TRACELINK UNIVERSITY

Batch Record Review

A Batch Record Review checks a pharmaceutical batch's manufacturing and testing records to ensure Good Manufacturing Practices (GMP) and regulatory compliance.

What is batch record review

A batch record is a comprehensive log that captures the entire production journey of a batch, from raw materials and equipment used to process steps, personnel involved, test results, and any deviations.

Batch Record Review is a regulated quality assurance process where the manufacturing and testing records of a specific batch of a pharmaceutical product are reviewed to ensure compliance with GMP and regulatory standards (e.g., FDA, EMA) before the batch is released for distribution.

Advantages of batch record reviews

- **Product Quality:** Ensures that each batch meets required quality and safety specifications.
- **Regulatory Compliance:** Ensures checks required by global health authorities (e.g., FDA, EMA, WHO).
- **Traceability:** Provides a complete history of how the batch was manufactured and tested.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

- **Risk Mitigation:** Identifies deviations or non-conformances before the product reaches the market.
- **Audit Readiness:** Serves as a critical document during inspections or investigations.

How to use the batch record review 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.
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

© TraceLink Inc. 2009 - 2025 All Rights Reserved

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.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

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 batch record review

Add a batch record review

By default, a batch record 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 batch record review. To include additional fields, edit the batch record 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 Go.
6. Select Batch Record Review from the left menu.
7. Select New.
8. In the General section fill in the following fields:

© TraceLink Inc. 2009 - 2025 All Rights Reserved

a. Title field – The title of the new batch record review.
b. Description field – The description of the batch record under review.

9. Select Save.
   The batch record review is created in the Draft state.
10. To move the batch record review to To Do state, select Move to.

Modify a batch record review

Edit a batch record 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 Go.
6. Select Batch Record Review from the left menu.
7. Select the Display Identifier of the batch record review to edit.
8. Select Edit.
   In addition to the fields updated when creating the batch record review, additional fields will be displayed which can be updated if required.
9. In the General section update the following fields:
   a. Display Identifier field (auto-generated) - The Display Identifier of the Batch Record Review as in their internal system or ERP.
   b. Title field – The title of the new batch record review.
   c. Description field – The description of the batch record under review.
   d. Business Priority drop-down – The level of priority for the batch record review. Select from Low, Medium, High, and Critical.
   e. Due Date field – The target resolution date of the batch record review.
10. If you require to collaborate with an external partner, enter the details under the Participants section:

© TraceLink Inc. 2009 - 2025 All Rights Reserved

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

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 Number field – (Optional) The batch number of the impacted product.
    f. Lot Number field – The lot number of the impacted product.
    g. Batch Size field – The batch size of the impacted product.
    h. Manufacturing Date field – The manufacturing date of the product under review.
    i. Expiry Date field – The manufacturing date of the product under review.
    j. Manufacturing Site field – The manufacturing location of the product under review.
12. In the Batch Review Documentation section, add location information in the following fields:
    a. Document Name field – The document name and version of the batch record under review.
    b. Attachment field – The document file for the batch record review.
    c. Review Notes field – Notes for reviewers for the batch record.
    d. Last Modified field – The last modified date for the batch record review document.
13. In the Batch Review Status section, add information about review resolution in the following fields:

© TraceLink Inc. 2009 - 2025 All Rights Reserved

a. Review Status field – The outcome of the review for the batch record review document.
b. Approved On Date field – The date on which the batch record review is approved.

14. Select Save.

The batch record 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.

Batch Record Reviews workflow

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

Base State	Workflow State	Description
Draft	Draft	The batch record review is being created and updated, but it has not yet been submitted for processing.
To Do	To Do	The batch record review has been submitted and is waiting to be picked up for review.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Base State	Workflow State	Description
In Review	In Review	The batch record review is actively being examined and assessed by the appropriate stakeholders.
Completed	Completed	The review activities have been finished and the batch record review is ready for final closure.
Done	Done	The batch record review has been fully closed and no further action is required.

Monitor batch record reviews

A high level understanding of the state of all batch record 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.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

6. Select Batch Record Reviews Dashboard from the left menu.
   View the widgets in the dashboard, which display pre-defined queries to demonstrate the state of all batch record reviews at a high level.

Metric	Description
Status	Batch record reviews classified according to workflow status (Draft, To Do, In Review, Completed).
Priority	Batch record reviews classified according to business priority combined with workflow status.
Due Date	Batch record reviews classified according to upcoming or overdue due dates with the workflow status.
Location	Batch record reviews classified according to manufacturing sites and workflow status.
Assignee User	Batch record reviews classified according to each reviewer combined with workflow status.
Pending Clarifications	Batch record reviews classified according to the "Clarification Requested" state and “Clarification Provided” resolution.
Due Date Monitoring	
Batch Record Reviews Overdue	Batch record reviews past Due Date by currentState. Escalates compliance and execution risks.
Batch Record Reviews Due in Next 24 Hours	Batch record reviews due within 24 hours by currentState. Highlights items requiring immediate executive attention.
Batch Record Reviews Due in Next 7 Days	Batch record reviews due within 7 days by currentState. Supports short-term workload planning.
Batch Record Reviews Due in Future	Batch record 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 Batch Record Reviews Dashboard from the left menu.
   View the widgets in the dashboard, which display pre-defined queries to demonstrate the state of all batch record reviews at a high level.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

Metric	Description
Status	Batch record reviews classified according to workflow status (Draft, To Do, In Review, Completed).
Priority	Batch record reviews classified according to business priority combined with workflow status.
Due Date	Batch record reviews classified according to upcoming or overdue due dates with the workflow status.
Location	Batch record reviews classified according to manufacturing sites and workflow status.
Assignee User	Batch record reviews classified according to each reviewer combined with workflow status.
Pending Clarifications	Batch record reviews classified according to the "Clarification Requested" state and “Clarification Provided” resolution.
Due Date Monitoring	
Batch Record Reviews Overdue	Batch record reviews past Due Date by currentState. Escalates compliance and execution risks.
Batch Record Reviews Due in Next 24 Hours	Batch record reviews due within 24 hours by currentState. Highlights items requiring immediate executive attention.
Batch Record Reviews Due in Next 7 Days	Batch record reviews due within 7 days by currentState. Supports short-term workload planning.
Batch Record Reviews Due in Future	Batch record reviews due beyond 7 days by currentState. Supports capacity forecasting.

Search batch record 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 Go.
6. Select Batch Record Reviews 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. State field – The state in which the batch record review is, such as To Do, In Progress, or Done.

© TraceLink Inc. 2009 - 2025 All Rights Reserved

b. Display Identifier field – The display identifier of the batch record review.
c. Title field – The title of the batch record review document.
d. Initiator Company field – The business name and identifier of the company which initiated the batch record review.
e. Assignee Company field – The business name and identifier of the company which is assigned the batch record review.
f. Assignee Reviewer field – The name of the user who is assigned the batch record review.
g. Initiating Users field – The users who initiated the batch record review request.
h. Review Status field – The outcome of the review for the batch record review document.
i. Business Priority field – The business priority of the batch record review.
j. Due Date field – The due date of the batch record review.
k. Last Modified Date field – The period of time in which the batch record review was last updated.

9. Select Apply.

   All batch record reviews matching the filter criteria are displayed.

© TraceLink Inc. 2009 - 2025 All Rights Reserved