TRACELINK UNIVERSITY

Document Review

A Document Review allows internal and external stakeholders to collaborate to evaluate and approve documents critical to regulated pharmaceutical processes.

What is document review

Document Review is a formal business process in which internal and external stakeholders collaborate to evaluate and approve documents critical to regulated pharmaceutical processes. These documents may include SOPs, quality agreements, regulatory submissions, validation protocols, and more.

Advantages of document reviews

- **Compliance:** Ensures documents comply with regulatory standards (FDA, EMA, ICH, etc.).
- **Accuracy:** Prevents errors in manufacturing, labeling, or quality processes..
- **Alignment:** Coordinates cross-functional and cross-organizational input.
- **Auditability:** Maintains a traceable history of reviews, decisions, and revisions.
- **Accountability:** Assigns clear responsibility for each review and approval step.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

How to configure the document review marketplace solution

Before using the document 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.
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.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

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.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

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 document review

Add a document review

By default, a document review 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 document review. To include additional fields, edit the document review 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 Document Review from the left menu.
6. Select New.
7. In the General section fill in the following fields:
   a. Document Title field – The title of the new document review.
   b. Description field – The description of the document review.
8. Select Save.

   The document review is created in the Draft state.
9. To move the work item to To Do state, select Move to.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Modify a document review

Edit a document review

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 Document Review from the left menu.
6. Select the Display Identifier of the document review to edit.
7. Select Edit.
   In addition to the fields updated when creating the document review, additional fields will be displayed which can be updated if required.
8. In the General section update the following fields:

   a. Display Identifier field - The Display Identifier of the Document Review as in their internal system or ERP.

   b. Document Title field – The title of the document under review.
   c. Description field – The description of the document under review.
   d. Document Type field – Defines the specific nature of the document.
   e. Document Version field – Indicates the version of the document under review.
   f. Document ID field – A unique identifier to support internal tracking and audit.
   g. Business Priority field – The level of priority for the document review. Select from Low, Medium, High, and Critical.
   h. Created By field – The person who initiated the document review.
   i. Created Date field – The date when the review was initiated.
9. If you require to collaborate with an external partner, enter the following

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Initiator Company details under the Participants section:

a. Business Name field – The name of the company that created the document review.
b. Identifier Type field – The identifier type of the company, such as GLN, SGLN, etc.
c. Identifier Value field – The identifier value of the company.

10. 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 document review.
    b. Identifier Type field – The identifier type of the company, such as GLN, SGLN, etc.
    c. Identifier Value field – The identifier value of the company.
11. 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 document review.
    b. Name field – The name of the user who is required to take action on the document review.
12. If you need to add review details, update the following fields under the Review Context section:
    a. Review Type field - Defines the type of review, such as Periodic Review, Regulatory Review, Deviation-Triggered Review. etc.
    b. Review Cycle Due Date field - The deadline for review completion.
    c. Department field - The department responsible for the document review.
13. If you need to add information about the review participants, update the following fields under the Reviewer List section:
    a. Reviewer Email field – Email address of the person assigned to review the document.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

   b. Reviewer Name field – Name of the person assigned to review the document.
   c. Reviewer Role field – Defines access and permissions in the review cycle.
   d. Review Due Date field – Deadline for individual reviewers.
   e. Review Status field – Status of each review assignment. Default to “Not Started”.
   f. Review Decision field – Captures final verdict by each reviewer.
   g. Comments field – Feedback or observations from reviewer.
14. If you need to attach files, update the Attachments section:
   a. Primary Document field – The main document under review.
   b. Supporting Documents field – Any additional documents to support the primary document.
15. In the Impacted Products section, add product information in the following fields:
   a. Product Name field – The name of the impacted product.
   b. Impact Type field – Classifies the nature of impact on each product. For e.g. Specification Change, Labeling Change, Regulatory Filing Impact, etc.
   c. Impact Summary field – Description of how the document affects the product.
   d. Effective Date field – The date when the changes become effective for the impacted products.
16. In the Impacted Locations section, add location information in the following fields:
   a. Impacted Site field – Sites, plants, or facilities impacted by the document.
   b. Impact Type field – The type of operational impact on each site.
   c. Impact Summary field – The type of operational impact on each site.
   d. Effective Date field – The date when the changes become effective for the impacted products.
17. In the Review Closure section, add information about review resolution in the

© TraceLink Inc. 2009 - 2025 All Rights Reserved

following fields:

a. Resolution field – The overall verdict for the document after all reviews are complete.
b. Closure Comments field – The summary or justification provided during final closure.
c. Closed By field – The user who completed the review.
d. Closed Date field – The date when the document review was closed.

18. In the Comments and Attachments section, add information in the following fields:
    a. Commented By 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 document review.
20. Select Save.
    The document review 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.

Document reviews workflow

The following workflow states are used to track the progress of a document review:

Base State	Workflow State	Description
Draft	Draft	The document review task is being created or prepared and has not yet been submitted for review.
To Do	Ready for Review	The document has been submitted by the author and is ready for reviewers to begin the review process.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Base State	Workflow State	Description
In Progress	Under Review	The document is actively being reviewed, and reviewers are providing feedback, comments, or approvals.
Done	Completed	The document review has been finalized, and the document has been approved, closed, or recorded as reviewed.

Monitor document reviews

A high level understanding of the state of all document reviews 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 Document Reviews Dashboard from the left menu.
   View the widgets in the dashboard, which display pre-defined queries to demonstrate the state of all document reviews at a high level.

Metric	Description
Status - Open	Document reviews classified by status (Draft, Ready for Review, Under Review).
Status - Open vs Closed	Document reviews classified by reviews in Open state vs reviews in Closed state.
By Week	Document reviews initiated in the past 4 weeks.
Business Priority	Document reviews classified by priority (Critical, High, Medium, Low).
Review Volume	Document reviews classified by review volume for each document type.
Resolution Summary	Document reviews classified by resolution summary (Approved, Approved with Rework Required, Rejected, Withdrawn, Review Not Required, Invalidated).

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Metric	Description
Reviewer Load Distribution	Document reviews classified by the number of documents assigned to every reviewer.
Due Date Monitoring	
Overdue Document reviews	Document reviews past Due Date by currentState. Escalates compliance and execution risks.
Due in Next 24 Hours	Document reviews due within 24 hours by currentState. Highlights items requiring immediate executive attention.
Due in Next 7 Days	Document reviews due within 7 days by currentState. Supports short-term workload planning.
Due in Future	Document reviews 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 Document Reviews Dashboard from the left menu.
   View the widgets in the dashboard, which display pre-defined queries to demonstrate the state of all document reviews at a high level.

Metric	Description
Status - Open	Document reviews classified by status (Draft, Ready for Review, Under Review).
Business Priority	Document reviews classified by priority (Critical, High, Medium, Low).
Average Response Time(Hours/Days)	Document reviews classified by the average time taken to respond by the Partner.
Review Volume	Document reviews classified by review volume for each document type.
Average Turnaround Time(Hours/Days)	Document reviews classified by the average turnaround time taken by the Partner.
Due Date Monitoring	
Overdue Document reviews	Document reviews past Due Date by currentState. Escalates compliance and execution risks.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Metric	Description
Due in Next 24 Hours	Document reviews due within 24 hours by currentState. Highlights items requiring immediate executive attention.
Due in Next 7 Days	Document reviews due within 7 days by currentState. Supports short-term workload planning.
Due in Future	Document reviews due beyond 7 days by currentState. Supports capacity forecasting.

Search document reviews

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 Document Reviews from the left menu.
6. Select Filter.
7. 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 document review.
    b. Document Title field – The title of the document.
    c. State field – The state in which the document review is, such as To Do, In Progress, or Done.
    d. Creation Time field – The time when the document review was created.
    e. Initiator Company field – The business name and identifier of the company which initiated the document review.
    f. Assignee Company field – The business name and identifier of the company which is assigned the document review.
    g. Due Date field – The due date of the document review.
    h. Document Type field – The type of document under review.
    i. Business Priority field – The business priority of the document review.
    j. Last Modified field – The period of time in which the document review

© TraceLink Inc. 2009 - 2025 All Rights Reserved

was last updated.

8. Select Apply.

   All document reviews matching the filter criteria are displayed.

© TraceLink Inc. 2009 - 2025 All Rights Reserved