TRACELINK UNIVERSITY

Supplier License Review

In the pharmaceutical supply chain, a supplier license review is a structured process used to verify that suppliers maintain valid regulatory licenses, certifications, and approvals required for pharmaceutical manufacturing, distribution, or related regulated activities.

What is a supplier license review

A supplier license review ensures that supplier regulatory licenses and certifications remain valid and compliant with regulatory requirements. The supplier license review process typically involves the following steps:

1. **Initiation:** A supplier license review is initiated to verify the regulatory standing of a supplier.
2. **Documentation Collection:** Regulatory licenses and certifications are collected from the supplier.
3. **Verification:** Compliance teams validate the authenticity and validity of submitted licenses.
4. **Assessment:** The supplier's licenses are evaluated against applicable regulatory requirements.
5. **Clarification:** After assessing the supplier's licenses, the supplier is requested to provide clarification for any irregularities or discrepancies.
6. **Approval:** Compliance or regulatory teams approve the review outcome.

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Types of supplier license reviews

- **Manufacturing License Review:** Verification of supplier manufacturing authorization licenses.
- **Distribution License Review:** Validation of wholesale or distribution licenses.
- **Import and Export License Review:** Verification of regulatory permissions required for cross-border product movement.
- **Quality Certification Review:** Verification of quality certifications such as GMP or ISO.
- **Regulatory Registration Review:** Validation of regulatory registrations applicable to the supplier.

How to configure the supplier license review marketplace solution

Before using the supplier license review marketplace solution, Solution Designers must first configure the solution in Opus Solution Environment (OSE) by completing the following steps:

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.

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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:

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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 supplier license review

Add a supplier license 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-

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down in the header.

5. Select Go.
6. Select Supplier License Reviews from the left menu.
7. Select New.
8. In the General section fill in the following fields:
    a. Title field – The title of the supplier license review.
    b. Description field – The description of the supplier license review.
9. Select Save.

    The supplier license review is created in the Draft state.
10. To move the supplier license review to To Do state, select Move to.

Modify a supplier license review

Edit a supplier license 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 Supplier License Review from the left menu.
7. Select the Display Identifier of the review to edit.
8. Select Edit.
9. Update the following information in the General section:
    a. Display Identifier field – System-generated ID for the supplier license review.
    b. Title field – Supplier License Review title.
    c. Request Reason field – Why licenses are requested. Select from Onboarding, Renewal, Expansion, or Regular Audit.
    d. Due Date field – Target completion date for the review.

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e. Description field – Additional context or information.

10. Update the following information in the Participants section:
    a. Initiator Company field – Company requesting licenses.
    b. Assignee Company field – Supplier providing licenses.
    c. Compliance Owner field – Accountable owner for the review.
11. Update the following information in the Licenses & Certifications section:
    a. Certificate/License Type field – Regulatory-recognized license or certification being reviewed.
    b. Other Certificate / License Type field – Specify the license or certification type if Other is selected.
    c. Jurisdiction field – Issuing geography, such as country or state.
    d. Regulatory Authority field – Issuing authority.
    e. License/Certificate Number field – Supplier-provided identifier.
    f. Expiration Date field – Validity date for the license or certification.
    g. Validity field – Compliance status. Select from Valid, Invalid, or Under Renewal.
    h. Documents field – Upload one or more files as license proof.
    i. Notes field – Additional context.
    j. If clarification is required for the submitted license information, update the following fields in the Clarification Handling section:
        i. License/Certificate Number field – Supplier-provided identifier for the license row requiring clarification.
        ii. Clarification Reason field – Reason for requiring the clarification. Select from Missing, Invalid, Expired, Under Renewal, or Others.
        iii. Clarification Request field – Clarification request sent to the supplier.
        iv. Requested By field – Requester details.
        v. Supplier Response field – Supplier explanation.
        vi. Expected Resolution Date field – Target resolution date.
        vii. Response By field – Responder details.
12. Update the following information in the Compliance Review Summary section:

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a. Overall Compliance Assessment field – Overall compliance decision. Select from Compliant, Partially Compliant, or Non-Compliant.
b. Review Notes field – Compliance comments.
c. Review Date field – Review completion date.
d. Prior Audit Failure field – Indicates whether there was a prior audit failure.
e. Reviewer field – Reviewer details.

13. Update the following information in the Closure Summary section:
    a. Closure Status field – Final closure outcome. Select from Closed-Compliant, Closed-With Exceptions, Closed-With Conditions, Closed-Non-Compliant, or Closed-Re-review Required.
    b. Closure Notes field – Closure rationale.
    c. Date Closed field – Formal closure date.
    d. Closed By field – User who closed the supplier license review.
14. Add comments in the Comments and Attachments section.
    a. Comment Author field – User who entered the comment.
    b. Comment Text field – Comment content.
    c. Attachments field – Supporting CAPA documentation.
15. Review the Followers section to view the list of users following the Supplier License Review record.
16. Select Save.

Workflow

The workflow defines the lifecycle of a record from creation to completion. Each state represents a stage in the collaboration process between the Owner and Partner organizations.

Workflow State	Description
Draft	The record is created but not yet shared with external participants. Owners can update information before initiating collaboration.
To Do	The record has been shared with participants and is awaiting action from the assigned organization or user.

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Workflow State	Description
In Progress	The assigned participant is actively working on the task or reviewing the information provided.
Done	The workflow has been completed and the record is closed.

Monitor supplier license reviews

A high level understanding of the state of all supplier license 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 Supplier License Reviews.
7. Select Dashboards.

Metric	Description
Current Trends	
Supplier License Reviews by Status – Open	Total number of Supplier License Reviews records categorized by currentState (Draft, To Do, In Progress). Provides real-time visibility into license coordination lifecycle distribution and bottlenecks.
Supplier License Reviews by Business Priority	Total number of Supplier License Reviews records by priority by currentState (Draft, To Do, In Progress). Enables compliance tracking by business urgency.
Open Supplier License Reviews by License Status	Open Supplier License Reviews categorized by License Status (Valid, Invalid, Under Renewal) by currentState. Identifies compliance exposure and renewal risk.
Supplier License Reviews by License Type	Distribution by License Type (GMP, GDP, Wholesaler, Import, Export, Controlled Substance, etc.) by currentState. Identifies high-volume regulatory domains and exposure areas.
Due Date Monitoring	
Overdue Supplier License Reviews	Supplier License Reviews records past Due Date by currentState. Escalates compliance and license lapse risks.

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Metric	Description
Due in Next 24 Hours	Supplier License Reviews records due within 24 hours by currentState. Indicates reviews requiring immediate compliance attention.
Due in Next 7 Days	Supplier License Reviews records due within 7 days by currentState. Supports short-term workload and renewal planning.
Due in Future	Supplier License Reviews records due beyond 7 days by currentState. Supports compliance capacity forecasting.
Network Performance	
Supplier License Reviews by Partner	Supplier License Reviews grouped by Supplier Company stacked by currentState (Draft, To Do, In Progress). Identifies supplier-specific compliance risk and coordination workload.
Supplier License Reviews by Jurisdiction	Supplier License Reviews categorized by Jurisdiction by currentState. Tracks geographic regulatory exposure.
Clarification Rate	Percentage of Supplier License Reviews entering the Clarification Required sub-state. Identifies documentation gaps and supplier responsiveness issues.
Organizational Performance	
Supplier License Reviews by Compliance Owner	Distribution of Supplier License Reviews by Compliance Owner. Enables workload balancing and accountability.
Supplier License Reviews by Closure Outcome	Closed Supplier License Reviews categorized by Closure Status (Closed Compliant, Closed With Conditions, Closed Non Compliant). Measures supplier compliance quality.
Average Time to Close Supplier License Reviews	Average duration from creation to Done state. Measures license coordination efficiency.
On-Time Closure Rate	Percentage of Supplier License Reviews closed before Due Date. Tracks compliance SLA adherence.

View the dashboard (Partner)

Steps to access

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 Supplier License Reviews.
7. Select Dashboards.

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Metric	Description
Current Trends	
Supplier License Reviews by Status – Open	Supplier License Reviews categorized by currentState (Draft, To Do, In Progress). Provides visibility into active license coordination tasks.
Supplier License Reviews by Business Priority	Total number of Supplier License Reviews by priority by currentState. Enables prioritization of compliance-critical submissions.
Supplier License Reviews by License Status	Open Supplier License Reviews categorized by License Status. Identifies renewal and invalid documentation risk.
Supplier License Reviews by License Type	Distribution of license types assigned to the partner organization. Highlights regulatory scope and exposure.
Due Date Monitoring	
Overdue Supplier License Reviews	Supplier License Reviews past Due Date by currentState. Escalates partner compliance delays.
Due in Next 24 Hours	Supplier License Reviews due within the next 24 hours. Indicates urgent compliance actions.
Due in Next 7 Days	Supplier License Reviews due within the next 7 days. Supports short-term workload planning.
Due in Future	Supplier License Reviews due in future. Provides planning visibility for compliance activities.
Network Performance	
Supplier License Reviews Failed Prior by Partner	Supplier License Reviews grouped by partners where reviews failed. Identifies site-specific compliance exposure.
Supplier License Reviews by Jurisdiction	Supplier License Reviews categorized by Jurisdiction. Tracks regulatory obligations by region.
Organizational Performance	
Average Time to Close Partner-Owned Supplier License Reviews	Average closure duration for partner-owned supplier license reviews. Measures partner responsiveness.
Supplier License Reviews by Closure Outcome (My Organization)	Closed Supplier License Reviews categorized by Closure Status. Reflects documentation readiness and compliance maturity.

Search supplier license 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.

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6. Select Supplier License 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. Display Identifier field – Search by display identifier.
    b. Title field – Supports partial or full text search.
    c. State field – Filter by workflow state such as Draft, To Do, In Progress, or Done.
    d. Creation Time field – Search by SLC creation timestamp.
    e. Requesting Company field – Search by the initiating company.
    f. Supplier Company field – Search by the supplier company.
    g. Compliance Owner field – Search by the assigned compliance owner.
    h. Due Date field – Filter by the target due date.
    i. Request Reason field – Filter by request reason such as Onboarding, Renewal, Expansion, or Audit.
    j. Overall Compliance Assessment field – Filter by compliance assessment such as Compliant, Partially Compliant, or Non-Compliant.
    k. Last Modified field – Search by last updated timestamp.

9. Select Apply.

    All supplier license reviews matching the filter criteria are displayed.

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