Implementation of Electronic Records and Electronic Signatures(ERES)

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Companies whose manufactured products and processes, such those in life sciences (medical devices, pharmaceutical, biotechnology, biopharmaceutical) food and beverage and some chemical companies, are increasingly regulated by government agencies. These manufacturing companies must keep detailed records of their design, inventory and product manufacturing processes. Current practice in these many of these regulated industries is to maintain paper records of all information pertaining to the manufacture of their products.

More companies want to maintain and store these records in electronic format to reduce this paperwork burden. This is of particular importance for regulated industries in light of the Food and Drug Administration's (FDA) regulation on electronic records and signatures called 21 CFR Part 11.

Oracle Electronic Records and Signatures is a configurable framework for securely capturing, storing, retrieving and printing electronic records and signatures. Critical supply chain management business events are now enabled in the areas of inventory, manufacturing, quality and shipping.

Inline processing is supported when a signature needs to be captured immediately, so you do not delay further processing. If multiple signatures are required, the screen captures the first signature, then a notification is sent to subsequent approvers to capture the remaining signatures. If the signers are not available immediately, the Back button is available to return to the transaction in progress. The new or updated transaction data is not committed to the database and is held in a pending status until all approvals are complete.
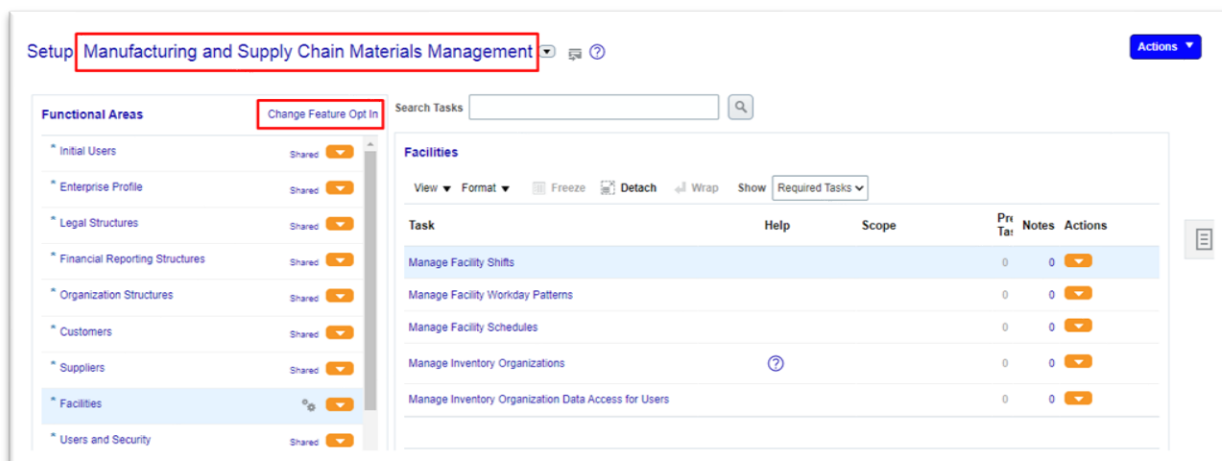
The e-signatures and e-records approval processes can be of the following types:

Inline approval process: In this process, approvals must be obtained before a transaction is saved. You can't save a transaction if the record is rejected.

Deferred approval process: In this process, transactions are saved in Pending Approval status before initiating the e-signature process. The transaction is updated to Approved status after the approvals are obtained

Implementation: -

Select 'Manufacturing and Supply Chain Materials Management' in Setup and Click 'Change Feature Opt In' hyperlink

Opt-In page opens up. Select 'Facilities' row and click 'Features' Edit icon

Ensure Feature Name: <Capture Electronic Records and Electronic Signatures for SCM Transactions> is Enabled.
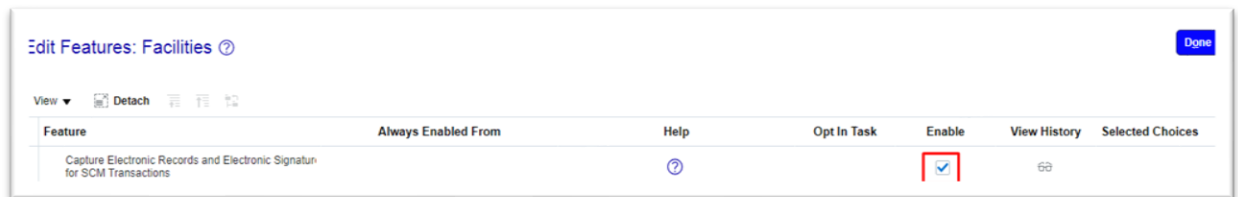
Enable MFG transactions in respective Org using ERES/EDR FSM setup

Select 'Manufacturing and Supply Chain Materials Management' in Setup and select 'Facilities' Functional Area. Choose 'All Tasks' from Facilities and click 'Configure Electronic Signature Preferences' task
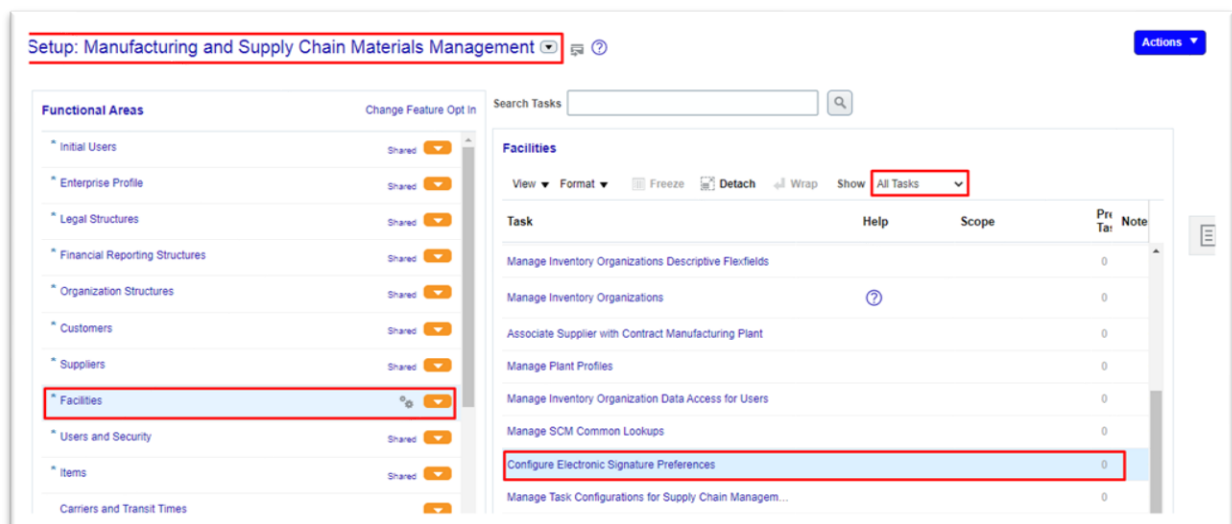
It launches configure E-signature preferences page.

Click on + icon and search for the organization for which you want to enable ERES.

Select the desired organization on left hand side and enable the 'Signature Enabled' check box for below highlighted Manufacturing Transactions.

Perform BPM Workflow setup in 101 Org for the MFG transactions

BPM Setup allows for approval of transactions by leveraging different participant types. Following sections explain the different participant types available for us.

BPM Framework allows the below 4 different participant types

1. Parallel approval
2. Single
3. Serial
4. FYI

Participant Types:

1. Parallel approval – Operation transactions Parallel Approvers
   Participant Type Parallel signifies that all the approvers can act on their tasks in parallel and the approval outcome is based on the Voting policy and the policy currently used is 100% for Approval and 1% for Reject.
   This above entails that the outcomes will be approved only when all the approvers approve the transaction. Even if one approver rejects, the transaction outcome will be set to reject.

2. <u>Single – Operation Transaction Approvers.</u>

   In single Approval we can assign a single resource (or more) for the approval and all approvers are expected to approve for the transaction outcome to be approved.

3. <u>Serial Approval – Operation Transaction Serial Approvers.</u>

   Participant Type Serial signifies that the approval hierarchy operates in a sequence and the approval notification goes to the next level only on successful outcome for the current state. E.g.; 2nd approver gets the notification to take an action only after the 1st approver approves and after the 2nd approver approves it goes to the 3rd approver and so on.

   In case of a rejection by any approver the transaction outcome is rejected and the notification gets withdrawn (does not go to the next approver).

4. <u>FYI – Operation Transaction Submitter.</u>

   Participant Type FYI signifies that the recipient need not take any action as this is for information purposes only. No Action is expected from the recipient in this case and neither does this have any impact on the final outcome of the transaction.

   Select 'Manufacturing and Supply Chain Materials Management' in Setup and select 'Facilities' Functional Area. Choose 'All Tasks' from Facilities and click 'Manage task configuration for Supply Chain Management' task.
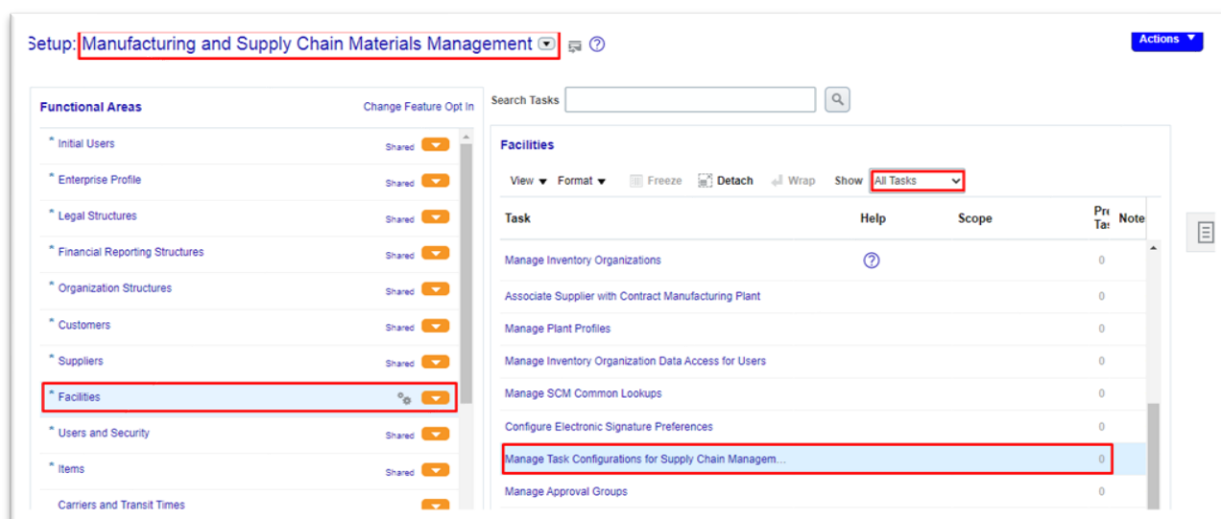
1. Search for respective Manufacturing BPM Transaction from Search under 'Tasks to be configured' left pane.
2. BPM Task: WorkDefinitionApproval
3. Click on Edit button - Go for Assignees tab - we have 4 different Assignees (Participant Types) in Assignees tab.
4. Put the cursor on blue dotted line then go to rule button highlighted and click on it.
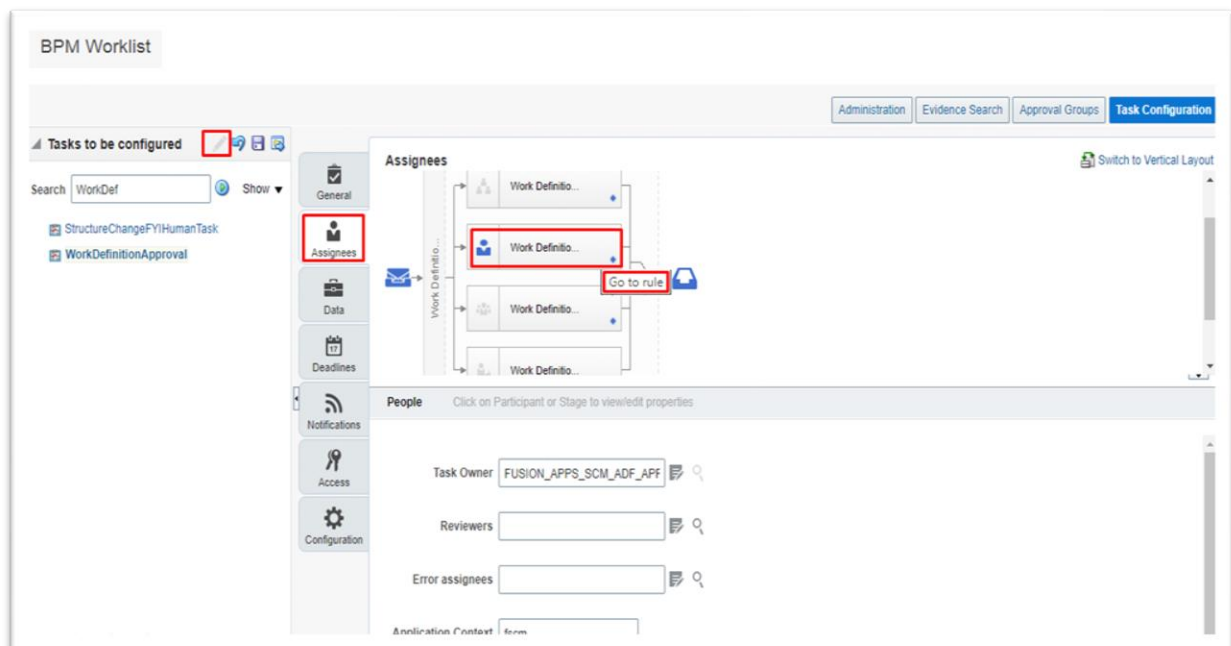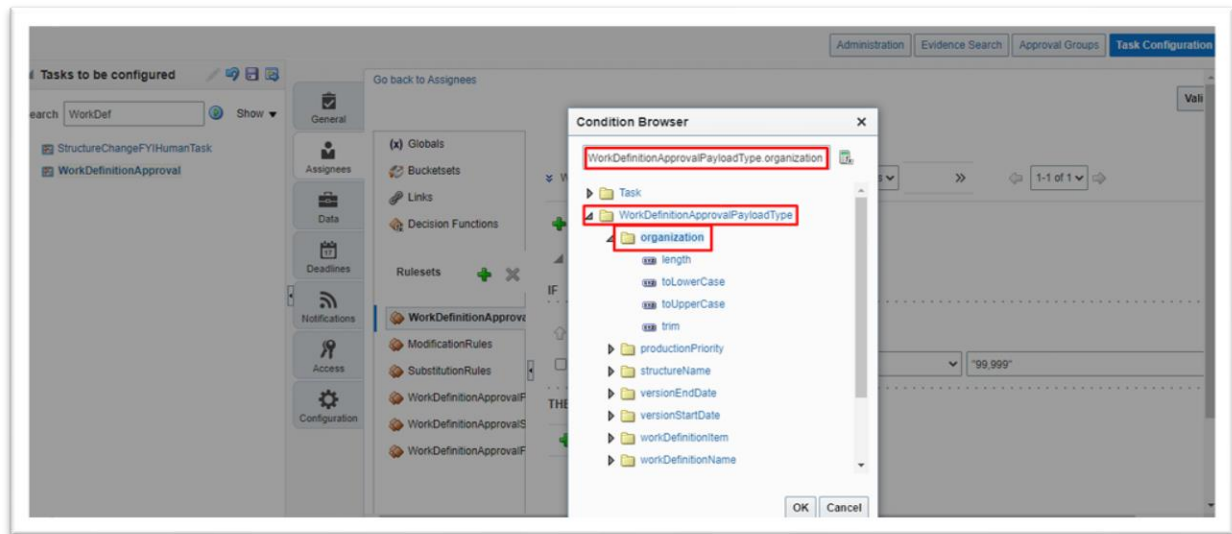

Rule set page opens (example shown for one BPM Task below).
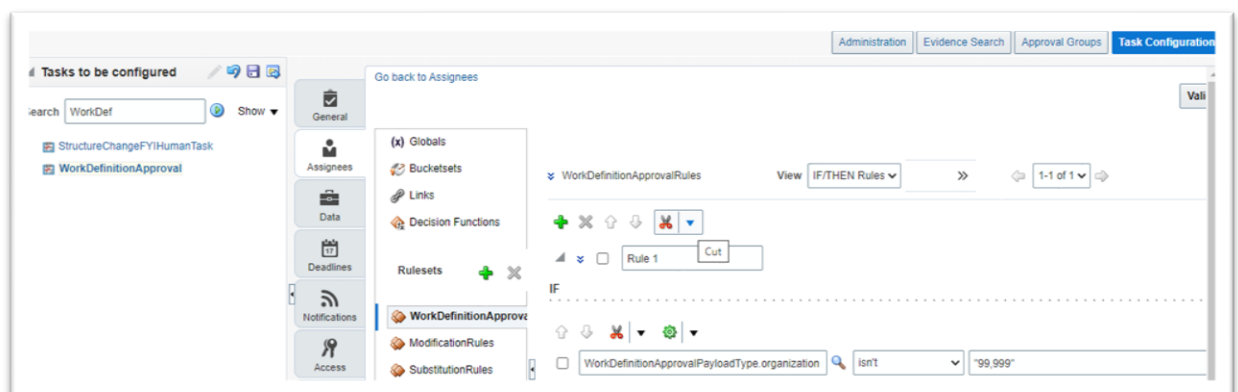
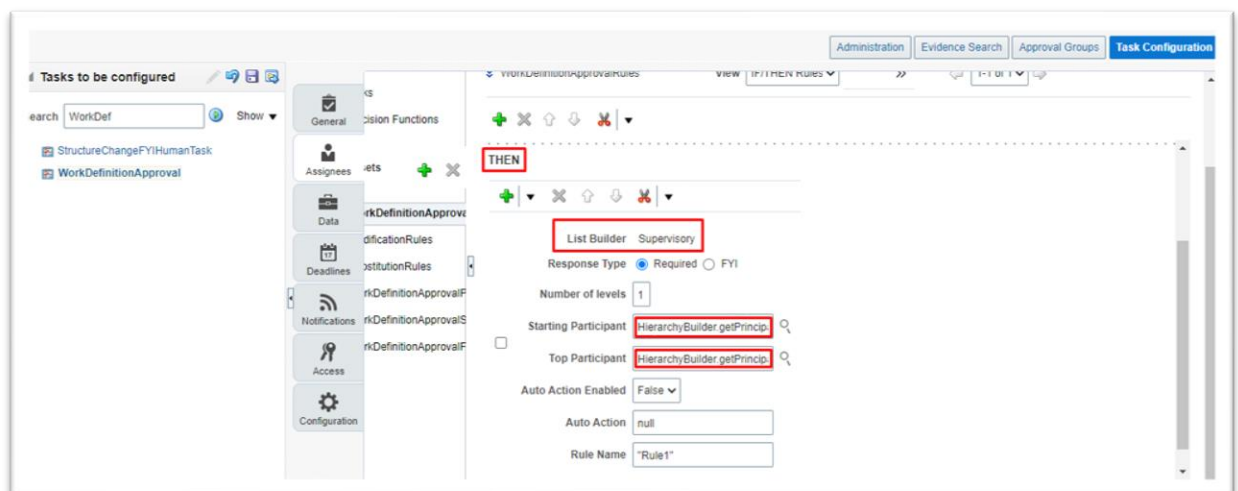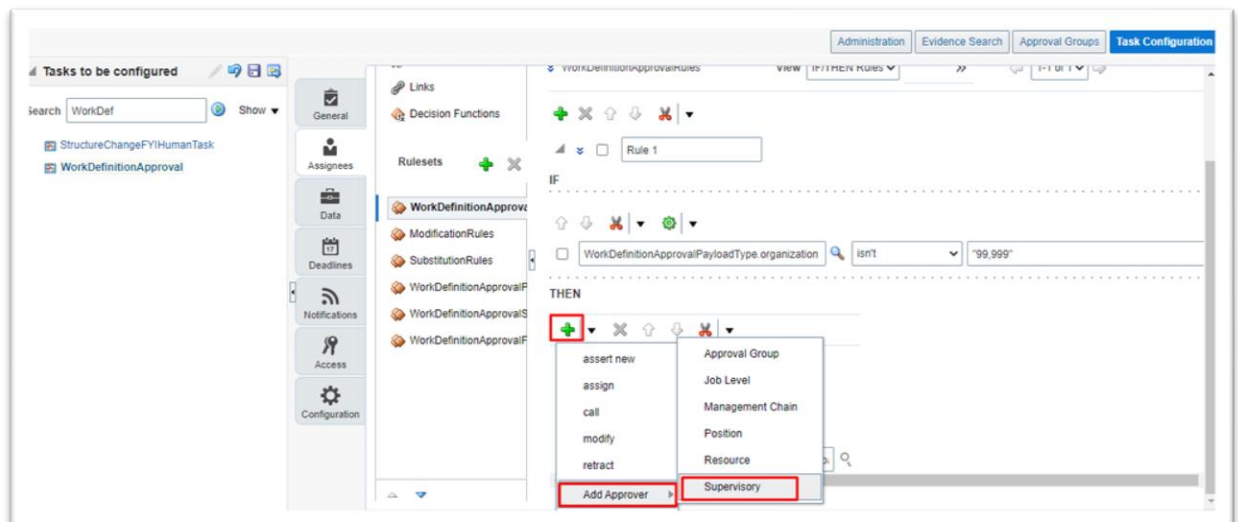Click on '+ 'for Adding Rule
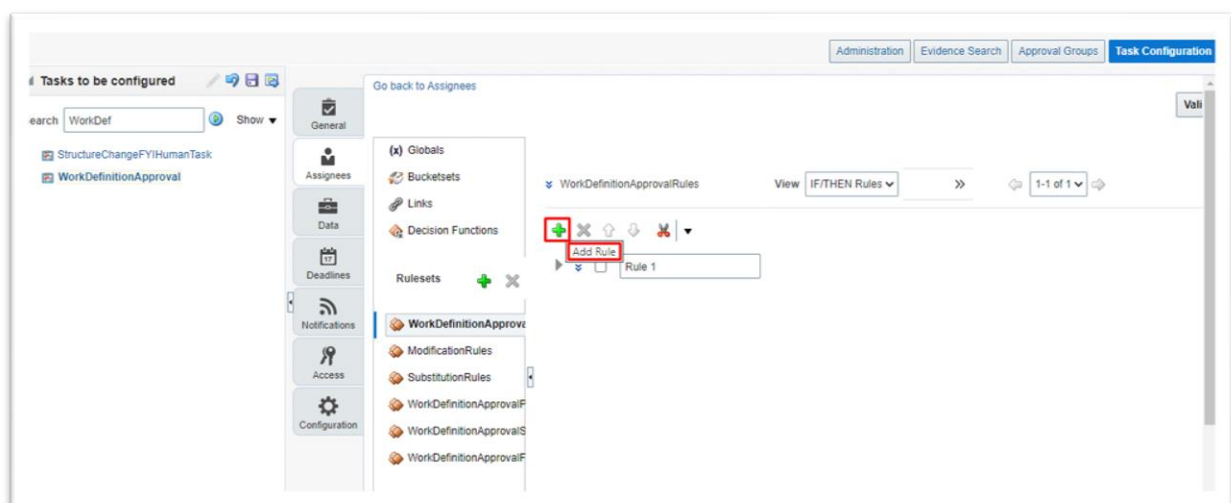
1. Expand the Rule1- IF AND THEN CONDITIONS OPEN

2. Click on If Condition Search Icon Condition Browser opens

3. Select the Work Definition Approval payload -Organization Code and click on OK

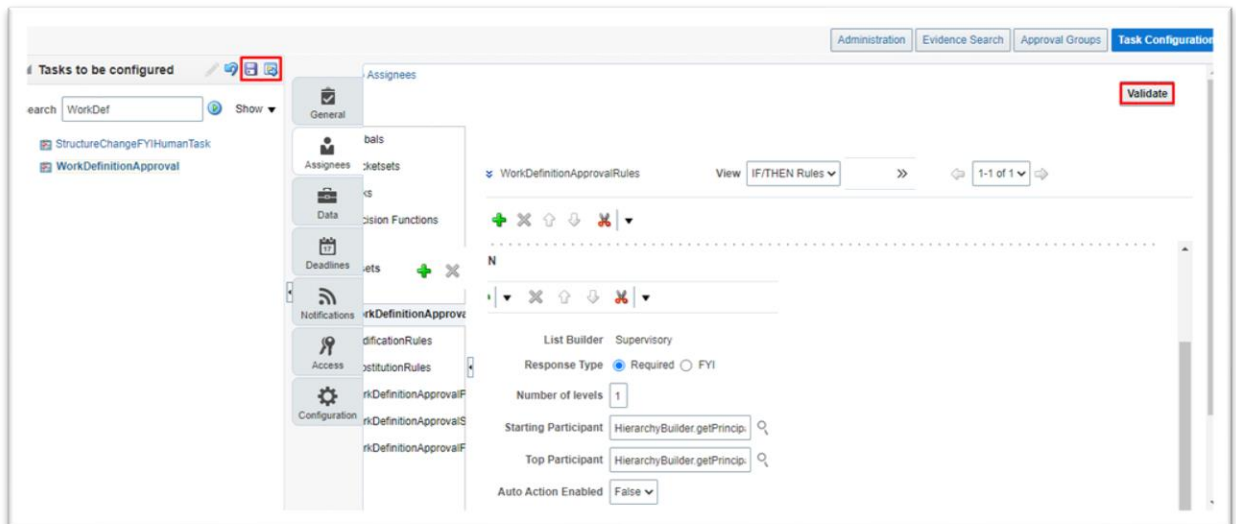Give the Org Name like "99,999"

Click on + icon Then Condition → Add Approver→Supervisory
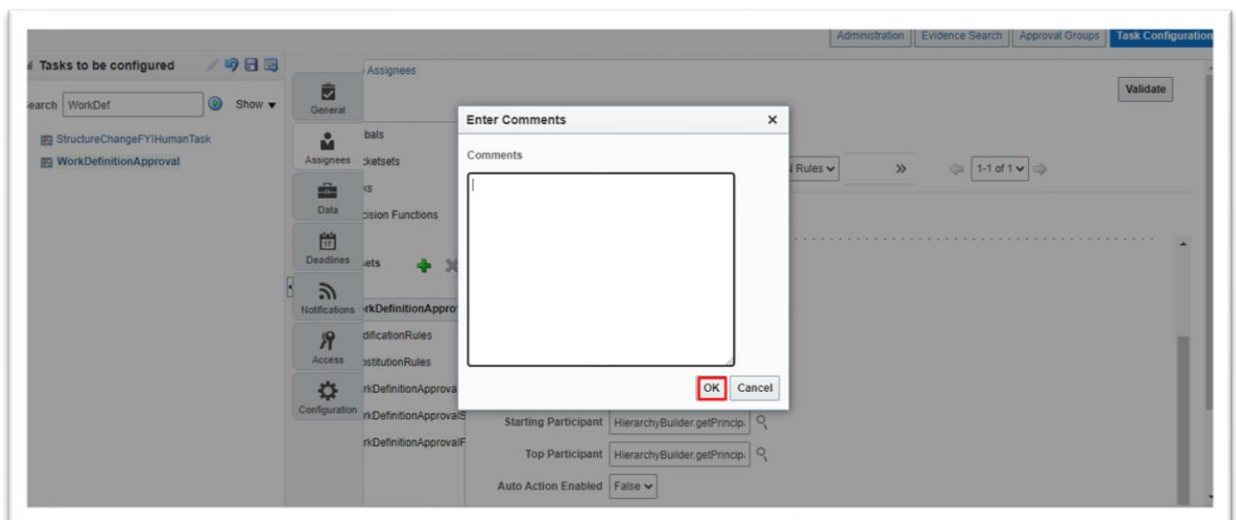
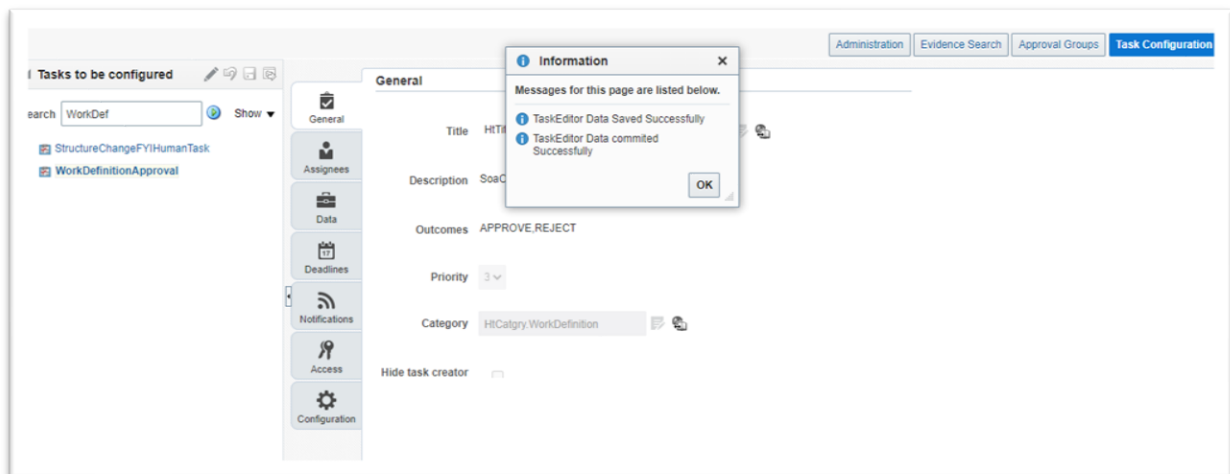Click on Validate, Save and Commit task

Note: Here, the rule is set for the single level of self-approval.

Click on OK

Ensure that you see the below successful message.

Create, approve the work definition and verify whether the rule is successfully activated or not.

Once you click on Submit for Approval, it checks if the organization is enabled for ERES or not.

When the E-Signatures page is launched ERES will evaluate the BPM rules that we have configured above and fetch the appropriate approvers for the transaction. These approvers will get a notification with the E-Record PDF document that can be reviewed and acted upon by the approver.

E-Records Search:

Electronic Record column in the results table will be displaying the e-record as an attachment, which will be downloaded as a PDF file by clicking on the link.

About Author:

Arun Polkampalli is working with Trinamix Inc, as Functional Consultant with rich experience in SCM Functional Modules. and area of expertise are Manufacturing and Inventory.