|  |  |  |
| --- | --- | --- |
| **Project No.:** | «${form.ProjectNo}» | |
| **Protocol Title/No.:** | *«#if($form.ProtocolNo == "") N/A #else ${»* | |
| **Date of Occurrence:**  (DD-MMM-YYYY) | «${form.StrDateOfOccurrence}» | |
| **Date of Discovery:**  (DD-MMM-YYYY) | «${form.StrDateOfDiscovery}» | |
| **Deviated SOP Doc. ID & Title/**  **Version/Effective Date:**  (DD-MMM-YYYY) | SOP Document ID & Title: «${form.deviatedSOPDocument.document.DocI»  Version: «${form.deviatedSOPDocument.Version}»  Effective Date: «$date.format('dd-MMM-yyyy', $form.deviat» | |
|  |  | |
| **Deviation Details:** | «${form.DeviationDetails}» | |
| **Corrective Action** | | **Preventive Action** |
| **(Expected) Completion Date: «$form.StrCorrectiveCompletionDate»**  (DD-MMM-YYYY) | | **(Expected) Completion Date: «$form.StrPreventiveCompletionDate»**  (DD-MMM-YYYY) |
| «${form.CorrectiveAction}» | | *«${form.PreventiveAction}»* |

«#foreach($approvalLine in $approvalLines»

**«#if($approvalLine.LineType == "Approved »**

**Reviewer: ** **Accepted  Rejected**

(If a requester is a project manager or team manager, the Head of Department should be the reviewer.)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Comments: N/A** | | | | | | |
| N/A |  | N/A |  | N/A |  | N/A |
| Print Name |  | Title |  | Signature |  | Date (DD-MMM-YYYY) |

**«#end»**

**«${approvalLine.LineType}»:**  **Accepted  Rejected**

(If a requester is a project manager or team manager, the Head of Department should be the reviewer.)

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Comments:**«${approvalLine.comments}» | | | | | | |
| «${approvalLine.Name}» |  | «${approvalLine.JobTitle}» |  |  |  | «${approvalLine.Date}» |
| Print Name |  | Title |  | Signature |  | Date (DD-MMM-YYYY) |

«#end»

|  |
| --- |
| **\* SOP Deviation Reporting Guidelines**   * *Discuss with the Team Manager/Head of Department or Project Manager if you have discovered SOP deviation.* * *The SOP deviation should be documented in this SOP Deviation Report.* * *If SOP deviation is related to project activities, it should be reviewed by the Project Manager. Otherwise, it should be reviewed by the Team Manager/Head of Department.* * *If Project Manager is the first reviewer, the Team Manager/Head of Department of the Project Manager MUST be included as a second reviewer.* * *Please add the relevant Team Manager/Head of Department as a reviewer if more than one department should be involved for CAPA resolution.* * *All original SOP Deviation Report must be delivered to the QA team, and additional documents for evidence can be required if necessary.* |