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Audits and Inspections

Audits and Inspections enable pharmaceutical organizations to coordinate regulatory inspections and supplier audits across the supply chain network. The solution supports inspection planning, collaboration with external partners, documentation management, and tracking of findings and closure outcomes.

What are Audits and Inspections

Audits and Inspections are structured evaluations conducted internally or by regulatory authorities to assess compliance with quality standards, internal procedures, and applicable regulatory requirements. The audit and inspection process in the pharmaceutical industry typically involves the following steps:

1. **Initiate Inspection Record:** Create and log a new inspection record to formally track the regulatory or internal inspection and related activities.
2. **Prepare for Inspection:** Gather required documentation, align stakeholders, and ensure systems, processes, and records are ready for the upcoming inspection.
3. **Execute Inspection:** Support the inspection by providing requested information, facilitating discussions with inspectors, and documenting inspection activities.
4. **Receive Inspection Report:** Record and review the official inspection report detailing findings, observations, or compliance status.

5. **Respond to Observations:** Develop and submit responses, corrective actions, or remediation plans to address observations identified during the inspection.
6. **Close Inspection:** Complete all required follow-up actions and formally close the inspection once responses are accepted and obligations are fulfilled.

Types of Audits and Inspections

- **Regulatory Inspection:** Inspections conducted by health authorities such as FDA, EMA, or other regulatory bodies to verify regulatory compliance.

- **Internal Audit:** Audits performed internally to evaluate adherence to company procedures, quality systems, and regulatory requirements.

- **Supplier Audit:** Audits conducted to verify supplier compliance with contractual and regulatory obligations.

- **Pre-Approval Inspection:** Inspections conducted prior to product approval or facility authorization.

- **Follow-Up Inspection:** Inspections performed to verify that previous findings or CAPA actions have been successfully implemented.

How to configure the audits and inspections marketplace solution

Before using the audits and inspections solution, configure the solution in OPUS Solution Environment.

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 an audit or inspection

Add an audit or inspection

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 Audits and Inspections from the left menu.
7. Select New.
8. In the General section fill in the following fields:
   a. Title field – Provide a clear and descriptive title for the supplier risk assessment.
   b. Description field – Briefly describe the reason or scope of the assessment.
9. Select Save.

   The audit or inspection is created in Draft state.
10. Select Move to to progress the assessment.

Modify audits and inspections

Edit an audit or inspection

1. Select the Main Menu icon.
2. Select My Networks.
3. Select the required network.
4. Select Go.
5. Select Audits and Inspections.
6. Select the Display Identifier of the audit or inspection.
7. Select Edit.
8. In the General section update the following fields:
   a. Display Identifier – Unique identifier for the audit or inspection.
   b. Title – Name of the audit or inspection.

   c. Description – Description of the audit.
   d. Audit Type – Type of inspection or audit.
   e. Priority – Priority level.
   f. Due Date – Target completion date.
9. In the Participants section update the following fields:
   a. Initiator Company – Company initiating the audit.
   b. Assignee Company – Company responsible for responding.
   c. Assignee User – Assigned user responsible for action.
10. In the Observations section update the following fields:
    a. Observation Summary – Summary of the inspection findings.
    b. Observation Category – Category of finding.
    c. Observation Severity – Severity level.
11. In the Closure Summary section update the following fields:
    a. Closure Outcome – Final inspection result.
    b. Closure Notes – Summary of closure.
    c. Closed By – User closing the record.
    d. Closed Date – Date the audit was closed.
12. In the Comments and Attachments section add comments or files.
13. The Followers section displays users following the audit.
14. Select Save.

Monitor audits and inspections

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 Audits and Inspections from the left menu.
7. Select Dashboards.

   View the widgets in the dashboard which display pre-defined queries representing the state of all audits and inspections.

Dashboard	Description
Current Trends	
Audits and Inspections by Status – Open	Total number of audit records categorized by workflow state.
Audits and Inspections by Priority	Audits grouped by business priority.
Due Date Monitoring	
Overdue Audits and Inspections	Audits where due date has passed.
Organizational Performance	
Average Time to Close	Average duration between creation and closure.

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 Audits and Inspections from the left menu.
7. Select Dashboards.

   View the widgets in the dashboard which display pre-defined queries representing the state of audits and inspections.

Dashboard	Description
Current Trends	
Audits and Inspections by Status – Open	Open audits grouped by workflow state.
Audits and Inspections by Priority	Distribution of audits by priority.
Due Date Monitoring	
Overdue Audits	Audits where response deadlines have passed.

Search audits and inspections

1. Select the Main Menu icon.

2. Select My Networks.
3. Select the required network.
4. Select Audits and Inspections.
5. Select Filter.
6. In the Filters panel enter one or more of the following fields:
    a. Display Identifier – Search by audit ID.
    b. Title – Search by audit title.
    c. State – Draft, To Do, In Progress, Done.
    d. Creation Time – Date the audit was created.
    e. Initiator Company – Company initiating the audit.
    f. Assignee Company – Company responsible for responding.
    g. Due Date – Target due date.
    h. Priority – Priority level.
    i. Last Modified – Date the record was last updated.
7. Select Apply.