evaluation, and Management.*

2.3 Personnel must be aware that not all circumstances necessitate a deviation. It is recommended that the deviation be verbally discussed with a representative of the CQP before completion.

2.4 Deviations (planned or unplanned) must be initiated and documented for any departure or variation from the following key SOPs, which include, but are not limited to:

2.4.1 Donor and Recipient Evaluation, Selection, and Management

2.4.2 Administration of the Preparative Regimen

2.4.3 Administration of any Cellular Therapy Product

2.4.4 Product Processing and Testing

2.4.5 Equipment, Supply, and Environmental Management

3 SCOPE AND RESPONSIBILITIES

3.1 This procedure is referenced when reporting, investigating, documenting, approving, and tracking events via MasterControl (MC), for the STCL and the APBMT Program.

3.2 Refer to the OOS procedure(s) (e.g., STCL-QA-007 *Non-Conforming Products – Receipt, Processing, Distribution, and Disposition*) for details on evaluating and documenting events of this type.

3.3 Refer to STCL-DIST-006 FRM2 *Adverse Event Reporting Form* and APBMT-COMM-030 FRM1 *Adverse Event Form* for handling any adverse event of reaction.

3.4 The APBMT and STCL's personnel are responsible for promptly notifying their Supervisor and/or Manager when an event or deviation from a policy, process, or

procedure is identified, to allow the initiation of the event to occur within three business days of discovery.

3.5 Trained personnel are responsible for completing COMM-PAS-013 FRM1 *Deviation and Investigation Report* and modifying step routes as needed to ensure the applicable Supervisor, Manager, Medical Director, relevant Subject Matter Experts (SMEs), and/or the CQP when applicable, are included. Responsibilities also may include external sponsor/vendor notification consistent with their current quality agreement with APBMT and/or Duke University Health System (DUHS), in conjunction with input from the CQP, as applicable.

3.6 The assigned Medical Director or designee directly responsible reviews and either approves or rejects all initiated deviations.

3.7 The CQP responsibilities include:

3.7.1 Review and approval of all Deviations/Investigations for completeness and appropriate level of detail.

3.7.2 Verify bracketing as necessary to assess quality impact on product(s).

3.7.2.1 Verify appropriate quarantine of associated product(s), as applicable, until the investigation is complete and the product(s) are approved by the CQP to be released from quarantine.

3.7.2.2 Utilize available databases (i.e. MasterControl) to prevent release/upload of associated product(s), as necessary, while an investigation is ongoing.

3.7.3 CQP must ensure there is no product impact from any deviations/investigations before releasing a product and/or signing a Certificate of Analysis. Although most commonly the events are fully closed and approved, it is acceptable for this process to occur outside of MasterControl if necessary due to time constraints. A MasterControl event must be initiated for reference, and CQP should be consulted to identify an appropriate way to document the situation and assessments in real time. The documentation, such as a Memo or an expanded description in the associated batch record, must include a product impact assessment prior to issuing final quality assurance (QA) approval for release.

3.7.4 Monitor the Deviation/Investigation system to facilitate timely closure of reports.

3.7.5 Initiate investigations based on identified trends, as applicable.

3.7.6 Provide status updates to applicable staff, in an effort to facilitate thorough and timely closure of Deviations/Investigations and CAPAs and to communicate identified trends.

4 DEFINITIONS/ACRONYMS

4.1 **AEs**: Adverse Experiences

4.2 **APBMT**: Adult and Pediatric Blood and Marrow Transplant Program

4.3 **BPDR**: Biological Product Deviation Report

4.4 **CAPA**: Corrective and Preventive Action

4.5 **Corrective Action**: Action taken to eliminate the cause of a detected event or deviation. Corrective action is taken to prevent the recurrence of a problem. Please note that any action taken to address the cause of a problem is part of a CAPA (ex. additional training or changes to procedures, processes or systems).

4.6 **cGMP**: current Good Manufacturing Practices

4.7 **cGTP**: current Good Tissue Practices

4.8 **Complaint**: An event in which customer expectations are not met. Complaints are also documented when a vendor or supplier fails to meet the expectations of the program/manufacturer. Complaints may or may not also be classified as deviations.

4.9 **Containment Actions**: Sorting or immediate assessment to segregate nonconforming parts from conforming parts.

4.10 **Correction**: Action to eliminate a detected nonconformity.

4.11 **DCS**: Document Control System

4.12 **Deviation and Investigation Report**: Form used to document the findings of an initiated deviation

4.13 **Events**: Examples may include planned and unplanned deviations from SOP, customer complaints, out-of-specification or unexpected results, internal and external audit findings, or recurring problems/trends.

4.14 **External Reporting**: The dissemination of information to an outside party as required by any applicable regulation, standard, contract or quality agreement. This could include reporting to FDA, an external sponsor, or another entity.

4.15 **Final Quality Approval**: The point in the review and approval process after which a Deviation and Investigation report is considered to be complete/final and in a form that may be disseminated to an outside party as a complete/final document.

4.16 **Investigation**: A thorough and comprehensive collection of information to support the resolution of the event identified with the goal of identifying the root cause of the event.

4.17 **ISBT label**: is a standard labeling format that ensures a consistent layout of critical information for product labels.

4.18 **MasterControl**: An electronic 21 CFR compliant data management system that maintains all events and associated investigations.

4.19 **Nonconformity**: A departure of a quality characteristic from its intended level or state that occurs with severity sufficient to cause an associated product or service not to meet a specification requirement. A nonconformance may or may not be classified as a deviation.

4.20 **Out of Specification (OOS) Result**: Any measurement or assay result that falls outside of established specifications or other established acceptance criteria as defined by product specifications.

4.21 **Planned Deviation**: A deviation from a policy, process, or procedure that is anticipated and requires prior approval by a designated Physician or Medical/Program Director and CQP.

4.22 **Preventive Action**: An activity or step implemented to prevent the initial occurrence of a problem, based on an understanding of the product or process. Please note that any action taken to prevent the initial occurrence of a problem is part of a CAPA (ex., additional training or changes to procedures, processes, or systems)

4.23 **QA**: Quality Assurance. The sum of activities planned and performed provides confidence that systems and their elements that influence the quality of a product are functioning as expected and are relied upon.

4.24 **QC**: Quality Control. Includes the activities and controls used to determine the accuracy of the establishment's equipment and operations in manufacturing and product release.

4.25 **CQP**: APBMT Clinical Quality Program

4.26 **Repeat Deviation**: A deviation that re-occurs within a 2-year period. Repeat deviations indicate that the root cause of previous, similar deviations has not been correctly identified or remediated, or actions have not been taken in a timely manner to effectively address the root cause.

4.27 **Root Cause**: An identified reason for the presence of a defect, problem, deviation, or nonconformity, the most basic reason which, if eliminated, would prevent recurrence. The root cause can also be defined as the source or origin of an event.

4.28 **SOP**: Standard Operating Procedures

4.29 **SQIPP**: Safety, Quality, Identity, Purity, Potency

4.30 **STCL**: Stem Cell Laboratory

4.31 **Unplanned Deviation**: An unexpected event or error that deviates from a policy, process, or procedure; e.g., written procedure or instructions not followed, failure to sample and test, improper material storage, use of equipment/reagents outside of calibration/expiration date.

5 MATERIALS

5.1 N/A

6 EQUIPMENT

6.1 Computer access to MasterControl

7 SAFETY

7.1 N/A

8 PROCEDURE

8.1 Event Notification

8.1.1 Personnel notify their Supervisor and/or Manager upon discovery of an event or deviation from a policy, process, or procedure.

8.1.2 The Supervisor and/or Manager ensures immediate containment action, if applicable, is initiated and notifies the CQP and Medical Director, as necessary. Quality agreements should be consulted too, in conjunction with the CQP, to determine if immediate external sponsor reporting is required.

8.1.3 CQP will run reports at a minimum monthly frequency of all new events initiated in the preceding weeks. This report will be minimally distributed to CQP management.

8.2 Time Requirements and Report Monitoring

8.2.1 Trained personnel initiate COMM-PAS-013 FRM1 *Deviation and Investigation Report* via MasterControl, within three business days, upon the discovery of a deviation.

8.2.1.1 If more than 3 business days have elapsed before the initiation of a deviation/investigation report in MasterControl, an explanation of why the launching of the deviation/investigation report was delayed past the target timeframe is required within the investigation section of the associated deviation/investigation report.

8.2.2 COMM-PAS-013 FRM1 *Deviation and Investigation Report* should be completed and submitted for review expediently, unless extenuating circumstances delay a thorough investigation to identify the root cause. The target timeframe for deviation/investigation resolution is 30 days.

8.2.2.1 If more than 30 days have elapsed before the report is closed, a written rationale for the delay is required within the investigation section of the associated deviation/investigation report.

8.2.3 Deviation/Investigation progress will be actively monitored by the CQP through a variety of mechanisms, which may include but are not limited to regular meetings discussing event management and/or regular reports that are sent to applicable Department Managers, Quality Director, and Medical Director(s). These meetings and reports will highlight key statistics such as discovery/initiation date and report duration.

8.2.3.1 At a target frequency of monthly, CQP convenes a meeting with applicable facility management to monitor deviation/investigation progress. Specifically, this meeting includes reporting on all deviation/investigations that are open greater than 30 days. If facility management or management representatives are unable to attend the meeting or due to scheduling, an in-person meeting is not practical,

updates for the corresponding deviation/investigation progress may be provided electronically.

8.3 Completing COMM-PAS-013 FRM1 *Deviation and Investigation Report*

8.3.1 See COMM-PAS-013 *Deviation and Investigation, Appendix A* for guidance on completing the form.

8.3.2 If the initiator of COMM-PAS-013 FRM1 *Deviation and Investigation Report* is not the Supervisor and/or Manager, modify step routes, as applicable, to include the Supervisor and/or Manager for review and approval.

8.3.3 Verify that the appropriate Medical Director, as applicable, is selected for review and approval routes. Modify step routes as necessary.

8.4 Unplanned Deviations

8.4.1 Refer to COMM-PAS-013 *Deviation and Investigation, Appendix A* for instructions on completing an unplanned deviation.

8.4.2 Refer to COMM-PAS-014 *Risk Assessment Procedure* for assistance on evaluating and determining how to assess risk to facilitate completion of a risk assessment that is captured within COMM-PAS-013 FRM1 *Deviation and Investigation Report,* and if a CAPA is required due to this risk assessment.

8.4.2.1 Within COMM-PAS-013 FRM1 *Deviation and Investigation Report*, risk assessments should be expanded to include potential, related outcomes that could occur in the future despite not having occurred in this specific event, so that any potential preventive actions can be evaluated and captured appropriately as a CAPA. To accomplish this, a systemic view should be taken when looking at the event/issue to help determine if any changes can be made to facilitate a reduced risk of a similar event occurring in the future.

8.4.3 Refer to procedure COMM-PAS-015 *Corrective and Preventive Actions* for additional information and instructions on completing a CAPA, if deemed necessary.

8.4.3.1 Action(s) taken to address the root cause of a problem or prevent initial occurrence of a problem is a CAPA regardless of the risk evaluation score assigned (ex., additional training or changes to procedures, processes, equipment, or systems). Specific consideration for a CAPA should be made for any event scored as a 5 on any risk parameter (severity, probability, or detectability), even if the overall risk score is not within parameters. If no CAPA is deemed necessary when a single parameter is scored a 5, rationale should be provided within the Risk Assessment Summary/Conclusion field of the Report, as described in Appendix A, addressing specifically how the risk was evaluated to be at an acceptable level.

8.4.3.2 If a CAPA is warranted, a specific plan for the implementation, monitoring, and follow-up (effectiveness checks) will be drafted for approval using COMM-PAS-015 *FRM1 CAPA Report*.

8.4.3.3 If a change/action occurred during the associated Deviation/Investigation Report and the actions are completed before closure of the associated COMM-PAS-013 FRM1 *Deviation and Investigation Report*, actions that fulfill the requirements stated within COMM-PAS-015 *Corrective and Preventive Actions* should still be captured as a CAPA on a corresponding COMM-PAS-015 FRM1 *CAPA Report*.

8.4.3.4 If a CAPA is implemented, ensure the corrective and/or preventive actions are noted in the designated CAPA section of COMM-PAS-013 FRM1 *Deviation and Investigation Report*. Details and the effectiveness check will be documented and monitored per COMM-PAS-015 *Corrective and Preventive Actions.*

8.4.4 Documentation of an unplanned deviation is required when an equipment change/repair results from an issue that could not be captured solely by COMM-PAS-004 *Change Control*, which may be due to the need for an expanded product impact assessment. The qualification status of the equipment should be assessed during the investigation.

8.4.5 Thorough investigations using all available data at the time of the investigation to determine the root cause and to assess quality impact to other products should be completed and documented on COMM-PAS-013 FRM1 *Deviation and Investigation Report*. If no definitive root cause can be identified, the most probable root cause(s) should be discussed in the report. In certain cases, specific tools may be needed to assist with clearly identifying the root cause.

8.4.5.1 Refer to COMM-PAS-017 JA1 *Root Cause Analysis Job Aid* for additional details, expectations, and guidance on root cause analysis. Formal Root Cause Analysis tools, such as “5 Whys” and Fishbone Analysis, are acceptable techniques to determine and ensure thorough root cause analysis.

8.4.5.2 In scenarios where the root cause is not readily identifiable, is undetermined, or is determined to be “a failure to follow SOP” documentation of the formal Root Cause Analysis tool/exercise utilized to determine this root cause is required within COMM-PAS-013 FRM1 *Deviation and Investigation Report*.

8.4.6 Any events related to an external contracted vendor, service provider, or test laboratory should refer to COMM-PAS-017 JA2 *Vendor Event Job Aid*.

8.5 Planned Deviations

8.5.1 Planned deviations are acceptable in scenarios with a short timeline to implement a transitory or temporary change due to an unforeseen event or requirement.

8.5.1.1 Planned deviations are not allowed for changes known to be permanent at the time of submission and that should be immediately captured through the change control process, COMM-PAS-004 *Change Control*.

8.5.2 Refer to COMM-PAS-013 *Deviation and Investigation, Appendix A* for instructions on completing a planned deviation.

8.5.3 Refer to COMM-PAS-014 *Risk Assessment Procedure* for assistance on evaluating and determining how to assess risk to facilitate completion of a risk assessment that is captured within COMM-PAS-013 FRM1 *Deviation and Investigation Report,* and if a CAPA is required due to this risk assessment.

8.5.3.1 Within COMM-PAS-013 FRM1 *Deviation and Investigation Report*, risk assessments should be expanded to include potential, related outcomes that could occur in the future despite not having occurred in this specific event, so that any potential preventive actions can be evaluated and captured appropriately as a CAPA. To accomplish this, a systemic view should be taken when looking at the event/issue to help determine if any changes can be made to facilitate a reduced risk of a similar event occurring in the future.

8.5.4 Refer to procedure COMM-PAS-015 *Corrective and Preventive Actions* for additional information and instructions on completing a CAPA, if deemed necessary.

8.5.4.1 Action(s) taken to address the root cause of a problem or prevent initial occurrence of a problem is a CAPA regardless of the risk evaluation score assigned (ex., additional training or changes to procedures, processes, equipment, or systems). Specific consideration for a CAPA should be made for any event scored as a 5 on any risk parameter (severity, probability, or detectability), even if the overall risk score is not within parameters. If no CAPA is deemed necessary when a single parameter is scored a 5, rationale should be provided within the Risk Assessment Summary/Conclusion field of the Report, as described in Appendix A, addressing specifically how the risk was evaluated to be at an acceptable level.

8.5.4.2 If a CAPA is warranted, a specific plan for the implementation, monitoring, and follow-up (effectiveness checks) will be drafted for approval using COMM-PAS-015 *FRM1 CAPA Report*.

8.5.4.3 If a change/action occurred during the associated Deviation/Investigation Report and the actions are completed before closure of the associated COMM-PAS-013 FRM1 *Deviation and Investigation Report*, actions that fulfill the requirements stated within COMM-PAS-015 *Corrective and Preventive Actions* should still be captured as a CAPA on a corresponding COMM-PAS-015 FRM1 *CAPA Report*.

8.5.4.4 If a CAPA is implemented, ensure the corrective and/or preventive actions are noted in the designated CAPA section of COMM-PAS-013 FRM1 *Deviation and Investigation Report*. Details and the effectiveness check will be documented and monitored per COMM-PAS-015 *Corrective and Preventive Actions.*

8.5.5 Approval by the Supervisor and/or Manager, Medical Director, and CQP should be documented prior to implementing the planned deviation from policy, process, or procedure.

8.5.6 An electronic version of the planned deviation is maintained in the MasterControl system, and a reference to the approved planned deviation report is added within the associated file, such as product files or batch records, as applicable.

8.6 Documentation of Unique Product Identifiers Affected

8.6.1 In typical situations, all affected unique product identifiers are included in COMM-PAS-013 FRM1 *Deviation and Investigation Report* and are used to identify products related to an event.

8.6.1.1 For planned deviations, it may be necessary to open a supplemental deviation to document associated ISBTs, if they are not known at the time of report approval. Refer to section 8.9.3 of this procedure.

8.6.2 For atypical situations, CQP can utilize bracketed date ranges included in the Title/Problem Statement of COMM-PAS-013 FRM1 *Deviation and Investigation Report* to identify products associated with an event in the case that no ISBTs are included.

8.7 Review Process

8.7.1 As part of the review process, CQP completes an assessment on all submitted deviations/investigations to determine the necessity for Biological Product Deviation Reporting (BPDR) as well as any external reporting to outside vendors/sponsors per applicable quality agreement. CQP also designates an event code.

8.7.2 CQP assesses step routing for completeness and accuracy and modifies steps as necessary to ensure thorough review.

8.7.3 Review and approval routes include, at a minimum, the following roles:

8.7.3.1 Initiator

8.7.3.2 Medical Director

8.7.3.3 CQP Representative.

8.7.4 Reviewers may reject any route step during the review and approval process to ensure consistent and accurate documentation.

8.7.5 CQP will ensure any associated lots and batch records units are removed from quarantine, if applicable, upon resolution of a deviation.

8.7.6 If, during the review process, it is determined that the deviation/investigation report is no longer necessary, CQP must be consulted, and a path for aborting the event in MasterControl can be determined.

8.8 Tracking and Trending

8.8.1 CQP generates DEV reports regularly to facilitate tracking and trending, dashboards, management review, and also to support lookbacks for similar deviations during investigations.

8.8.1.1 For reference, examples of quarterly trending data generated by CQP include, but are not limited to:

- Quarterly reports
- Deviation reports and dashboards
- Management review

8.8.1.2 If a repeat deviation is noted on review of the previous 2 years of deviation data, within COMM-PAS-013 FRM1 *Deviations and Investigation Report*, the report must include an investigation into any perceived trend, including whether previous actions intended to address root cause were effective. Any CAPAs, if required, must address the effectiveness of previous corrective actions in relation to repeat deviations.

8.9 Maintenance of Records

8.9.1 COMM-PAS-013 FRM1 *Deviation and Investigation Report*, and associated forms are maintained in MasterControl and are accessible for printing and review. Reports may be generated by Document Control System (DCS) staff upon request.

8.9.2 For events impacting or potentially affecting product, during review, CQP will verify that COMM-PAS-013 FRM1 *Deviation and Investigation Report* is referenced appropriately within the associated file/batch record to alert file reviewers of the event.

8.9.3 In the event COMM-PAS-013 FRM1 *Deviation and Investigation Report* is found to need additional documentation after closure; e.g., missing data such as ISBT product identifiers, relevant attachments, or other pertinent information, an additional report may be opened as a supplement to the initial report.

8.9.3.1 The title of the report should be populated as "Supplement to (insert Deviation and Investigation number)".

8.9.4 All records are maintained according to the associated Program's procedure(s) for Records Management and/or Records Retention.

9 RELATED DOCUMENTS/FORMS

9.1 COMM-PAS-013 FRM1 Deviation and Investigation Report

9.2 COMM-PAS-013 JA1 Root Cause Analysis Job Aid

9.3 COMM-PAS-013 JA2 Vendor Event Job Aid

9.4 COMM-PAS-029 Management Review and Responsibility

9.5 COMM-PAS-015 Corrective and Preventive Actions

9.6 COMM-PAS-014 Risk Assessment Procedure

9.7 STCL-DIST-006 FRM2 Adverse Event Reporting Form

9.8 STCL-QA-007 Non-Conforming Products – Receipt, Processing, Distribution, and Disposition

10 REFERENCES

10.1 21 CFR 211.22(a) – Responsibilities of a Quality Control Unit

10.2 21 CFR 211.100 – Written Procedures; Deviations

10.3 21 CFR 1271 – Human Cells, Tissues, and Cellular and Tissue-Based Products

10.4 FACT-JACIE International Standards for Cellular Therapy; Current Edition

10.5 FACT Common Standards for Cellular Therapies; Current Edition

11 REVISION HISTORY

Revision No.	Author	Description of Change(s)
01	M. Christen	• New document

Appendix A

Instructions for completing COMM-PAS-013 FRM1 *Deviation and Investigation Report*:

- Complete the Deviation/Investigation Report, filling in all required information.
- Record N/A in any section that does not apply.

Data Field	Instructions
Deviation/Investigation Number (Form Number)	The event (form) number is auto-populated by MasterControl.
Initiated By	This field is auto-populated by MasterControl to indicate which user initiated the Deviation/Investigation Report.
Date Initiated	This field is auto-populated by MasterControl to indicate what date the Deviation/Investigation Report was initiated.
Tab 1: General Information	
Program	Select the applicable program in which the event occurred.
Project Affected/Impacted (Select All that Apply)	Select applicable product(s)/project(s) impacted by this event.
Date Discovered	Enter the date the issue being investigated/documented was discovered.
Date(s) Affected	Document the time period in which the Deviation/Investigation may have affected the donor, recipient, or product by selecting the data range in the fields provided. For situations where only one date is impacted, please list the same date in both fillable fields in MasterControl. ***Note:*** *For planned deviation, enter time period for which the planned deviation is needed. If a specific date range does not apply, enter N/A.*
Title	Enter a title that clearly identifies what the Deviation/Investigation Report is about.
Supply/Reagent	Enter name and lot number of supply reagent, if applicable.
Equipment	Enter name and serial number of equipment, if applicable.
Tab 2: Problem Statement and Containment	
Problem Statement	Clearly describe the situation. Identify the problem being addressed at the start of the narrative. If applicable, state the requirement/procedure not met and describe the deviation from the requirement. State the date the event occurred. Include a description of how and when the event was identified. ***Note:*** *If deviation is planned, include justification for action.*
Containment Actions	Detail all containment (immediate) actions taken, in chronological order to resolve the problem. Include dates completed. Examples: Stop of shipment/supply, Destruction of Product or Product Recall, Suspend production process. **Note**: Action(s) taken to address the root cause of a problem or to prevent initial occurrence of a problem is not typically a containment/immediate action. This is a CAPA (ex. additional training or changes to procedures, processes or systems.) ***If deviation is planned, specify:*** *What the action(s) will be* *Who will do it* *When it will be done*

Data Field	Instructions
Tab 3: Investigation and Root Cause	
Investigation (Identifying Root Cause)	Define the scope of the event in greater detail and include applicable dates on which events/actions occurred. If investigation is conducted over time, update/refine the investigation as new information is discovered. Include: ○ Information that was gathered, reviewed and/or evaluated ○ Applicable dates/date ranges and an explanation of each ○ Results of the reviews/evaluations of the information ○ Summary of information gathered to help identify root cause(s) and/or contributing factors ○ Consideration if the event may have impact to product, other processes, documents, samples, results, etc. If other programs/departments will be impacted, notify the department/management, as appropriate. ○ If the report was initiated > 3 business days after the date of discovery, written rationale for the delay is required. ○ If the report remains open > 30 days after the date of discovery, written rationale for the delay is required. ○ As a best practice, it is recommended to include both the **SOP** and **Step Number** from which the Deviation occurred ***Note:*** *Planned deviations by nature may contain fewer investigation components/details. N/A may be allowable if certain details are present.*
Root Cause (Statement of Detailed Root Cause)	Statement of Root Cause identified during investigation. Please ensure that this is a statement of the root cause of the issue and not solely a re-statement of what happened. If needed, utilize root cause analysis tool (some details below), such as "5 Whys". ***Note:*** *If deviation is planned, please still include a root cause.*
Root Cause Analysist Tool Attached?	In scenarios where root cause is not readily identifiable, is undetermined, or is determined to be "a failure to follow SOP": documentation of the formal Root Cause Analysis tool/exercise utilized to determine this root cause is required and should be in the event or attached. In this situation, minimally a specific tool for the root cause analysis must be named (ex. "5 Whys") and described, if the root cause is to remain as "Failure to follow SOP". Other tools could include brainstorming, fishbone analysis, or FMEA, among others.
Tab 4: Deviation Information and Reporting	
Deviation Identification	Complete this section to document, by listing SOP numbers, if any deviation from SOP was identified. As a best practice, please list the SOP Step/Section number that was deviated from in the Investigation. This section is also used to differentiate between planned and unplanned deviations.
Report(s) associated with this Deviation/Investigation	Enter any report number(s) associated with this Deviation/Investigation (other Deviation(s), Adverse Events, complaint(s), validations, OOS, risk assessment report)
External Reporting	This section is completed to document the determination if additional regulatory or other external reporting such as to a vendor or sponsor may be required per the applicable quality agreement. If notification is required prior to event closure, then documentation, such as email, FAX etc., should, ideally, be attached to the document in the Attachments section. This section is to be populated by author/initiator if known at time of report and/or CQP at time of review.
Tab 5: Risk Assessment and Rationale	

Data Field	Instructions
Risk Assessment	Reference SOP *COMM-QA-077 Risk Assessment Procedure* to assess risk on all three parameters (severity, probability, and detectability). An individual score should be assigned and detailed rationale provided for that assigned score. Risk assessments should be expanded to include potential, related outcomes that could occur in the future despite not having occurred in this specific event so that any potential preventive actions can be evaluated and captured appropriately as a CAPA. To accomplish this, a systemic view should be taken when looking at the event/issue to help determine if any changes can be made to facilitate reduced risk of a similar event occurring in the future. The final score will help assess if a CAPA is required due to risk. A CAPA may still be appropriate even if not required due to risk.
Combined Risk Assessment Score	Use the Risk Assessment Matrix to assign a numerical value for each risk parameter in the risk assessment. Multiply the scores to obtain the final, combined risk assessment score.
Risk Assessment Summary/Conclusion	Use this field to populate a summary of the overall risk assessment if not sufficiently detailed in the individual parameter fields above; any additional information about the expanded risk assessment can also be described here. If one risk parameter is scored a 5 during the risk evaluation and no CAPA is launched, justification will be required and captured within this field, addressing specifically how the risk was evaluated to be at an acceptable level. Finally, this field may be utilized to describe any impact to risk assessment reports per *COMM-QA-080 Quality Risk Management* if not otherwise addressed in the event or risk documentation already provided. The field can be N/A if no additional details are needed.
Tab 6: CAPA	
CAPA Number	Enter number of CAPA Report generated. Enter N/A if no CAPA.
Summary of CAPA	Give an overview of CAPA(s) to be implemented in associated CAPA report (if applicable). As a best practice, please route any associated CAPA (first routing) concurrently with the corresponding Deviation/Investigation Report.
Tab 7: UPIs/Quarantine/Licensure	
Unique Product Identifier(s) Affected [Lot Number/ISBT]	Add associated product identifier(s), as applicable, based on the investigation.
Was quarantined applied to product associated with this report?	Select radial button to indicate applicable quarantine of product and describe rationale.
If all specifications for licensure are met, is there any reason that product(s) cannot be released under the license due to this event?	Select appropriate toggle to indicate any change to license status and describe rationale. Select N/A if the event solely involves a non-CCBB or licensed MC3 GMP product.
Tab 8: Event Coding and BPDR	
QA Assessment (Completed by CQP)	CQP will reference program specific SOPs for BPDR assessment.
Event Code (Completed by CQP)	Select the event code from the data set that most closely matches the root cause.

Data Field	Instructions
Deviation Category	Select the deviation category from the data set that most closely matches the root cause.
Tab 9: Attachments and Appendix	
Attachment(s)	Use this function to attach all applicable documents.
Appendix from COMM-PAS-017	The Appendix from COMM-PAS-017 is attached for easy reference.

Signature Manifest

Document Number: COMM-PAS-013 **Revision:** 01
Title: Deviations and Investigations
Effective Date: 01 Jul 2025

All dates and times are in Eastern Time.

COMM-PAS-013 Deviations and Investigations

Author

Name/Signature	Title	Date	Meaning/Reason
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