**{{ DevReportTitle }}**

**DNRN # \_\_\_\_\_\_\_\_\_**

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| --- | --- |
| **Deviation / Nonconformance details** | |
| Discovery Date/Time |  |
| Location (area, room, zone, etc.) |  |
| Observers (Names, positions) |  |
| Related Documents and Records |  |
| Related Equipment and Facilities (IDs) |  |
| Affected products, materials, processes |  |
| Detailed description of the Event: | |
| Initial assumed Event type | ☐ Deviation ☐ Nonconformance |
| Initial assumed Category | ☐ Minor ☐ Major ☐ Critical |
| Corrections were taken prior {{ DevNotificationTitle }} submission: | |
| Segregation measures were taken for Nonconforming Products or Materials prior {{ DevNotificationTitle }} submission: | |

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| **Scope of investigation** | | |
| Departments/Teams/ functions to be involved |  |  |

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| **Investigators:** (to be signed off by all involved subject matter experts) | |
| Name | Department/Position |
| Name | Department/Position |
| Name | Department/Position |

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| **Assessment and reviewing details** | |
| Interviewing with Originator, Observers, other personnel |  |
| Documents and records review |  |
| SOPs review |  |
| Equipment, systems, facilities review |  |
| Premises, rooms, areas review |  |
| Personnel review |  |
| Materials review |  |
| Others |  |

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| **Review of Deviation / Nonconformance Type and Category**  Initial assumed Event Type and Category shall be reviewed justified by investigators according to Quality Risk Management procedure. | |
| Reviewed Event type | ☐ Deviation ☐ Nonconformance |
| Reviewed Category | ☐ Minor ☐ Major ☐ Critical |

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| **Chronological description investigation progress (dates, actions, observations, results)** |
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| **Risk Assessment Summary** |
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| **Root Cause analysis Summary** |
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| **Impact on Product/Process Summary** |
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| **Escalation proposals** |
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| **Additional Corrections were taken after {{ DevNotificationTitle }} submission:** |
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| **Additional segregation measures were taken for Nonconforming Products or Materials after {{ DevNotificationTitle }} submission:** |
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| **Final disposition decision for Nonconforming Products or Materials:** |
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| --- | --- |
| **Proposed CAPAs** | |
| **Reference CAPA number** | **Description** |
| **Reference CAPA number** | **Description** |

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| **{{ DevReportTitle }} Conclusion and proposals** |
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| **{{ DevReportTitle }} prepared by:** (to be signed off by all involved investigators) | |
| Investigator | Name/Date/Signature |
| Investigator | Name/Date/Signature |

|  |  |
| --- | --- |
| **{{ DevReportTitle }} reviewed by:** (to be signed off by Department Heads of involved subject matter experts) | |
| Department Head or Team Lead | Name/Date/Signature |
| Department Head or Team Lead | Name/Date/Signature |

|  |  |
| --- | --- |
| **{{ DevReportTitle }} approved by:** | |
| {{ QualityOrganizationHead }} | Name/Date/Signature |