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COMM-QA-042 JA4
VENDOR EVENT JOB AID

This job aid, COMM-QA-042 JA4, applies when using COMM-QA-042 *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 the MC3 Quality Management System.

In addition to Appendix A in COMM-QA-042 *Deviations and Investigations*, a number of key considerations should be documented in COMM-QA-042 FRM4 *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, test laboratory.
  - Which services they provided 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. MC3 technical subject matter experts (SMEs) and Quality Assurance (QA) should have an opportunity to read the investigation before it is finalized, unless otherwise dictated by a formal agreement.
- The MC3 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 MC3 contributions to the deviation or event, those should be documented and included too in the final MC3 documentation on COMM-QA-042 FRM4 *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-QA-002 *Supplier Qualifications*) within the MC3 QMS needs to be updated in response to this issue.

Signature Manifest

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Author

Name/Signature	Title	Date	Meaning/Reason
Patrick Killela (PK37)		31 Jan 2022, 02:58:56 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		31 Jan 2022, 05:39:58 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Lisa Eddinger (LE42)		31 Jan 2022, 06:09:36 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandra Mulligan (MULLI026)		31 Jan 2022, 06:39:49 PM	Approved