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Change Request

In the pharmaceutical supply chain, a change request is a formal proposal to modify an existing process, system, material, document, or equipment.

What is a change request

A change request ensures that any alterations to an existing process, system, material, document, or equipment are systematically evaluated, approved, and implemented without compromising product quality, safety, or regulatory compliance. The change control process in the pharmaceutical industry typically involves the following steps:

1. **Initiation:** A change request is formally documented, detailing the proposed change and its rationale.
2. **Impact Assessment:** An evaluation is conducted to assess the potential effects of the change on product quality, safety, and compliance.
3. **Approval:** The change request is reviewed and approved by a cross-functional team, often including quality assurance, regulatory affairs, and operations.
4. **Implementation:** Once approved, the change is implemented according to a predefined plan, ensuring minimal disruption to ongoing operations.
5. **Verification:** Post-implementation reviews are conducted to confirm that the change has achieved its intended outcomes without unintended

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consequences.

6. **Documentation:** All steps of the change control process are thoroughly documented for traceability and regulatory compliance.

Types of change requests

- **Process Changes:** Modifications in manufacturing procedures, such as altering mixing times or temperatures.
- **Material Changes:** Switching suppliers for active pharmaceutical ingredients (APIs) or excipients.
- **Equipment Changes:** Upgrading or replacing machinery used in production or packaging.
- **Documentation Changes:** Revising standard operating procedures (SOPs), batch records, or quality manuals.
- **Facility Changes:** Renovations or expansions that might affect production environments.
- **Regulatory Changes:** Implementing new guidelines issued by regulatory bodies like the FDA or EMA.

How to configure the change request marketplace solution

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

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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

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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.

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

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Add a change request

Add a change request

By default, a change request 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 change request. To include additional fields, edit the change request to view all available fields and update the required 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 Change Request 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 change request.
    b. Description field – The description of the change request.
9. Select Save.
   The change request is created in the Draft state.
10. To move the change request to To Do state, select Move to.

Modify a change request

Edit a change request

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.

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4. Select a Partner or location from the Select your Partner or Location drop-down in the header.
5. Select Go.
6. Select Change Requests from the left menu.
7. Select the Display Identifier of the change request to edit.
8. Select Edit.
   In addition to the fields updated when creating the change request, 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 change request.
   b. Title field – The title of the change request.
   c. Due Date field – The date when the change request is due.
   d. Description field – Detailed description of the change request.
   e. Change Type field – Defines the type of change requested, such as Supplier, Design, Facility, Process, etc.
   f. Priority field – The level of priority for the change request. Select from Low, Medium, High, and Critical.
   g. List ID field – Display Identifier of the Parent List to which this Change Request is added as Child.
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 change request.
    b. Identifier Type field – The identifier type of the initator company, such as GLN or SGLN.
    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

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to take action on the change request.

b. Identifier Type field – The identifier type of the assignee company, such as GLN or SGLN.
c. Identifier Value field – The value of the identifier.

12. You can specify the user who is assigned the change request 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 change request.
    b. Name field – The name of the user who is required to take action on the change request.
13. Add details of the users responsible to address the change request in the Responsible User section.
    a. Name field – The name of the user responsible for the change request.
    b. Role field – The role of the user responsible for the change request.
    c. Department field – The department of the user responsible for the change request.
    d. Contact Information field – The contact information of the user responsible for the change request.
14. Add details about the area of impact for the change request in Impact Assessment section.
    a. Impact Area field – Indicates the nature of the impact.
    b. Overall Impact Summary field – A summary of the potential impact across domains.
    c. Risk Level field – The level of severity of the change request.
    d. Risk Notes field – Description of potential risks.
    e. Locations Affected field – The list of impacted locations.
    f. Is Approval Required for This Impact? field – Indicates whether the specific impact area (e.g., regulatory, manufacturing, quality) requires

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internal or external approval before the change can be implemented.

g. If you selected Regulatory Impact in the Impact Assessment section, add the required information in the Regulatory Impact section.
    i. Product Name field – The name of the product for which regulatory approval is affected.
    ii. Item Code Type field – Unique identifier type assigned to the product.
    iii. Item Code Value field – Unique identifier value assigned to the product.
    iv. Dosage Form field – The physical form in which the product is administered.
    v. Strength field – Dosage strength of the product.
    vi. Countries Affected field – Countries where regulatory filings or notifications are required.
    vii. Regulatory Bodies Involved field – Agencies responsible for regulatory oversight.
    viii. Re-approval Required field – Indicates if a new or revised approval is needed
    ix. Submission Timeline field – Planned date of regulatory submission.
    x. Documents to Update field – Regulatory documents or dossiers that need revision.
h. If you selected Quality Impact in the Impact Assessment section, add the required information in the Quality Impact section.
    i. Product Name field – The name of the product for which quality approval is affected.
    ii. Item Code Type field – Unique identifier type assigned to the product.
    iii. Item Code Value field – Unique identifier value assigned to the product.

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iv. Lot Numbers Affected field – The specific Lot IDs impacted by the change.
v. Quality Systems Affected field – The quality management process area that is affected.
vi. Additional Testing Needed field – Indicates whether new or extended testing is required.
vii. SOPs/Work Instructions to Update field – Quality or lab procedures that need updating.
viii. Validation Required field – Whether validation of the quality process is necessary.

i. If you selected Supply Chain/Logistics Impact in the Impact Assessment section, add the required information in the Supply Chain/Logistics Impact section.

i. Product Name field – The name of the product for which logistics or supply chain approval is affected.
ii. Item Code Type field – Unique identifier type assigned to the product.
iii. Item Code Value field – Unique identifier value assigned to the product.
iv. Inventory Impact field – Description or quantity of stock that may be affected.
v. Delay in Delivery field – The number of days by which the delivery could be delayed.
vi. Alternate Routes Available field – Alternative logistics paths or vendors available.

j. If you selected Financial Impact in the Impact Assessment section, add the required information in the Financial Impact section.

i. Estimated Cost Change field – The forecasted increase or decrease in cost.

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ii. Penalties or Compliance Risks field – The description of any legal, contract, or penalty risks.

k. If you selected Manufacturing/Process Impact in the Impact Assessment section, add the required information in the Manufacturing/Process Impact section.

   i. Product Name field – The name of the product for which manufacturing is affected.
   ii. Item Code Type field – Unique identifier type assigned to the product.
   iii. Item Code Value field – Unique identifier value assigned to the product.
   iv. Equipment or Process Affected field – Machines, lines, or procedures affected by the change.
   v. Expected Downtime field – The estimated downtime due to the change.
   vi. Manufacturing Validation Required field – Indicates if the change must be validated at the plant.
   vii. SOPs to Update field – Manufacturing procedures to be modified.

l. If you selected Product/Material Impact in the Impact Assessment section, add the required information in the Product/Material Impact section.

   i. Product Name field – The name of the product for which product or raw material is affected.
   ii. Item Code Type field – Unique identifier type assigned to the product.
   iii. Item Code Value field – Unique identifier value assigned to the product.
   iv. Dosage Form field – The physical form in which the product is

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administered.

v. Strength field – Dosage strength of the product.
vi. Pack Size field – The size or quantity per sales unit.
vii. Label Type Affected field – The packaging label level impacted.
viii. Packaging Material Affected field – The specific packaging materials affected.
ix. Material Type field – The nature of the affected material or component.
x. Material Name field – The name of the affected material or component.
xi. Material Code field – The internal or vendor-specific material code.
xii. Shelf Life Impacted field – Indicates the shelf life or expiry of the product is affected.
xiii. Substitute/Alternate Approved field – Indicates the new material has regulatory approval as an alternate.
xiv. Product Formulation Changed field – Indicates if the recipe or formulation is impacted.
xv. Batch Reprocessing Required field – Indicates if the existing batches need to be reprocessed.
xvi. Affected Batches field – Identifies the affected batches that use the impacted material.
xvii. Product Registrations Affected field – Product filings impacted by the material change.

m. If you selected IT/System Impact in the Impact Assessment section, add the required information in the IT/System Impact section.

i. Systems Impacted field – The enterprise systems affected by the change.
ii. Integration Impact field – Details of API, interface, or data flow changes.

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iii. Data Model Change Required field – Indicates if a database structure update is needed.
iv. Deployment Date field – The scheduled date for system change rollout.
v. Validation/Testing Required field – Indicates if system testing or validation is needed.

n. If you selected Partner/Third-Party Impact in the Impact Assessment section, add the required information in the Partner/Third-Party Impact section.

i. Partner / Vendor Affected field – The external parties impacted by the change.
ii. Contract Changes Needed field – Indicates if any contracts require renegotiation or addenda.
iii. Onboarding/Training Required field – Indicates if the partner staff needs to be trained.
iv. SLAs Affected field – Service level agreements that might be impacted.

o. If you selected Customer Impact in the Impact Assessment section, add the required information in the Customer Impact section.

i. Product Name field – The name of the product for which the customer is directly affected.
ii. Item Code Type field – Unique identifier type assigned to the product.
iii. Item Code Value field – Unique identifier value assigned to the product.
iv. Marketed Brand Name field – The brand label used in customer communications.
v. Customer Segments Affected field – Customer groups affected by

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the change.

vi. Impact on Availability or Service field – The description of any delay or shortage.

15. Add details about the steps required to implement the change in the Implementation Plan section.

    a. Plan Description field – The detailed description of the implementation steps.
    b. Start Date field – The planned start date for implementation.
    c. End Date field – The planned end date for implementation.
    d. Verification Required field – Indicates if post-implementation verification is needed.
    e. Verification Status field – The status of the verification process. This field is applicable only if the Verification Required field is set to Yes.
    f. Verification Date field – The date when verification was completed. This field is applicable only if the Verification Required field is set to Yes.

16. Add details of how the change request was processed and concluded in the Closure Summary section.

    a. Closure Status field – Indicates how the change request was concluded.
    b. Closure Notes field – A concise explanation of the final decision or summary of actions taken.
    c. Actual Implementation Date field – The date when the change was executed.
    d. Verification Date field – The date when the change was verified.
    e. Verified By User field – The name of the user who verified the change.
    f. Closure Confirmed By field – The name of the user who verified that all closure conditions were completed.

17. In the Comments and Attachments section, add information in the following fields:

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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.

18. The Followers section displays names of the users who are following the change request.
19. Select Save.
    The change request is updated.

Owners can edit the Assignee Details section while the document 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.

Change Requests workflow

The following workflow states are used to track the progress of a change request:

Base State	Workflow State	Description
Draft	Draft	The change request is being created and refined, but it has not yet been submitted for review.
To Do	Submitted	The change request has been submitted and is awaiting triage, assignment, or initial review.
In Progress	Under Review	The change request is actively being evaluated by the appropriate stakeholders.
In Progress	Ready for Approval	The review is complete and the change request is awaiting a final approval decision.
In Progress	Under Implementation	The approved change is being implemented and carried through to completion.
Done	Closed	The change request has been completed and closed with a final outcome such as implemented, rejected, or cancelled.

Monitor change requests

A high level understanding of the state of all change requests that you have access to.

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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 Change Requests Dashboard from the left menu.
   View the widgets in the dashboard, which display pre-defined queries to demonstrate the state of all change requests at a high level.

Metric	Description
Current Trends	
Status - Open	Change requests classified according to workflow status (Draft, To Do, In Progress).
Open vs Resolved	Change requests that were opened and closed within a selected timeline.
Business Priority	Change requests classified according to business priority combined with workflow status.
Change Type	Change requests classified according to the change type combined with workflow status.
Due Date Monitoring	
Change Requests Overdue	Change requests past Due Date by currentState. Escalates compliance and execution risks.
Change Requests Due in Next 24 Hours	Change requests due within 24 hours by currentState. Highlights items requiring immediate executive attention.
Change Requests Due in Next 7 Days	Change requests due within 7 days by currentState. Supports short-term workload planning.
Change Requests Due in Future	Change requests due beyond 7 days by currentState. Supports capacity forecasting.
Network Performance	
Partner	Change requests classified according to the Partner Company combined with workflow status.
Organizational Performance	
Impact Area	Change requests classified according to the impact area (e.g., Regulatory, Supply Chain, Financial) combined with workflow status.

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Metric	Description
Outcome	Change requests classified according to the outcome (e.g., Implemented, Rejected, No Change Required, Cancelled) combined with workflow status.
Resolution Time	Change requests classified according to the resolution time combined with workflow status. Resolution time is the time duration between the created date and the closed date of the change request.

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 Change Requests Dashboard from the left menu.

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

Metric	Description
Current Trends	
Business Priority	Change requests classified according to business priority combined with workflow status.
Status - Open	Change requests classified according to workflow status (Draft, To Do, In Progress).
Open vs Resolved	Change requests that were opened and closed within a selected timeline.
Change Type	Change requests classified according to the change type combined with workflow status.
Due Date Monitoring	
Change Requests Overdue	Change requests past Due Date by currentState. Escalates compliance and execution risks.
Change Requests Due in Next 24 Hours	Change requests due within 24 hours by currentState. Highlights items requiring immediate executive attention.
Change Requests Due in Next 7 Days	Change requests due within 7 days by currentState. Supports short-term workload planning.
Change Requests Due in Future	Change requests due beyond 7 days by currentState. Supports capacity forecasting.
Organizational Performance	

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Metric	Description
Outcome	Change requests classified according to the outcome (e.g., Implemented, Rejected, No Change Required, Cancelled) combined with workflow status.
Impact Area	Change requests classified according to the impact area (e.g., Regulatory, Supply Chain, Financial) combined with workflow status.

Search change requests

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 Change Requests 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 change request.
    b. Title field – The title of the change request.
    c. State field – The state in which the change request is, such as To Do, In Progress, or Done.
    d. Creation Time field – The time when the change request was created.
    e. Initiator Company field – The business name and identifier of the company which initiated the change request.
    f. Assignee Company field – The business name and identifier of the company which is assigned the change request.
    g. Due Date field – The due date of the change request.
    h. Change Type field – The type of change requested.
    i. Business Priority field – The business priority of the change request.
    j. Last Modified field – The period of time in which the change request was

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last updated.

9. Select Apply.

   All change requests matching the filter criteria are displayed.

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