**{{ DevReportTitle }}**

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

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

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

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

|  |  |
| --- | --- |
| **Assessment and reviewing details** | |
| Interview of the Originator, Observers, and others personnel |  |
| Documents and records review |  |
| SOPs review |  |
| Equipment, systems, facilities review |  |
| Premises, rooms, areas review |  |
| Personnel review |  |
| Others |  |

|  |  |
| --- | --- |
| **Review of Deviation / Nonconformity 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 ☐ Nonconformity |
| Reviewed Category | ☐ Minor ☐ Major ☐ Critical |

|  |
| --- |
| **Chronological description investigation progress (dates, actions, observations, results)** |
|  |

| **Risk Assessment Summary** |
| --- |
|  |

|  |
| --- |
| **Root Cause analysis Summary** |
|  |

|  |
| --- |
| **Impact on Product/Process Summary** |
|  |

|  |
| --- |
| **Escalation proposals** |
|  |

|  |
| --- |
| **Additional Corrections were taken after {{ DevNotificationTitle }} submission:** |
|  |

|  |
| --- |
| **Additional segregation measures were taken for Nonconforming Products after {{ DevNotificationTitle }} submission:** |
|  |

|  |
| --- |
| **Final disposition decision for Nonconforming Products:** |
|  |

|  |  |
| --- | --- |
| **Proposed CAPAs** | |
| **Reference CAPA number** | **Description** |
| **Reference CAPA number** | **Description** |

|  |
| --- |
| **{{ DevReportTitle }} Conclusion and proposals** |
|  |

|  |  |
| --- | --- |
| **{{ 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 Line Manager | Name/Date/Signature |
| Department Head or Line Manager | Name/Date/Signature |

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