TRACELINK UNIVERSITY

Product Complaint

Product complaint includes issues reported by customers, healthcare providers, distributors, or internal stakeholders about a pharmaceutical product.

What is product complaint handling

Product Complaint Handling is a regulated quality and pharmacovigilance process where issues reported by customers, healthcare providers, distributors, or internal stakeholders about a pharmaceutical product are logged, investigated, and resolved. These complaints may involve product quality defects, packaging errors, labeling mistakes, adverse drug reactions (ADRs), or distribution failures.

Types of product complaints

- **Product Quality:** Covers defects that affect the physical characteristics of the drug product.
- **Packaging Defect:** Encompasses issues with the external or protective packaging.
- **Labeling Error:** Applies to inaccuracies or omissions in printed or affixed labels.

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- **Adverse Drug Reaction:** Refers to unexpected or harmful responses experienced after using the drug as prescribed.

- **Distribution Issues:** Concerns linked to the supply chain and product delivery.

- **Counterfeit or Fraud:** Suspicion or confirmation of falsified products in the supply chain.

- **Other:** Covers all complaints that do not fit into the standard categories. Examples include user or operator error, duplicate complaint submissions, or issues that fall outside the defined scope of product, packaging, labeling, ADR, distribution, or fraud.

How to configure the product complaint marketplace solution

Before using the product complaint 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.
5. On the Search Solutions page, filter the list of solutions to find the required

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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.
    b. Company Solution field – Select the solution that you saved as a

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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 product complaint

Add a product complaint

By default, a product complaint 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 product complaint. To include additional fields, edit the product complaint to view all available fields and update the required fields.

1. Select the Main Menu icon.

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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 Product Complaint 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 product complaint.
    b. Description field – The description of the product complaint.
9. Select Save.
   The product complaint is created in the Draft state.
10. To move the product complaint to To Do state, select Move to.

Modify a product complaint

Edit a product complaint

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 Product Complaint from the left menu.
7. Select the Display Identifier of the product complaint to edit.
8. Select Edit.
   In addition to the fields updated when creating the product complaint, additional fields will be displayed which can be updated if required.
9. In the General section update the following fields:

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a. Display Identifier field – The display identifier of the product complaint.
b. Title field – The title of the product complaint.
c. Business Priority field – The level of priority for the product complaint. Select from Low, Medium, High, and Critical.
d. Complaint Source field – The source of the product complaint. For example: Company Websites, Email, Regulatory Authority Portals, etc.
e. Reported to Regulator field – Indicates if this been submitted to PV authorities.
f. Category field – The type of the product complaint. For example: Product Quality, Packaging Defect, Labeling Error, etc.
    i. If you selected Product Quality in the Category drop-down, add the required sub-category information:
        a. Sub-category field – The sub-category of the selected category. For example: Physical Appearance Issue, Contamination (Particulate/Microbial), etc.
        b. Batch/Lot Number field – The batch involved in the complaint.
        c. Sample Available field – Indicates if a physical sample is available.
        d. Visual Inspection Notes field – Observations from physical inspection.
        e. Lab Testing Required field – Indicates whether lab analysis is needed.
    ii. If you selected Packaging Defect in the Category drop-down, add the required sub-category information:
        a. Sub-category field – The sub-category of the selected category. For example: Damaged Packaging, Improper Sealing, etc.
        b. Packaging Type field – The type of packaging which is defective.
        c. Batch/Lot Number field – The batch or lot involved in the complaint.

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d. Impact on Label Readability field – Indicates if the defect affects label clarity.
e. Leaflet Present field – Indicates if the product insert was included.

iii. If you selected Labeling Error in the Category drop-down, add the required sub-category information:
a. Sub-category field – The sub-category of the selected category. For example: Incorrect Product Name, Incorrect Strength / Dosage, Mismatched Batch or Expiry Info, etc.
b. Correct Label Reference field – The correct label that was intended for the product.
c. Label Type field – The type of label.
d. Regulatory Impact field – Indicates if the complaint requires regulatory notification.

iv. If you selected Adverse Drug Reaction (ADR) in the Category drop-down, add the required sub-category information:
a. Sub-category field – The sub-category of the selected category. For example: Unexpected Side Effect, Lack of Efficacy, Allergic Reaction, etc.
b. Patient Age field – The age of the affected patient.
c. Gender field – The gender of the affected patient.
d. Reaction Description field – The description of the adverse event.
e. Medical Attention Required field – Indicates whether hospitalization or treatment was needed.
f. Reported to Regulator field – Indicates if this been submitted to PV authorities.

v. If you selected Distribution/Delivery Issue in the Category drop-down, add the required sub-category information:
a. Sub-category field – The sub-category of the selected category.

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For example: Cold Chain Violation, Shipment Delay, Damaged During Transport, etc.

b. Shipping Carrier field – The name of the logistics provider.
c. Tracking Number field – The shipment tracking ID.
d. Delivery Date field – The date the shipment was received.
e. Temperature Data Available field – Indicates if temperature log is available.
f. Product Condition on Arrival field – Description of product state upon delivery.

vi. If you selected Counterfeit/Suspected Fraud in the Category drop-down, add the required sub-category information:

a. Sub-category field – The sub-category of the selected category. For example: Falsified Product Appearance, Suspected Tampering, Product Not Matching Label Claims, etc.
b. Source of Product field – Indicates where the product was obtained.
c. Suspected Issue Description field – The description of why the product is suspicious
d. Regulatory Authority Notified field – Indicates if this been reported to a health authority.
e. Authentication Performed field – Indicates if a verification test was performed.

g. Complaint Log Date field – The date when the issue was observed.
h. Due Date field – The due date of the product complaint.
i. Description field – The detailed description of the product complaint.
j. Sample Available field – Indicates if a physical sample is available.
k. Attachments field – Supporting documents or images if any.

10. If you require to collaborate with an external partner, enter the details under the Participants section:

a. Initiator Company field – The name of the company that created the

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product complaint. This field is automatically populated with the logged-in user.

b. Assignee Company field – The name of the Partner company that is assigned to take action on the product complaint.

11. In the Product Information section, add information about the impacted product in the following fields:
    a. Product Name field – The name of the impacted product.
    b. Item Code Type field – The item code type of the impacted product.
    c. Item Code Value field – The item code value of the impacted product.
    d. Product GTIN field – The GTIN of the impacted product.
    e. Batch/Lot Number field – (Optional) The batch or lot number of the impacted product.
12. Select Save.

    The product complaint 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.

Product complaints workflow

The following workflow states are used to track the progress of a product complaint:

Base State	Workflow State	Description
Draft	Draft	The product complaint has been created and is in its initial state. It remains editable by the user who created it.
To Do	To Do	The product complaint has been received and is awaiting assignment or initial review.
In Progress	Under Investigation	The product complaint has been assigned to the responsible team, such as CMO or QA, for detailed investigation and assessment.
In Progress	Resolved	The investigation has been completed and a resolution has been proposed.
Done	Done	The product complaint has been fully addressed and formally closed.

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Monitor product complaint

A high level understanding of the state of all product complaints 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 Product Complaints Dashboard from the left menu.
   View the widgets in the dashboard, which display pre-defined queries to demonstrate the state of all product complaints at a high level.

Metric	Description
Status	Product complaints classified by status (Draft, To Do, In Progress).
Product	Product complaints classified by products to analyze which product received the most and the least complaints.
Clarification Rate by Complaint Type	Product complaints classified by the clarification rate for each complaint type.
Assignee	Product complaints classified by the users who are assigned the complaints.
Type	Product complaints classified by complaint type (Packaging, Labeling, Efficacy)
Due Date	Product complaints classified by due date (nearing due date or past due).
Log Source	Product complaints classified by the origin of the complaint (e.g., customer, partner, internal).
Due Date Monitoring	
Product Complaints Overdue	Product complaints past Due Date by currentState. Escalates compliance and execution risks.
Product Complaints Due in Next 24 Hours	Product complaints due within 24 hours by currentState. Highlights items requiring immediate executive attention.
Product Complaints Due in Next 7 Days	Product complaints due within 7 days by currentState. Supports short-term workload planning.

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Metric	Description
Product Complaints Due in Future	Product complaints 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 Product Complaints Dashboard from the left menu.

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

Metric	Description
Workflow Step	Product complaints classified by the number of complaints in each workflow state for different Partner sites.
Product	Product complaints classified by the product for different Partner sites.
Overdue Complaints	Product complaints classified by due date (due or past due) for different Partner sites.
Due Date	Product complaints classified by due date (nearing due date or past due).
Due Date Monitoring	
Product Complaints Overdue	Product complaints past Due Date by currentState. Escalates compliance and execution risks.
Product Complaints Due in Next 24 Hours	Product complaints due within 24 hours by currentState. Highlights items requiring immediate executive attention.
Product Complaints Due in Next 7 Days	Product complaints due within 7 days by currentState. Supports short-term workload planning.
Product Complaints Due in Future	Product complaints due beyond 7 days by currentState. Supports capacity forecasting.

Search product complaint

1. Select the Main Menu icon.
2. Select My Networks.
3. Select a [POET Network] from the Select your Network drop-down in the

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header.

4. Select a Partner or location from the Select your Partner or Location drop-down in the header.
5. Select Go.
6. Select Product Complaint 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. Status field – The status of the product complaint.
    b. Assigned To field – The user who is assigned the complaint.
    c. Created By field – The user who created the product complaint.
    d. Product Name field – The name of the affected product.
    e. Batch/Lot Number drop-down – The batch or lot affected.
    f. Severity drop-down – The severity of the product complaint.
    g. Complaint Type field – The type of complaint.
    h. Complainant Type field – The person who filed the complaint.
    i. Created Date Range field – The date when the complaint was created.
    j. Last Modified Date field – The date when the complaint was last modified.

9. Select Apply.
   All product complaints matching the filter criteria are displayed.

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