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CAPA Exchanges

In regulated pharmaceutical and life sciences supply chains, CAPA (Corrective and Preventive Action) exchanges enable organizations and their partners to collaboratively investigate quality issues, implement corrective actions, and prevent recurrence across the network.

What is a CAPA Exchange

A CAPA exchange is a structured process used to investigate issues, identify root causes, define corrective and preventive actions, and verify their effectiveness. CAPA exchanges ensure regulatory compliance, operational transparency, and cross-partner accountability. The CAPA exchange lifecycle typically includes the following steps:

1. **Issue Detection:** A quality event such as a deviation, complaint, audit finding, or incident triggers a CAPA record.
2. **Assignment:** A CAPA owner is assigned to coordinate investigation and resolution activities.
3. **Root Cause Investigation:** Teams collaborate to determine the underlying cause of the issue.
4. **Corrective Actions:** Immediate measures are defined to correct the issue.
5. **Preventive Actions:** Long-term improvements are implemented to prevent recurrence.

6. **Effectiveness Verification:** The implemented actions are evaluated to ensure the issue is resolved.
7. **Closure:** The CAPA exchange is formally closed once effectiveness is confirmed and documentation is complete.

Types of CAPA Exchanges


- **Deviation CAPAs:** Triggered by manufacturing or operational deviations.
- **Complaint CAPAs:** Initiated due to product quality complaints.
- **Audit CAPAs:** Created from audit findings requiring remediation.
- **Excursion CAPAs:** Initiated when environmental or operational excursions occur.
- **Incident CAPAs:** Initiated from operational or supply chain incidents.

How to configure the CAPA Exchanges marketplace solution

Before using the CAPA Exchanges 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 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 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.

Add a CAPA Exchange

Add a CAPA Exchange

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 CAPA Exchanges from the left menu.
7. Select New.
8. In the General section fill in the following fields:
 - a. Title field - Title describing the CAPA exchange.
 - b. Description field - Description of the issue, including context and supporting details.
9. Select Save.

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

Modify a CAPA Exchange

Edit a CAPA Exchange

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 CAPA Exchanges from the left menu.
7. Select the Display Identifier of the CAPA exchange to edit.
8. Select Edit.
9. In the General section update the following fields:
 - a. Display Identifier field - System-generated CAPA identifier.
 - b. Title field - CAPA title summarizing the issue.
 - c. Due Date field - Target completion date for the CAPA.
 - d. Description field - Description of the CAPA issue.
 - e. CAPA Category field - Manufacturing, Logistics, Transportation,

Commerce, or Other.

f. CAPA Reason field – Deviation, Complaint, Audit, Excursion, or Incident.

g. Business Priority field – Critical, High, Medium, or Low.

10. In the Participants section update the following fields:

a. Initiator Company field – Company that initiated the CAPA.

b. Assignee Company field – Responsible partner company.

c. CAPA Owner field – Person accountable for CAPA execution.

11. In the Impact Assessment section update the following fields:

a. Risk Level field – Critical, High, Medium, or Low.

b. Regulatory Impact field – Indicates compliance or regulatory reporting impact.

c. Customer Impact field – None, Potential, or Confirmed.

d. Impact Assessor field – Responsible evaluator.

12. In the Root Cause Analysis section update the following fields:

a. Root Cause Summary field – Final root cause description.

b. Root Cause Method field – RCA methodology used.

c. Is Recurring field – Indicates if issue is recurring.

d. Root Cause Analysis Documents field – Supporting RCA documentation.

e. Lead Investigator field – Person responsible for investigation.

13. In the Corrective Actions section update the following fields:

a. Action Plan field – Immediate corrective action.

b. Action Owner field – Responsible person.

c. Action Due Date field – Target completion date.

d. Supporting Documents field – Corrective action evidence.

e. Criteria for Acceptance field – Acceptance criteria for corrective action.

14. In the Preventive Actions section update the following fields:

a. Action Plan field – Preventive measure.

b. Action Owner field – Responsible person.

c. Action Due Date field – Preventive action deadline.

d. Supporting Documents field – Preventive documentation.

- e. Criteria for Acceptance field - Acceptance criteria.
15. In the Effectiveness Check section update the following fields:
- a. Effectiveness Criteria field - Definition of success.
 - b. Effectiveness Result field - Effective, Ineffective, or Partially Effective.
 - c. Date Verified field - Verification date.
 - d. Effectiveness Check Document field - Effectiveness verification report.
 - e. Evaluation Specialist field - Responsible evaluator.
16. In the Closure Summary section update the following fields:
- a. Closure Status field - Closed-Effective, Closed-Ineffective, or Withdrawn.
 - b. Closure Notes field - Summary and justification for closure.
 - c. Date Closed field - Formal closure date.
 - d. Closed By field - Responsible person closing the CAPA.
17. In the Comments and Attachments section update the following fields:
- a. Comment Author field - User who entered the comment.
 - b. Comment Text field - Comment content.
 - c. Attachments field - Supporting CAPA documentation.
18. The Followers section displays users following the CAPA exchange.

CAPA Exchanges workflow

The following workflow states are used to track the progress of a CAPA exchange:

| Base State | Workflow State | Description |
|------------|----------------|--|
| Draft | Draft | The CAPA exchange is being created and initial issue details are captured. The CAPA has not yet been formally submitted for review or investigation. |

| Base State | Workflow State | Description |
|-------------|---------------------------|--|
| To Do | To Do | The CAPA exchange has been formally logged and assigned to a responsible owner. Initial impact assessment and investigation planning may begin. |
| In Progress | Under Investigation | Root cause analysis is actively being conducted. Internal teams and external partners collaborate to identify the underlying cause of the issue. |
| In Progress | Under Implementation | Corrective and preventive actions are being executed. Assigned owners implement action plans and upload supporting evidence. |
| In Progress | Under Effectiveness Check | The effectiveness of the implemented actions is being evaluated to confirm that the issue has been resolved and will not recur. |


| Base State | Workflow State | Description |
|------------|----------------|--|
| Done | Closed | The CAPA exchange is formally completed after successful verification of effectiveness and completion of all required documentation. |

The workflow ensures visibility, accountability, and traceability of CAPA activities across the supply chain network.

Monitor CAPA Exchanges

A high level understanding of the state of all CAPA exchanges 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 CAPA Exchanges Dashboard from the left menu.

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

| Metric | Description |
|---------------------------------|---|
| Current Trends | |
| CAPA Exchanges by Status - Open | Total number of CAPA Exchanges categorized by currentState (Draft, To Do, In Progress). Provides real-time visibility into CAPA lifecycle distribution and bottlenecks. |

| Metric | Description |
|---|--|
| CAPA Exchanges by Business Priority | Total number of CAPA Exchanges by priority by currentState (Draft, To Do, In Progress). Enables CAPA tracking by business priority. |
| Open CAPA Exchanges by Risk Level | Open CAPA Exchanges categorized by Severity (Critical, High, Medium, Low) by currentState. Enables risk-based prioritization. |
| CAPA Exchanges by CAPA Reason | Distribution by Trigger Source (Deviation, Complaint, Audit, Excursion, Incident) by currentState. Identifies systemic issue origins. |
| Due Date Monitoring | |
| CAPA Exchanges Overdue | CAPA Exchanges past Due Date by currentState. Escalates compliance and execution risks. |
| CAPA Exchanges Due in Next 24 Hours | CAPA Exchanges due within 24 hours by currentState. Highlights items requiring immediate executive attention. |
| CAPA Exchanges Due in Next 7 Days | CAPA Exchanges due within 7 days by currentState. Supports short-term workload planning. |
| CAPA Exchanges Due in Future | CAPA Exchanges due beyond 7 days by currentState. Supports capacity forecasting. |
| Network Performance | |
| CAPA Exchanges by Partner | CAPA Exchanges grouped by Assignee Company and stacked by currentState. Identifies partner risk exposure and recurring issues. |
| CAPA Exchanges by Regulatory Impact | CAPA Exchanges categorized by Regulatory Impact (Yes/No) by currentState. Tracks compliance exposure. |
| Effectiveness Failure Rate | Percentage of CAPA Exchanges marked Not Effective. Identifies weak root cause analysis or preventive controls. |
| Organizational Performance | |
| CAPA Exchanges by CAPA Owner | Distribution of CAPA Exchanges by owner. Enables workload balancing. |
| CAPA Exchanges by Closure Status | Closed CAPA Exchanges categorized by Closure Status (Closed-Effective, Closed-Ineffective, Withdrawn). Measures CAPA quality and governance. |
| Average Time to Close CAPA Exchanges by Risk Level | Average duration from creation to Done state classified by risk level. |
| Average Time to Close CAPA Exchanges by Customer Impact | Average duration from creation to Done state classified by customer impact. |

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 CAPA Exchanges Dashboard from the left menu.

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

| Metric | Description |
|---|---|
| Current Trends | |
| CAPA Exchanges by Status - Open | CAPA Exchanges categorized by currentState (Draft, To Do, In Progress). Provides visibility into active CAPA Exchanges at the partner site. |
| CAPA Exchanges by Business Priority | Total number of CAPA Exchanges by priority by currentState (Draft, To Do, In Progress). Enables CAPA tracking by business priority. |
| CAPA Exchanges by Risk Level | Open CAPA Exchanges categorized by Severity. Identifies critical compliance risks. |
| CAPA Exchanges by CAPA Reason | Distribution by Trigger Source by currentState. Identifies recurring systemic issues. |
| Due Date Monitoring | |
| CAPA Exchanges Overdue | CAPA Exchanges past Due Date by currentState. Escalates partner compliance delays. |
| CAPA Exchanges Due in Next 24 Hours | CAPA Exchanges due within 24 hours by currentState. Highlights urgent action items. |
| CAPA Exchanges Due in Next 7 Days | CAPA Exchanges due within 7 days by currentState. Supports short-term partner workload planning. |
| CAPA Exchanges Due in Future | CAPA Exchanges due beyond 7 days by currentState. Provides planning visibility. |
| Network Performance | |
| CAPA Exchanges by Customer Impact | CAPA Exchanges categorized by Customer Impact. Tracks downstream service and product impact. |
| CAPA Exchanges by Regulatory Impact | CAPA Exchanges categorized by Regulatory Impact. Tracks compliance exposure at the partner site. |
| Organizational Performance | |
| Average Time to Close CAPA Exchanges by Risk Level | Average closure duration for partner-owned CAPA Exchanges classified by risk level. |
| Average Time to Close CAPA Exchanges by Customer Impact | Average closure duration for partner-owned CAPA Exchanges classified by customer impact. |
| CAPA Exchanges by Closure Status (My Site) | Closed CAPA Exchanges categorized by Closure Status for the partner site. Reflects CAPA quality and completion outcomes. |

Search CAPA Exchanges

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 CAPA Exchanges 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 – Unique identifier of the CAPA exchange.
 - b. Title field – Title of the CAPA exchange.
 - c. State field – Workflow state of the CAPA exchange such as Draft, To Do, In Progress, or Done.
 - d. Creation Time field – The date and time when the CAPA exchange was created.
 - e. Initiator Company field – The business name and identifier of the company that initiated the CAPA exchange.
 - f. Assignee Company field – The business name and identifier of the company assigned to the CAPA exchange.
 - g. CAPA Owner field – The user responsible for managing the CAPA exchange.
 - h. Due Date field – The due date by which the CAPA exchange must be completed.
 - i. CAPA Category field – Category classification of the CAPA exchange.
 - j. Trigger Source field – Event that triggered the CAPA exchange such as deviation, complaint, audit, or incident.
 - k. Risk Level field – Indicates the risk level associated with the CAPA

exchange.

l. Regulatory Impact field - Indicates whether the CAPA exchange has regulatory impact.

m. Last Modified field - Displays the time period when the CAPA exchange was last updated.

9. Select Apply.

All CAPA exchanges matching the filter criteria are displayed.

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