**<DevReportTitle>**

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

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| **Deviation details** | |
| Deviation 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 Deviation: | |
| Initial assumed Deviation Category | ☐ Minor  ☐ Major  ☐ Critical |
| Immediate actions taken before <DevNotificationTitle> was submitted, if any: | |

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

|  |  |
| --- | --- |
| **Deviation 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 reporter, 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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| **Chronological description investigation progress (dates, actions, observations, results)** |
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| **Risk Assessment Summary** | |
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| **Deviation Category**  Initial assumed Deviation Category shall be reviewed by investigators according to Quality Risk Management procedures. | **☐ Minor**  **☐ Major**  **☐ Critical** |

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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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| --- | --- |
| **Immediate actions were taken after Discovery** | |
|  | |
| **Proposed CAPAs** | |
| **Reference CAPA number** | **Description** |
| **Reference CAPA number** | **Description** |

|  |
| --- |
| **<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 |