**{{ Complaint\_Investigation\_Plan }}**

|  |
| --- |
| **Product details** |
| **CRN** |  |
| **Notification Date** |  |
| **Product** |  |
| **Strength of drug product** |  |
| **Lot/Batch number** |  |
| **Manufacturing date** |  |
| **Expiry date** |  |
| **Product packaging details** |  |
| **Description of complaint** |  |
| **Complaint category** |
| [ ]  **Delay** [ ]  **Mix-up** [ ]  **Quantity** [ ]  **Packaging** [ ]  **Labeling** [ ]  **Damage** [ ]  **Contamination** [ ]  **Falsified products** [ ]  **Transportation conditions** [ ]  **Data/documents processing**[ ]  **Safety/Security** [ ]  **N/A** |

|  |
| --- |
| **Scope of investigation** |
| **Departments/functions/processes to be involved** |
| **What areas should be investigated** |
| Department 1 |  |
| Department 2 |  |
| **What data should be collected and provided** |
| Department 1 |  |
| Department 2 |  |
| **What actions should be taken and expected timelines** |
| Department 1 | Action/Due Date |
| Department 2 | Action/Due Date |
| **What questions should be answered** |
| Department 1 |  |
| Department 2 |  |

|  |
| --- |
| **Proposed measures** |
| **Product shipment Return** | [ ]  **YES** [ ]  **NO** |
| **Product Recall** | [ ]  **YES** [ ]  **NO** |
| **Segregation/Quarantining measures** | [ ]  **YES** [ ]  **NO** |
| **Competent authorities notification** | [ ]  **YES** [ ]  **NO** |
| **Manufacturer/ MAH /Importer/ Supplier/ Customer/ Provider notification** | [ ]  **YES** [ ]  **NO** |
| **Comments:** |

|  |
| --- |
| **{{ Complaint\_Investigation\_Plan }} consent**(to be signed off by all representatives involved departments and functions) |
| SME | Date/Signature |
| SME | Date/Signature |
| {{ QualityOrganizationHead }} | Date/Signature |