TRACELINK UNIVERSITY

Manufacturing Incident

A manufacturing incident is any unexpected event during production that may impact product quality, safety, compliance, timelines, or supply.

What is a manufacturing incident

A manufacturing incident is any unexpected event that occurs during the manufacturing process and has the potential to affect product quality, patient safety, production time-lines, regulatory compliance, or supply continuity. For e.g. process deviations, equipment failures, contamination, labeling errors, human mistakes, or system malfunctions.

Types of manufacturing incidents

- **Deviation:** Unexpected variance from approved procedures, instructions, or process parameters.
- **Contamination:** Introduction of unwanted substances that compromise product integrity or safety.
- **Equipment Failure:** Breakdown or malfunction of machinery that disrupts the manufacturing process.

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- **Labeling or Packaging Issue:** Errors in labeling or packaging that may lead to misidentification or noncompliance.
- **Material Issues:** Problems related to the quality, identity, or suitability of raw or packaging materials.
- **Process Errors:** Mistakes in executing manufacturing steps or process controls.
- **Human Error:** Operator mistakes due to oversight, lack of training, or failure to follow procedures.
- **IT or System Fault:** Failures of computerized systems that support manufacturing or quality operations.

How to configure the manufacturing incident marketplace solution

Before using the batch record review marketplace solution, Solution Designers must first configure the solution in Opus Solution Environment (OSE) by following the steps listed below:

Save the marketplace solution as a company solution in OPUS Solution Environment

Solution Designers must first save the latest version of the marketplace solution from the marketplace catalog as a company solution.

1. Select the Main Menu icon.
2. Select OPUS Solution Environment.
3. Select Catalog from the left menu.
4. Select Marketplace Solutions.

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5. On the Search Solutions page, filter the list of solutions to find the required solution.
6. Find the latest version of the solution and select the Solution Name to open the solution.
7. On the Solution Details page, select Save As.
8. On the Save As panel, fill in the following fields:
    a. Solution Name field – The name of the solution that will be saved as a company solution.
    b. Description field – (Optional) The description of the solution.
9. Select Apply.

    The marketplace will be saved as a company solution in the Available tab on the left menu.

Create a network for the solution in OPUS Administration

After saving the solution as a Company Solution, Solution designers must create a network for the solution from OPUS Administration.

1. Select the Main Menu icon.
2. Select Administration.
3. Select Network and Apps from the left menu.
4. Select New.
5. In the Network Information section, fill in the following fields:
    a. Application drop-down – Select the application for which you want to configure the marketplace solution. For e.g. Process Orchestration for Empowered Teams.
    b. Network Name field – The name of the network being created.
    c. Network Description field – (Optional) The description of the network being created.
6. In the Solution section, fill in the following fields:
    a. Standard Solution toggle – This value must be no as the solution for which the network is being created is a marketplace solution.

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b. Company Solution field – Select the solution that you saved as a company solution in the previous procedure.

7. Select Save.

   The new network is created and the solution is ready for use.

Configure roles for the new network in OPUS Administration

After creating a network for the solution, Solution Designers must define roles for accessing the network.

1. Select the Main Menu icon.
2. Select Administration.
3. Select Users from the left menu.
4. Select Network Members from the left menu.
5. On the Search Network Members page, filter the list of network members by the network created in the previous procedure.
6. Select the user email of the user who created the network.
7. Select Edit.
8. In the Roles section, select the role required to access the network.
9. Select Save.

   The role to access the new network is configured.

For more information about configuring or customizing marketplace solutions as per your business needs, see OPUS Solution Environment Help Center.

Add a manufacturing incident

Add a manufacturing incident

By default, a manufacturing incident is created by a set of basic fields, which are widely used. However, depending on your business needs, you may need to include additional fields in the manufacturing incident. To include additional fields, edit the manufacturing incident to view all available fields and update the required

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fields.

1. Select the Main Menu icon.
2. Select My Networks.
3. Select a [POET Network] from the Select your Network drop-down in the header.
4. Select a Partner or location from the Select your Partner or Location drop-down in the header.
5. Select Go.
6. Select Manufacturing Incident from the left menu.
7. Select New.
8. In the General section fill in the following fields:
    a. Title field – The title of the new manufacturing incident.
    b. Description field – The description of the manufacturing incident.
9. Select Save.

   The manufacturing incident is created in the Draft state.
10. To move the manufacturing incident to To Do state, select Move to.

Modify a manufacturing incident

Edit a manufacturing incident

1. Select the Main Menu icon.
2. Select My Networks.
3. Select a [POET Network] from the Select your Network drop-down in the header.
4. Select a Partner or location from the Select your Partner or Location drop-down in the header.
5. Select Go.
6. Select Manufacturing Incident from the left menu.
7. Select the Display Identifier of the manufacturing incident to edit.
8. Select Edit.

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In addition to the fields updated when creating the manufacturing incident, additional fields will be displayed which can be updated if required.

9. In the General section update the following fields:
    a. Display Identifier field – The display identifier of the manufacturing incident.
    b. Title field – The title of the manufacturing incident.
    c. Due Date field – The due date of the manufacturing incident.
    d. Incident Description field – The detailed description of the manufacturing incident.
    e. Incident Category drop-down – The category of the manufacturing incident. For example: Deviation, Contamination, Equipment Failure, etc.
        i. If you selected Deviation in the Incident Category drop-down, add the required sub-category information:
            a. Sub-category drop-down – The sub-category of the manufacturing incident. For example: SOP Not Followed, Unauthorized Change, Inadequate Review, etc.
            b. SOP Number field – The reference number of the associated Standard Operating Procedure.
            c. Step Skipped/Changed field – The procedure step that was missed, altered, or performed incorrectly.
            d. Was QA Notified? field – The procedure step that was missed, altered, or performed incorrectly.
        ii. If you selected Contamination in the Incident Category drop-down, add the required sub-category information:
            a. Sub-category drop-down – The sub-category of the manufacturing incident. For example: Microbial, Particulate, Cross-contamination, etc.
            b. Environmental Monitoring Status field – The environmental monitoring status of the manufacturing incident. For example: Normal, Alert, or Action.

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c. Sample ID (if any) field – The identifier of any related test sample connected to the contamination.

iii. If you selected Equipment Failure in the Incident Category drop-down, add the required sub-category information:
   a. Sub-category drop-down – The sub-category of the manufacturing incident. For example: Breakdown, Calibration Drift, Alarm Ignored, etc.
   b. Equipment ID field – The unique identifier of the equipment involved in the incident.
   c. Last Maintenance Date field – The date on which the equipment was last maintained.
   d. Downtime Duration field – The total duration of downtime caused by the equipment failure (in hours).

iv. If you selected Labeling/Packaging in the Incident Category drop-down, add the required sub-category information:
   a. Sub-category drop-down – The sub-category of the manufacturing incident. For example: Wrong Label, Misprint, Barcode Issue, etc.
   b. Label Type field – The type of label that caused the incident.
   c. Was Product Released? field – Indicates whether the affected product batch was released to the market.

v. If you selected Material Issues in the Incident Category drop-down, add the required sub-category information:
   a. Sub-category drop-down – The sub-category of the manufacturing incident. For example: Expired Material, Wrong Material, Damaged Material, etc.
   b. Material Type field – The type of material that caused the manufacturing incident.
   c. Material Batch No. field – The batch or lot number of the affected material.

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d. Supplier Name field – The name of the vendor or supplier of the material.

vi. If you selected Process Error in the Incident Category drop-down, add the required sub-category information:
   a. Sub-category drop-down – The sub-category of the manufacturing incident. For example: Incorrect Timing, Step Out of Sequence, Incomplete Step, etc.
   b. Process Step field – The process step where the error occurred or failed.
   c. Operator ID field – The ID or name of the operator who executed the process.
   d. Was Batch Quarantined? field – Indicates whether the affected batch was quarantined for review.

vii. If you selected Human Error in the Incident Category drop-down, add the required sub-category information:
   a. Sub-category drop-down – The sub-category of the manufacturing incident. For example: Distraction, SOP Misunderstood, Training Gap, etc.
   b. Was Training Completed? field – Indicates whether the operator had completed the required training before the incident
   c. Suggested Retraining field – Indicates if retraining is recommended based on the incident review.

viii. If you selected IT/System Fault in the Incident Category drop-down, add the required sub-category information:
   a. Sub-category drop-down – The sub-category of the manufacturing incident. For example: System Downtime, Data Loss, Integration Error, etc.
   b. System Name field – The name of the IT/automation system where the fault occurred.
   c. Error Code field – The error code of the system, if available.

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d. Backup Successful? field – Indicates whether backup or recovery was successfully completed.

ix. If you selected Environmental Deviation in the Incident Category drop-down, add the required sub-category information:
   a. Sub-category drop-down – The sub-category of the manufacturing incident. For example: Temperature Excursion, Humidity Out of Range, Pressure Drop, etc.
   b. Parameter Breached field – The environmental parameter breached causing the manufacturing incident.
   c. Limit Breached field – The value of the threshold or specification limit that was exceeded.
   d. Duration field – The duration for which the parameter remained out of specification, in hours.

x. If you selected Supply Chain / Logistics in the Incident Category drop-down, add the required sub-category information:
   a. Sub-category drop-down – The sub-category of the manufacturing incident. For example: Temperature Excursion, Humidity Out of Range, Pressure Drop, etc.
   b. Shipment ID field – The environmental parameter breached causing the manufacturing incident.
   c. Transport Condition Breached field – The value of the threshold or specification limit that was exceeded.
   d. Was Product Quarantined? field – The duration for which the parameter remained out of specification, in hours.

xi. If you selected HSE / Safety Incident in the Incident Category drop-down, add the required sub-category information:
   a. Sub-category drop-down – The sub-category of the manufacturing incident. For example: Injury, Fire, Spill, etc.
   b. Safety Incident Type field – The type of safety incident that caused the manufacturing incident.

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   c. PPE Used field – Indicates if personal protective equipment was in use during the incident.
   d. Safety Officer Notified field – Confirms if the EHS/safety officer or team was alerted.

f. Date of Incident field – The date when the manufacturing incident occurred.
g. Affected Batch/ Lot No. field – The identifier of the specific product batch or lot impacted by the manufacturing incident.
h. Business Priority field – The business priority of the batch record review.

10. If you require to collaborate with an external partner, enter the following Initiator Company details under the Participants section:
    a. Business Name field – The name of the company that created the manufacturing incident.
    b. Identifier Type field – The identifier type of the initator company.
    c. Identifier Value field – The value of the identifier.
11. If you require to collaborate with an external partner, enter the following Assignee Company details under the Participants section:
    a. Business Name field – The name of the Partner company that is assigned to take action on the manufacturing incident.
    b. Identifier Type field – The identifier type of the assignee company.
    c. Identifier Value field – The value of the identifier.
12. You can specify an accountable entity at the Initiator Company or Assignee Company in the Assignee User section:
    a. Email field – The email of the user who is required to take action on the manufacturing incident.

    b. Name field – The name of the user who is required to take action on the manufacturing incident.

13. Add details about the area of impact for the manufacturing incident in Impact Assessment section.

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a. Severity field – The level of severity of the impact.
b. Has Regulatory Risk? field – Indicates if the incident poses potential compliance or reporting obligations.
c. Distribution Impact field – The impact on distribution of the product affected by the manufacturing incident.
d. Other Areas Affected field – The areas affected by the manufacturing incident.

14. In the Impacted Locations section, add location information in the following fields:
    a. Business Name field – The business name of the location affected
    b. Identifier Type field – The identifier type of the location affected
    c. Identifier Value field – The identifier value of the location affected
    d. Location Type field – The functional classification of the site based on its supply chain role.
    e. Location Affiliation field – Whether the site is owned by your company or managed by a third-party (e.g., CMO, 3PL).
    f. Impact Type field – Describes the kind of disruption experienced at this site due to the incident.
15. In the Impacted Products section, add information about product impacted in the following fields:
    a. Product Name field – The name of the product that is impacted by the manufacturing incident.
    b. Item Code Type field – The unique identifier type assigned to the product.
    c. Item Code Value field – The unique identifier value assigned to the product.
    d. Batch/Lot Number field – The The batch or lot number impacted.
    e. Quantity Impacted field – Total number of units affected in the incident.
16. In the Investigation & Resolution section, add information about how the incident was investigated and resolved in the following fields:
    a. Root Cause field – The underlying reason that led to the incident

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identified through the investigation process.

b. Corrective Action field – The steps taken to fix the issue and its impact on products, processes, or compliance.
c. Preventive Action field – Measures designed to prevent recurrence of the incident, ensuring long-term process or safety improvements.
d. Investigation Owner field – The person accountable for leading the investigation, coordinating stakeholders, and driving resolution.
e. Date Closed field – The official closure date once root cause, corrective, and preventive actions are completed and approved.

17. In the Closure Summary section, add information about how the manufacturing incident was closed in the following fields:
    a. Closure Status field – The closure status of the manufacturing incident.
    b. Closure Notes field – The reason for closure and any key details that support the final outcome.
18. In the Comments and Attachments section, add information in the following fields:
    a. Comment Author field (auto-generated) – The name of the user who entered the comment.
    b. Last Modified field – Displays the date and time when the comment was last modified.
    c. Comment Text field – Text of the comment.
    d. Attachments field – Name of the file attached.
19. The Followers section displays names of the users who are following the manufacturing incident.
20. Select Save.

    The manufacturing incident review is updated.

Owners can edit the Assignee Details section while the batch record review is in the Draft state. Once the work item moves to the To Do state, the Assignee Details section can be edited only once.

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Manufacturing incidents workflow

The following workflow states are used to track the progress of a manufacturing incident:

Base State	Workflow State	Description
Draft	Draft	The manufacturing incident is being created and documented, but it has not yet been submitted for review or action.
To Do	To Do	The manufacturing incident has been formally logged and is awaiting triage, assignment, or initial review.
In Progress	Under Investigation	The manufacturing incident is actively being analyzed by the assigned teams to determine its root cause, scope, and potential impact.
In Progress	Under Resolution	Corrective or preventive actions are being carried out to address the manufacturing incident and mitigate its impact.
Done	Done	The manufacturing incident has been resolved and formally closed with an appropriate closure outcome or reason.

Monitor manufacturing incident

A high level understanding of the state of all manufacturing incidents that you have access to.

View the dashboard (Owner)

1. Select the Main Menu icon.
2. Select My Networks.
3. Select a [POET Network] from the Select your Network drop-down in the header.
4. Select a Partner or location from the Select your Partner or Location drop-down in the header.
5. Select Go.
6. Select Manufacturing Incidents Dashboard from the left menu.
   View the widgets in the dashboard, which display pre-defined queries to demonstrate the state of all manufacturing incident at a high level.

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Metric	Description
Status - Open	Manufacturing incidents classified by status (Draft, To Do, In Progress).
Status - Open vs Resolved	Manufacturing incidents classified by the number of incidents that were opened and closed within a selected time period.
Business Priority	Manufacturing incidents classified by priority (Critical, High, Medium, Low).
Partner	Manufacturing incidents classified by status for each Partner company.
Impact Type	Manufacturing incidents classified by impact type (Delay, Recall, Rework, Hold)
Distribution Impact - Yes	Manufacturing incidents classified by status (To Do, In Progress, Done) that may have impacted product released to the market.
Location Type	Manufacturing incidents classified by location type.
Category and Subcategory	Manufacturing incidents classified by category and sub-category.
Due Date Monitoring	
Manufacturing Incidents Overdue	Manufacturing incidents past Due Date by currentState. Escalates compliance and execution risks.
Manufacturing Incidents Due in Next 24 Hours	Manufacturing incidents due within 24 hours by currentState. Highlights items requiring immediate executive attention.
Manufacturing Incidents Due in Next 7 Days	Manufacturing incidents due within 7 days by currentState. Supports short-term workload planning.
Manufacturing Incidents Due in Future	Manufacturing incidents due beyond 7 days by currentState. Supports capacity forecasting.

View the dashboard (Partner)

1. Select the Main Menu icon.
2. Select My Networks.
3. Select a [POET Network] from the Select your Network drop-down in the header.
4. Select a Partner or location from the Select your Partner or Location drop-down in the header.
5. Select Go.
6. Select Manufacturing Incidents Dashboard from the left menu.

   View the widgets in the dashboard, which display pre-defined queries to demonstrate the state of all manufacturing incident at a high level.

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Metric	Description
Status - Open	Manufacturing incidents classified by status (Draft, To Do, In Progress).
Business Priority	Manufacturing incidents classified by priority (Critical, High, Medium, Low).
Partner Location	Manufacturing incidents classified by Partner location combined by status (To Do, In Progress, Done).
Category and Subcategory	Manufacturing incidents classified by category and sub-category.
Average Time to Close Partner-Owned Incidents	Manufacturing incidents classified by the average time taken by the Partner to fully resolve the incident.
Due Date Monitoring	
Manufacturing Incidents Overdue	Manufacturing incidents past Due Date by currentState. Escalates compliance and execution risks.
Manufacturing Incidents Due in Next 24 Hours	Manufacturing incidents due within 24 hours by currentState. Highlights items requiring immediate executive attention.
Manufacturing Incidents Due in Next 7 Days	Manufacturing incidents due within 7 days by currentState. Supports short-term workload planning.
Manufacturing Incidents Due in Future	Manufacturing incidents due beyond 7 days by currentState. Supports capacity forecasting.

Search manufacturing incidents

1. Select the Main Menu icon.
2. Select My Networks.
3. Select a [POET Network] from the Select your Network drop-down in the header.
4. Select a Partner or location from the Select your Partner or Location drop-down in the header.
5. Select Go.
6. Select Manufacturing Incidents from the left menu.
7. Select Filter.
8. In the Filters panel, fill in one or more of the following fields to filter the results:
    a. Display Identifier field – The display identifier of the manufacturing incident.
    b. Title field – The title of the manufacturing incident.

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c. State field – The state of the manufacturing incident.
d. Creation Time drop-down – The date and time when the manufacturing incident was created.
e. Initiator Company drop-down – The company which initiated the manufacturing incident.
f. Assignee Company drop-down – The company which was assigned the manufacturing incident. .
g. Due Date field – The due date of the manufacturing incident.
h. Incident Category field – The category of the manufacturing incident.
i. Subcategory drop-down – The sub-category of the manufacturing incident.
j. Priority field – The business priority of the manufacturing incident.
k. Last Modified field – The date when the manufacturing incident was last modified.

9. Select Apply.

   All manufacturing incident matching the filter criteria are displayed.

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