|  |  |  |
| --- | --- | --- |
| **DEVIATION INTAKE FORM**   * Complete using Information from Preliminary Info form and Gemba meeting * Answer process confirmation questions in SmartSheet * **Upload this document to SmartSheet immediately following the Gemba** * NOTE: Hover over underlined text in either blue or red font, as this will have additional information or will be a direct link to document or website.   References: [QU-GOP-0000518](https://sanofi-qualipso.veevavault.com/ui/#doc_info/741670/1/0?newTvsl=true&sm=166360951704424380264&idx=0&pt=al&tvsl=), [QU-OPE-0166585](https://sanofi-qualipso.veevavault.com/ui/#doc_info/271775/1/0?newTvsl=true&sm=166360951704424489882&idx=0&pt=asl&tvsl=JmNvbmZpZ05hbWU9bGlicmFyeV9fdiZsb2NhdGlvbklkPTBUQjAwMDAwMDAwMDEwMiZzZWFyY2hUeXBlPWRvY3VtZW50JnNlYXJjaFRlcm09UVUtT1BFLTAxNjY1ODUmc2VhcmNoPVFVLU9QRS0wMTY2NTg1Jml2cD0xJmN1c3RvbURhdGElNUJ2aWV3SWQlNUQ9YWR2U2VhcmNoJmN1c3RvbURhdGElNUJiYWNrVG9MaW5rJTVEPXQlMkYwVEIwMDAwMDAwMDAxMDIlMkZhZHZTZWFyY2glM0ZzZWFyY2glM0RRVS1PUEUtMDE2NjU4NSUyNml2ciUzRDAlMjZpdiUzRDElMjZpdm8lM0RkZXNjJTI2c20lM0QxNjYzNjA5NTE3MDQ0MjQ0ODk4ODIlMjZzbWFydCUzRHRydWUlMjZpdnYlM0RSRVBPUlRJTkcmcmVzcGVjdEluZGV4PWZhbHNl), [QU-OPE-0110981](https://sanofi-qualipso.veevavault.com/ui/#doc_info/181234/1/0?newTvsl=true&sm=166360951704424531667&idx=0&pt=asl&tvsl=JmNvbmZpZ05hbWU9bGlicmFyeV9fdiZsb2NhdGlvbklkPTBUQjAwMDAwMDAwMDEwMiZzZWFyY2hUeXBlPWRvY3VtZW50JnNlYXJjaFRlcm09UVUtT1BFLTAxMTA5ODEmc2VhcmNoPVFVLU9QRS0wMTEwOTgxJml2cD0xJmN1c3RvbURhdGElNUJ2aWV3SWQlNUQ9YWR2U2VhcmNoJmN1c3RvbURhdGElNUJiYWNrVG9MaW5rJTVEPXQlMkYwVEIwMDAwMDAwMDAxMDIlMkZhZHZTZWFyY2glM0ZzZWFyY2glM0RRVS1PUEUtMDExMDk4MSUyNml2ciUzRDAlMjZpdiUzRDElMjZpdm8lM0RkZXNjJTI2c20lM0QxNjYzNjA5NTE3MDQ0MjQ1MzE2NjclMjZzbWFydCUzRHRydWUlMjZpdnYlM0RSRVBPUlRJTkcmcmVzcGVjdEluZGV4PWZhbHNl), [QU-OPE-0528937](https://sanofi-qualipso.veevavault.com/ui/#doc_info/869771/1/0?newTvsl=true&sm=166360951704424575499&idx=0&pt=asl&tvsl=JmNvbmZpZ05hbWU9bGlicmFyeV9fdiZsb2NhdGlvbklkPTBUQjAwMDAwMDAwMDEwMiZzZWFyY2hUeXBlPWRvY3VtZW50JnNlYXJjaFRlcm09UVUtT1BFLTA1Mjg5Mzcmc2VhcmNoPVFVLU9QRS0wNTI4OTM3Jml2cD0xJmN1c3RvbURhdGElNUJ2aWV3SWQlNUQ9YWR2U2VhcmNoJmN1c3RvbURhdGElNUJiYWNrVG9MaW5rJTVEPXQlMkYwVEIwMDAwMDAwMDAxMDIlMkZhZHZTZWFyY2glM0ZzZWFyY2glM0RRVS1PUEUtMDUyODkzNyUyNml2ciUzRDAlMjZpdiUzRDElMjZpdm8lM0RkZXNjJTI2c20lM0QxNjYzNjA5NTE3MDQ0MjQ1NzU0OTklMjZzbWFydCUzRHRydWUlMjZpdnYlM0RSRVBPUlRJTkcmcmVzcGVjdEluZGV4PWZhbHNl), [QualiPSO Landing Page: MA BioCampus,](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)[QU-SOP-0084216-Guidance document for investigating deviations involving SUT](https://api-eu.sanofi.com:8443/smartlink/api/qualipso/7670159) | | |
| Gemba Coach:  Gemba Facilitator:  Gemba Scribe:  Impacted/Discovering Department Reps: | | |
| **ENSURE REQUIRED SMEs ARE PRESENT AT START OF GEMBA**  Manufacturing:  Automation (DOT) / MES:  QA Digital Compliance:  Contamination Control:  Facilities / Engineering:  Cleaners:  MSAT:  Company Subject Matter Expert(s)\*:  QA Ops & QA CDI:  Other:  \*Due to FDA Response this individual(s) is listed as “Subject Matter Expert” in deviation description section under GEMBA attendees | | |
| **[Title](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D" \o "Include Product line, batch if applicable, Building, Deviating Event. Observer keeps in mind that the title will be used to identify recurrent deviations based on \“Search\” and systemic problems based on \“trend\” using natural language processing (NLP).)**  (Also see[GQCMS-QU-OPE-0039710-Guidance Relative to Investigation of Deviations](https://sanofi-qualipso.veevavault.com/ui/#doc_info/64757/1/0?newTvsl=true&sm=166360951704420361584&idx=0&pt=asl&tvsl=JmNvbmZpZ05hbWU9bGlicmFyeV9fdiZsb2NhdGlvbklkPTBUQjAwMDAwMDAwMDEwMiZzZWFyY2hUeXBlPWRvY3VtZW50JnNlYXJjaFRlcm09R1FDTVMtUVUtT1BFLTAwMzk3MTAmc2VhcmNoPUdRQ01TLVFVLU9QRS0wMDM5NzEwJml2cD0xJmN1c3RvbURhdGElNUJ2aWV3SWQlNUQ9YWR2U2VhcmNoJmN1c3RvbURhdGElNUJiYWNrVG9MaW5rJTVEPXQlMkYwVEIwMDAwMDAwMDAxMDIlMkZhZHZTZWFyY2glM0ZzZWFyY2glM0RHUUNNUy1RVS1PUEUtMDAzOTcxMCUyNml2ciUzRDAlMjZpdiUzRDElMjZpdm8lM0RkZXNjJTI2c20lM0QxNjYzNjA5NTE3MDQ0MjAzNjE1ODQlMjZzbWFydCUzRHRydWUlMjZpdnYlM0RSRVBPUlRJTkcmcmVzcGVjdEluZGV4PWZhbHNl)) | *Product(s) – Lot (or “Multiple Lots”) – Building Number – Short Description of Problem* | |
| [**Team**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | |
| [**Description**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)  [**Additional Information**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | **Extra Notes:** |
| [**Why**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | **Extra Notes:** |
| [**Who**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | **Extra Notes:** |
| [**How**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)  [**Additional Information**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)  [**For Non-Significant Events**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | **Extra Notes:** |
| [**How much**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | **Extra Notes:** |
| [**Reporter Entity**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | MA BioCampus |  |
| [**Department**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | **Extra Notes:** |
| [**Owning Entity (if associated with our site)**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)  [**Owning Entity (if we are the service provider)**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | **Extra Notes:** |
| [**Building**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | **Extra Notes:** |
| [**Room**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | **Extra Notes:** |
| [**Process**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)  [**ⓘ EMCU records**](file:///C:\Users\mciam01\Downloads\not%20a%20valid%20address) |  | **Extra Notes:** |
| [**Operation**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)  [**ⓘ EMCU records**](file:///C:\Users\mciam01\Downloads\not%20a%20valid%20address) |  | **Extra Notes:** |
| [**Date Detected**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | **Extra Notes:** |
| [**Event Raised Late Justification**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | **Extra Notes:** |
| [**Date Occurred Known**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | **Extra Notes:** |
| [**Asset Concerned? NOTE: Verify Owning entity is MA BioCampus**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | **Extra Notes:** |
| **Product Concerned?**  [**Yes**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)  [**No**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | If No for Product Concerned, select No for Product/Batches Child and proceed to Immediate Actions Taken  If Yes for Product Concerned, select Yes for Product/Batches Child and expand the table by clicking on the triangle by “Product/Batches Child Required” below” and complete the table | **Extra Notes:** |

**PRODUCT IMPACT / PRODUCT Designation**

**Product/Batches Child Required (not required if Product Concerned is no):**

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| --- | --- | --- |
| **Product/Batches Child** [**Comment (Batch):**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)[**Comment (Further Processing):**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)[**Comment (QI status)**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | [**Product:**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | **Extra Notes:** |
| [**Batch:**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) [**If Product is not available**](file:///C:\Users\mciam01\Downloads\not%20a%20valid%20address) | **Extra Notes:** |
| [**Impact:**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | **Extra Notes:** |
| [**Impact Rationale:**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | **Extra Notes:** |
| [**Handling Unit Impacted (Yes):**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)[**Handling Unit Impacted (No):**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | **Extra Notes:** |
| **Comment:** Batch (record batch here for NS events):Product Impact:Further Processing Decision:Batch Association Strategy:Environmental Impact:Equipment Impact: | **Confirm if equipment or product containment is required. If yes, create and assign required action items.** **Extra Notes:** |

**Intake Form Continued:**

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| [**Immediate Action Needed?**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)  [**Additional Information**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | Actions Required: | **Extra Notes:** |
| **Clinical Study Concerned?** | Select “No” by default |  |
| [**Third Party Concerned?**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | If No for Third Party Concerned, select No for TP Complaint Child and proceed to External References  If Yes for Third Party Concerned, select Yes for TP Complaint Child and expand the table by clicking on the triangle by “TP Complaint Child Required” below” and complete the table. | **Extra Notes:** |

**TP Complaint Child Required (not required if Third Party Concerned is No)**

|  |  |  |
| --- | --- | --- |
| **TP Complaint** **Child** | [**Title:**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | **Extra Notes:** |
| [**Description of complaint**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)**:** Specification Document #:  Issue detected: pre-use or post-use  PO number: [**Additional information:**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) Affected Qty:  Sanofi PN, Lot, HU (if applicable):  Vendor, Vendor PN, Lot Serial # (if available): **Instruct Manufacturing to circle or draw an arrow to defect on SUT if possible.** | **Extra Notes:** |
| [**Current Expected Response Date:**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | **Extra Notes:** |
| [**Owning Entity:**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) MA BioCampus |  |
| [**Third Party:**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | **Extra Notes:** |
| [**Core Material(s):**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | **Extra Notes:** |
| **Attachments Required**[**Review of Available Inventory using Athena transaction MMBE**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)[**Athena Material Transaction Screen Shot**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)**Photo and/or video of defect are REQUIRED!!**  **Photo and/or video guidance for Single Use Technology**:  *Photo: Take a photo of the whole item and a close up photo of the defect. If possible, take a picture of lot stamps to help vendor identify process used for production. Annotate the pictures with a description of the defect and circle the defect location.*  *Video: Take a video including the whole item and zoomed in up close to the defect area. During the video recording describe the defect vs the expected state and defect location.*  *Alternatively, in the exceptional cases where it is not possible to take a picture or video, the SUT drawing may be marked up with the defect location.* | **Extra Notes:** |
| **Questions to Ask to Determine additional actions required to return material to vendor:**[**Material Status**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)**Does the material require decontamination?**[**Current Material Location**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D)[**Has Material been properly labeled with PN, Lot, HU and Deviation #?**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | **Extra Notes:** |

**Intake Form Continued:**

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| --- | --- | --- |
| [**External References**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) |  | **Extra Notes:** |
| [**Comments**](https://sanofi.sharepoint.com/sites/quality-junction/SitePages/QualiPSO-Landing-Page--MA-BioCampus.aspx?OR=Teams-HL&CT=1704373524108&clickparams=eyJBcHBOYW1lIjoiVGVhbXMtRGVza3RvcCIsIkFwcFZlcnNpb24iOiIyNy8yMzExMDIyNDcwNSIsIkhhc0ZlZGVyYXRlZFVzZXIiOmZhbHNlfQ%3D%3D) | Non-Significant: Document the following points for owner conclusion  • *Summary of conclusion (including only high level summary of assignable cause as the full explanation is contained in “How”)*:  • *GxP Impact/Regulatory Compliance Statement*:    • *Refer to Product Child record for product impact, further processing decision and batch association strategy.*  • *Most assignable cause*:asdfsadf  • *Justification for why no further investigation is required*:  Stop Sign Clip Art Free Vector Does this event involve a violation to the dossier?  Significant: Document the following points for owner conclusion  • *Summary of conclusion*:  • *GxP Impact/Regulatory Compliance Statement:*  • *If not clear from intake details, justification for “no” to other criticality questions as applicable (use best judgement*)  • *Refer to Product Child record for product impact, further processing decision and batch association strategy.*  • *pRE-ME statement*:  Stop Sign Clip Art Free Vector Does this event involve a violation to the dossier? | **Extra Notes:** |
| **Criticality Assessment** | Impacted or Potential Impact on Product?  Select YES:  • When we cannot rule out that the deviation will have an impact on the safety, quality, identity, potency or purity of a product or the  performance of a device.  • When we work outside the validated range for critical parameters. The  process control strategy can be used as a guideline for this. | **Extra Notes:** |
| Safety, Patients, Data Reliability?  Select YES in the event of non-compliance with the content of the documents Sanofi has submitted to regulatory authorities or if we fail a  requalification. | **Extra Notes:** |
| Is The Event Indicative Of A Trend?  Select YES, when a trend is detected during anomaly trending, quarterly deviation trending, laboratory tests, complaints, etc. | **Extra Notes:** |
| Impact GxP And/Or Regulatory Compliance?  See below for some examples of when YES should be selected:  • Failure of controls within our system or lack of controls  • When we don't follow the change-control process.  • When we use processes, equipment or systems that are not qualified/validated.  • GxP activities performed by person not qualified for tasks  • Data Integrity Issues  • Data loss  • Pervasive systemic failure  • Gap in critical computerized system validation/cleaning, process validation  Note: This is not an exhaustive list, just a high level guide | **Extra Notes:** |
| Overall Criticality Assessment:  If 1 or more answer(s) is/are “YES”, the classification is Significant  If all answers are “No”, the classification is Non Significant | **Extra Notes:** |

**Additional Actions Required to progress deviation event:**

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| --- | --- | --- |
| **Action Item Description** | **Owner** | **Due Date** |
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