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

**DOCUMENT NUMBER:** COMM-PAS-013 JA2

**DOCUMENT TITLE:**
Vendor Event Job Aid

**DOCUMENT NOTES:**

## Document Information

| | |
|---|---|
| **Revision:** 01 | **Vault:** COMM-PAS-rel |
| **Status:** Release | **Document Type:** COMM-PAS |

## Date Information

| | |
|---|---|
| **Creation Date:** 20 Jun 2025 | **Release Date:** 01 Jul 2025 |
| **Effective Date:** 01 Jul 2025 | **Expiration Date:** |

## Control Information

| | |
|---|---|
| **Author:** MC363 | **Owner:** MC363 |
| **Previous Number:** None | **Change Number:** PAS-CCR-043 |

# COMM-PAS-013 JA2
# Vendor Event Job Aid

This job aid, COMM-PAS-013 JA2, applies when using COMM-PAS-013 *Deviations and Investigations* to investigate an issue, deviation, or event at an external contracted vendor, service provider, or test laboratory. This job aid is not intended to be a checklist or document that needs to be attached to the relevant event, but it should serve as a guide to help ensure consistency among external events and documentation of these issues.

In addition to Appendix A in COMM-PAS-013 *Deviations and Investigations*, a number of key considerations should be documented in COMM-PAS-013 FRM1 *Deviation and Investigation Report* for external vendor-associated events, including the following:

- Ensure the following details are contained in the event:
  - The name of the vendor, service provider, or test laboratory.
  - Which services did they provide that were related to the event, and for which program/projects/facility?
- The vendor should be asked to conduct its own investigation into the issue within the vendor/service provider/test laboratory QMS, in a timely manner. Document (and attach, if applicable) the vendor's investigation. Subject matter experts (SMEs) and CQP should have an opportunity to read the investigation before it is finalized, unless otherwise dictated by a formal agreement.
- The event should clearly describe the following:
  - Root cause analysis and identified root cause documented in the vendor's investigation.
  - Summary of any other key points raised in the vendor's investigation.
  - If there were any contributions to the deviation or event, those should be documented and included too in the final documentation on COMM-PAS-013 FRM1 *Deviation and Investigation Report*.
  - Describe and document any corrective or preventive actions committed by the vendor.
  - If applicable, include whether the CAPA(s) implemented were successful in correcting the identified root cause.
- In the investigation section, clearly detail whether there are any previous, related deviations, if the root causes are similar, and if any further action should be determined based on the scope of the related deviation list. In the related events section, include deviation number references for related previous deviations.
- Address how/if vendor management documentation (per COMM-PAS-017 *Supplier Qualifications*) within the QMS needs to be updated in response to this issue.

## Signature Manifest

**Document Number:** COMM-PAS-013 JA2 **Revision:** 01
**Title:** Vendor Event Job Aid
**Effective Date:** 01 Jul 2025

All dates and times are in Eastern Time.

### COMM-PAS-013 JA2 Vendor Event Job Aid

### Author

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Mary Beth Christen (MC363) | | 26 Jun 2025, 05:44:21 PM | Approved |

### Management

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Stefanie Sarantopoulos (SS595) | Professor of Medicine | 26 Jun 2025, 06:32:15 PM | Approved |

### Medical Director

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Joanne Kurtzberg (KURTZ001) | | 26 Jun 2025, 07:29:46 PM | Approved |

### Quality

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Mary Beth Christen (MC363) | | 27 Jun 2025, 12:36:42 AM | Approved |

### Document Release

| Name/Signature | Title | Date | Meaning/Reason |
|---|---|---|---|
| Amy McKoy (ACM93) | Document Control Specialist | 30 Jun 2025, 05:27:30 PM | Approved |