

Implementation of Electronic Records and Electronic Signatures(ERES)



Blog By – Arun Polkampalli

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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.

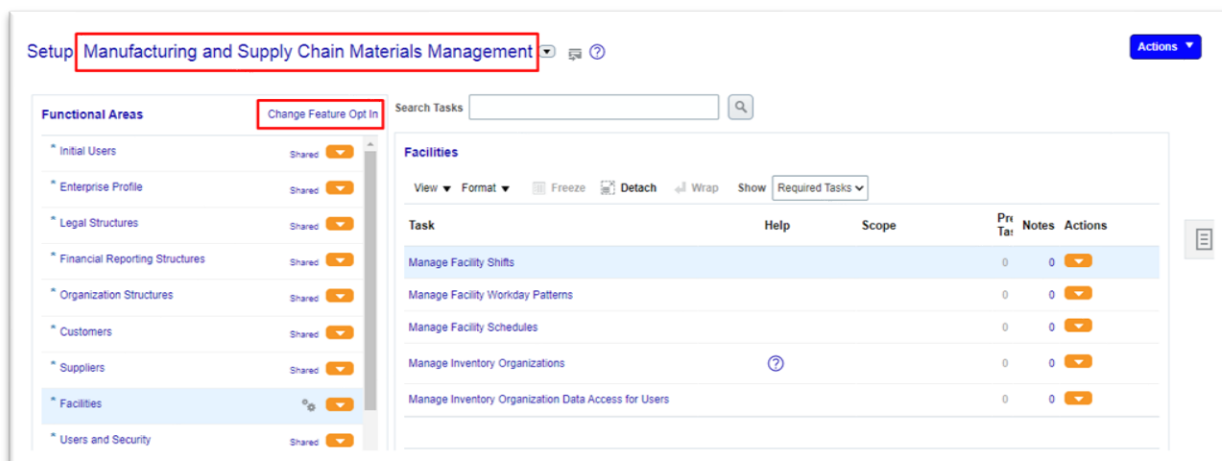
The e-signatures and e-records approval processes can be of the following types:

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



Setup **Manufacturing and Supply Chain Materials Management** Actions

Functional Areas Change Feature Opt In Search Tasks

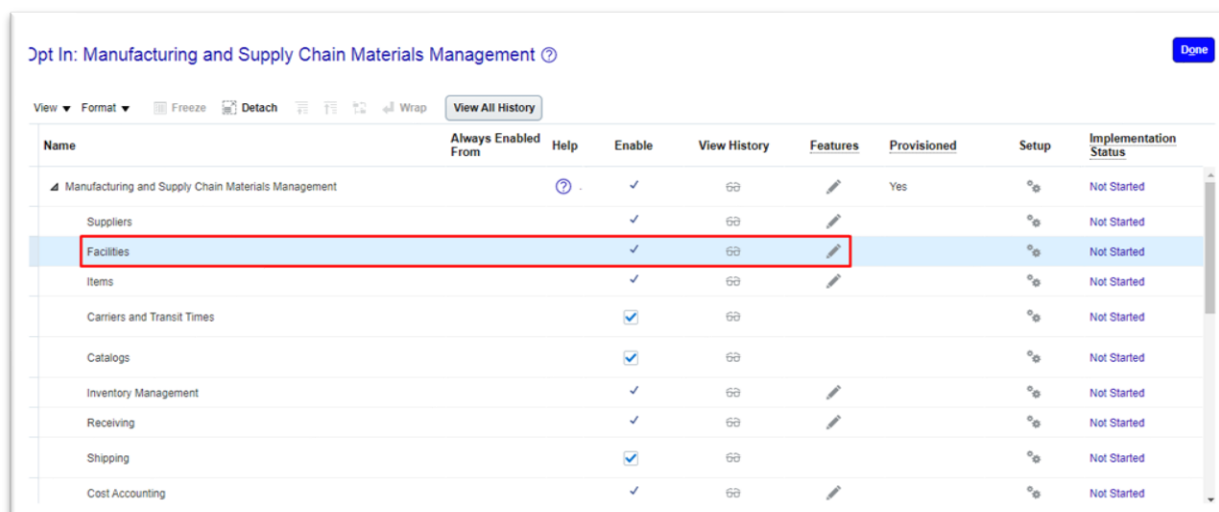
- * Initial Users Shared
- * Enterprise Profile Shared
- * Legal Structures Shared
- * Financial Reporting Structures Shared
- * Organization Structures Shared
- * Customers Shared
- * Suppliers Shared
- * **Facilities** Change Feature Opt In
- * Users and Security Shared

Facilities

View Format Freeze Detach Wrap Show Required Tasks

Task	Help	Scope	Pri Tar	Notes	Actions
Manage Facility Shifts			0 0		
Manage Facility Workday Patterns			0 0		
Manage Facility Schedules			0 0		
Manage Inventory Organizations	?		0 0		
Manage Inventory Organization Data Access for Users			0 0		

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

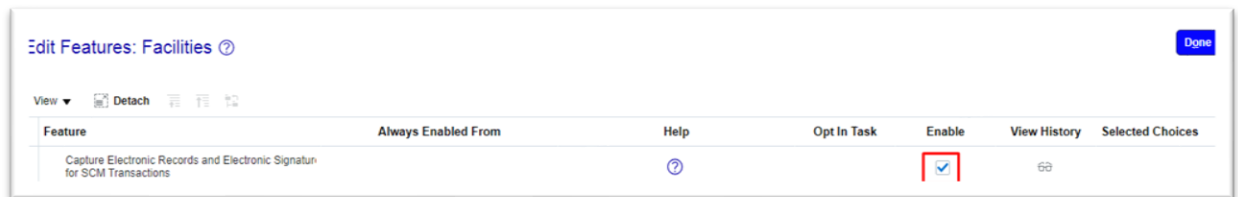


Opt In: Manufacturing and Supply Chain Materials Management Done

View Format Freeze Detach Wrap View All History

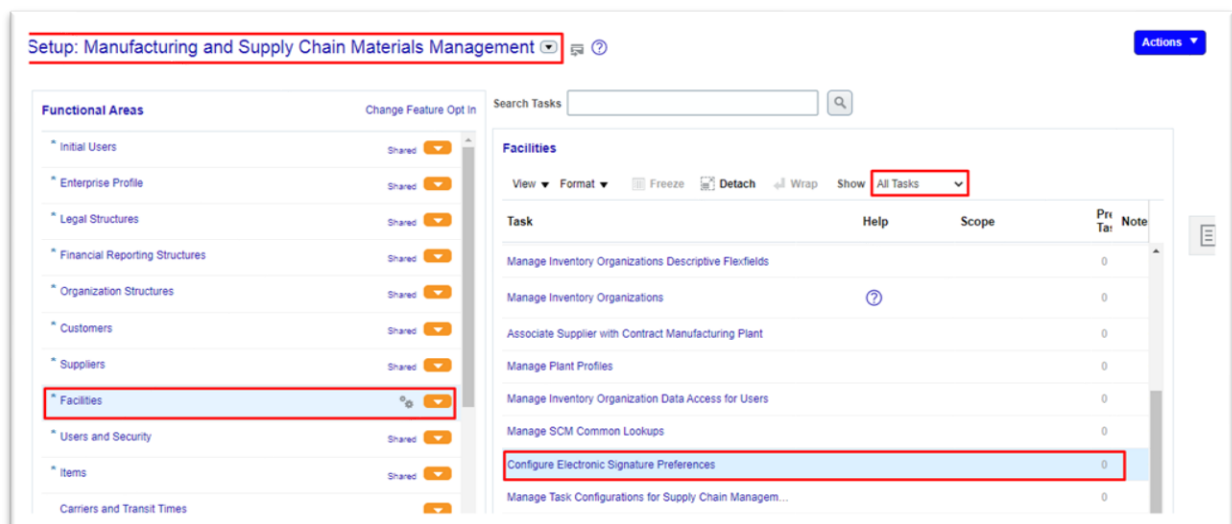
Name	Always Enabled From	Help	Enable	View History	Features	Provisioned	Setup	Implementation Status
Manufacturing and Supply Chain Materials Management		?	✓			Yes		Not Started
Suppliers			✓					Not Started
Facilities			✓					Not Started
Items			✓					Not Started
Carriers and Transit Times			✓					Not Started
Catalogs			✓					Not Started
Inventory Management			✓					Not Started
Receiving			✓					Not Started
Shipping			✓					Not Started
Cost Accounting			✓					Not Started

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.

Configure E-Signature Preferences

View ▼

Organization	Transaction	Signature Type	Signature Enabled
101 ×	Inventory Lot Update	In-line	<input type="checkbox"/>
	Inventory Serial Update	In-line	<input type="checkbox"/>
	Maintenance Exception Closure	Deferred	<input type="checkbox"/>
	Manufacturing Standard Operation Management	In-line	<input type="checkbox"/>
	Manufacturing Work Definition Management	Deferred	<input checked="" type="checkbox"/>
	Miscellaneous Transaction	In-line	<input type="checkbox"/>
	Orderless Transaction	In-line	<input type="checkbox"/>
	Production Exception Closure	Deferred	<input type="checkbox"/>
	Put Away	In-line	<input type="checkbox"/>
	Quality Inspection Disposition	In-line	<input type="checkbox"/>
	Receipt	In-line	<input type="checkbox"/>
	Receiving Transaction Correction	In-line	<input type="checkbox"/>

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. Single – Operation Transaction Approvers.

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. Serial Approval – Operation Transaction Serial Approvers.

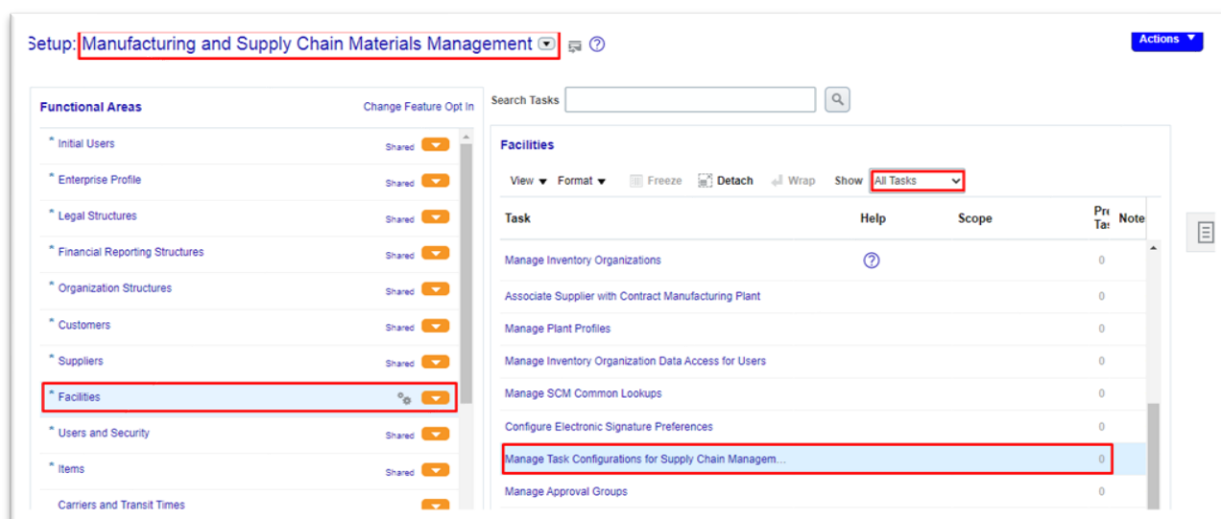
Participant Type Serial signifies that the approval hierarchy operates in a sequence and the approval notification goes to the next level only on successful outcome for the current state. E.g.; 2nd approver gets the notification to take an action only after the 1st approver approves and after the 2nd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

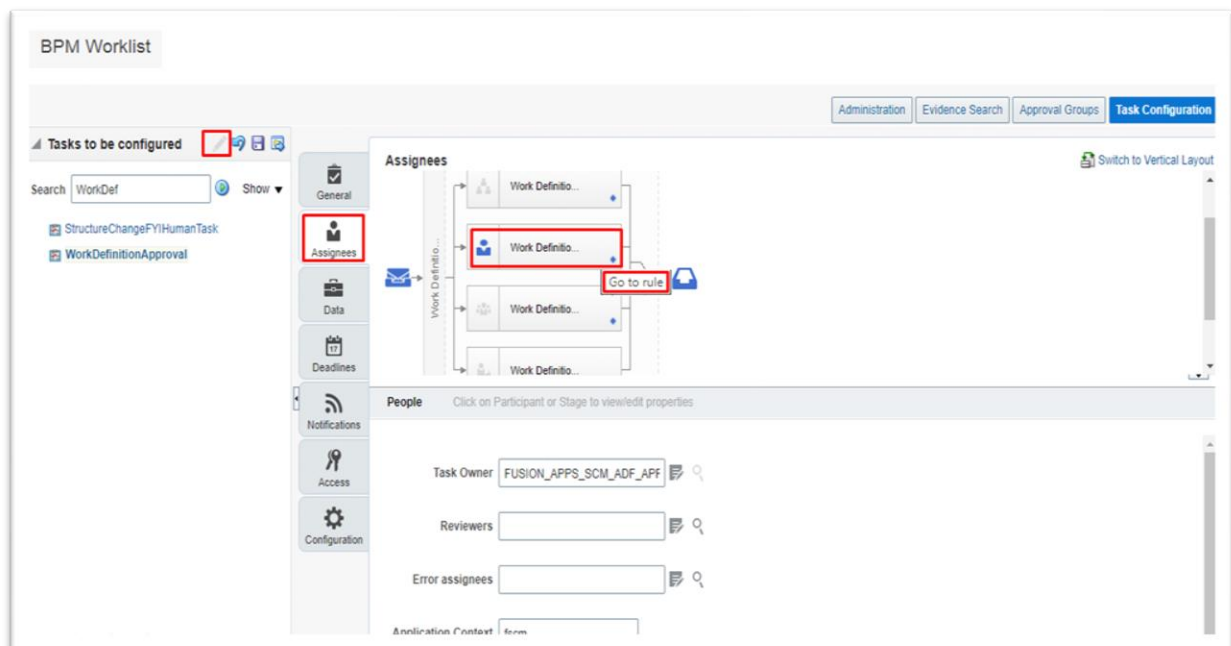
4. FYI – Operation Transaction Submitter.

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.

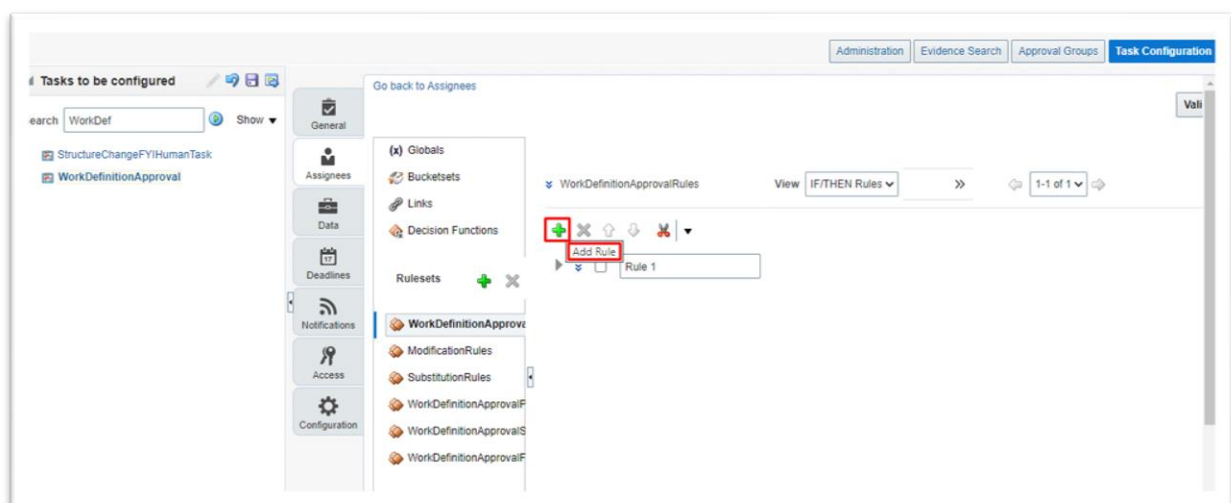


1. Search for respective Manufacturing BPM Transaction from Search under 'Tasks to be configured' left pane.
2. BPM Task: WorkDefinitionApproval
3. Click on Edit button - Go for Assignees tab - we have 4 different Assignees (Participant Types) in Assignees tab.
4. Put the cursor on blue dotted line then go to rule button highlighted and click on it.



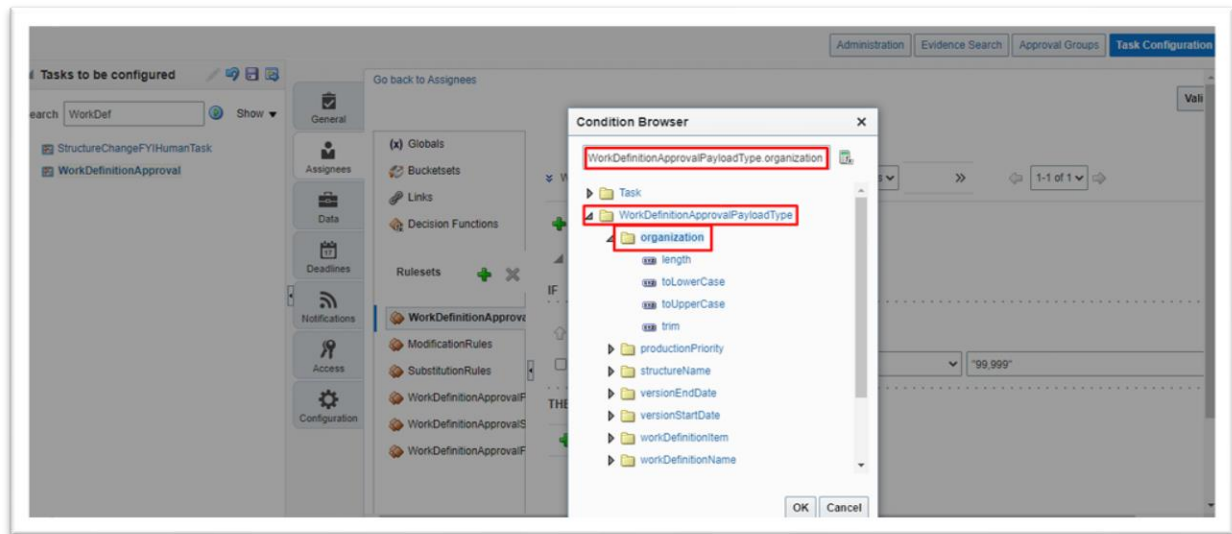
Rule set page opens (example shown for one BPM Task below).

Click on '+' for Adding Rule

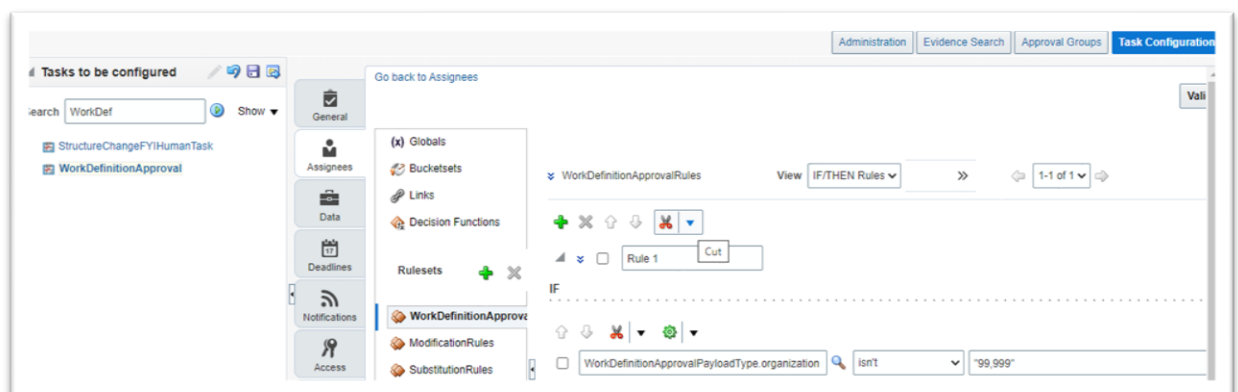


1. Expand the Rule1- IF AND THEN CONDITIONS OPEN

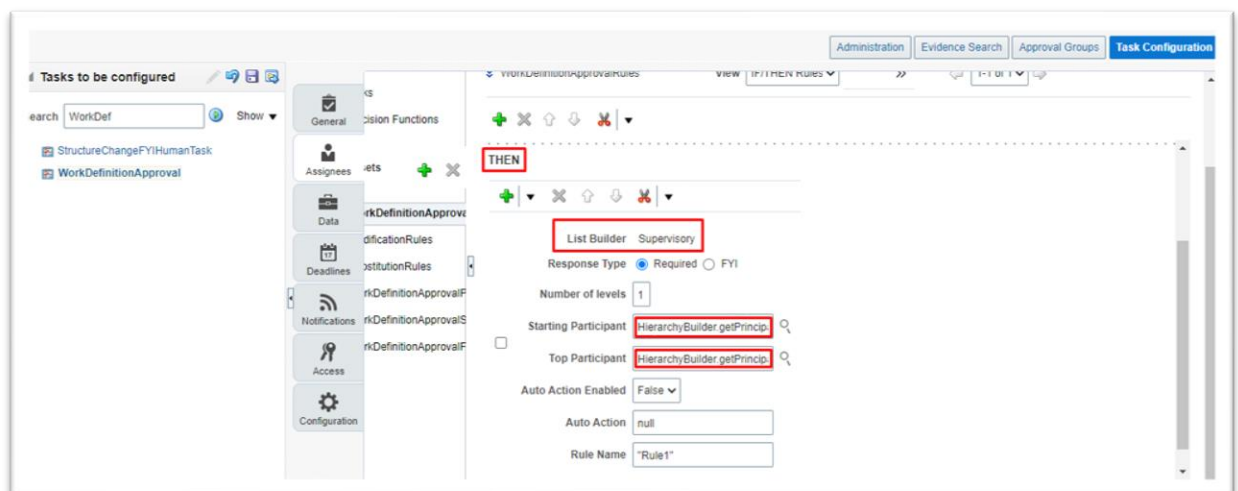
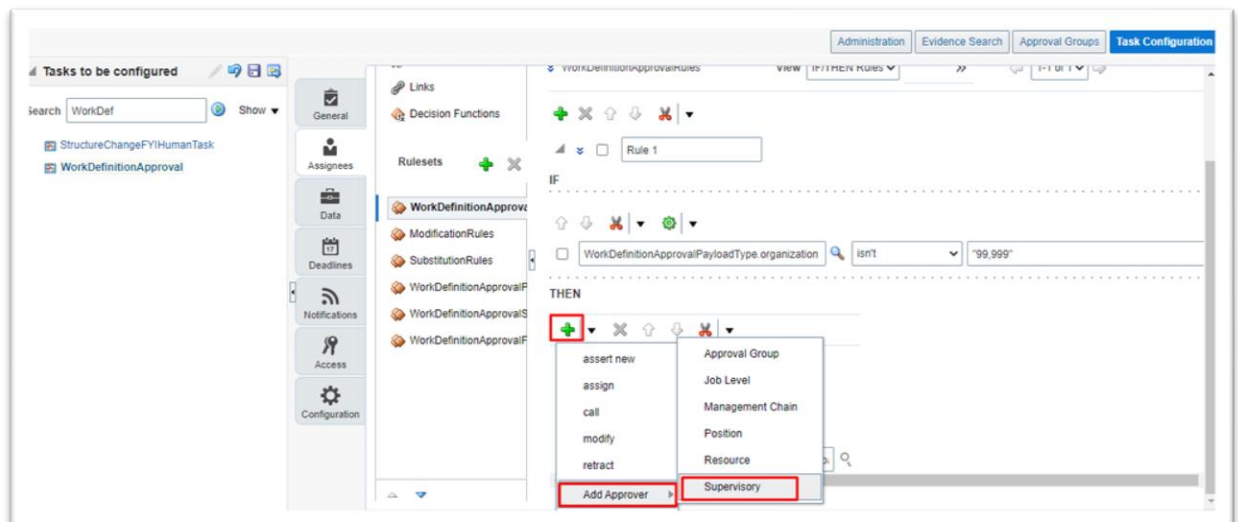
2. Click on If Condition Search Icon Condition Browser opens
3. Select the Work Definition Approval payload -Organization Code and click on OK



Give the Org Name like "99,999"

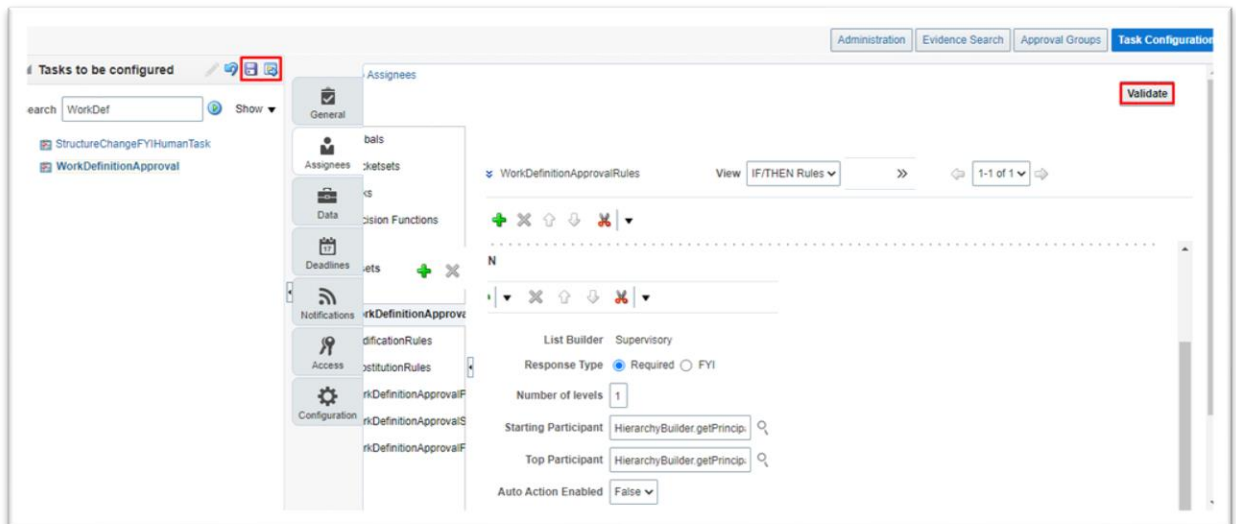


Click on + icon Then Condition → Add Approver→Supervisory

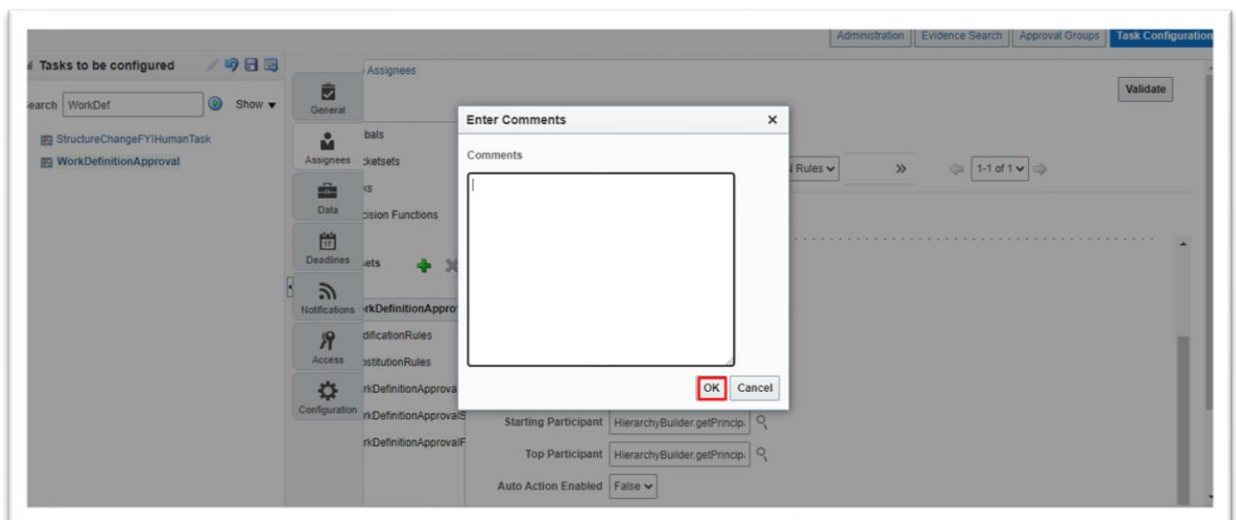


Click on Validate, Save and Commit task

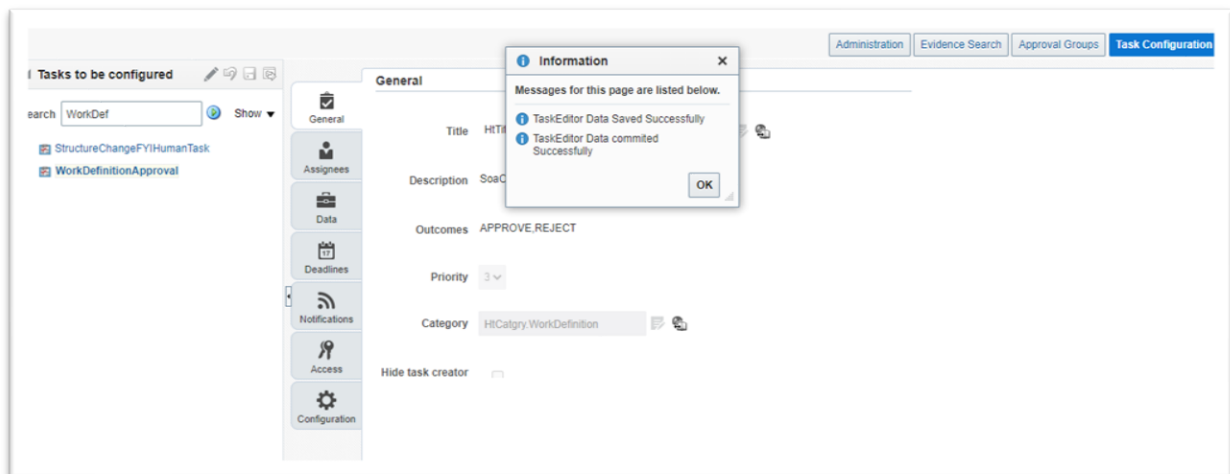
Note: Here, the rule is set for the single level of self-approval.



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 Records

Electronic Records

Task Number	Transaction Title	Transaction	Last Signed Date	Status	Signature History	Electronic Record
499965	The Work Definition Name A84, Version 2 for Item TX200-7 in O...	Manufacturing Work Definition Management	11/19/2021	Approved		IS_101_3000000021
499974	The Work Definition Name A84, Version 1 for Item TX200-7 in O...	Manufacturing Work Definition Management	11/19/2021	Approved		IS_101_3000000021
499848	The Work Definition Name A83, Version 1 for Item TX200-7 in O...	Manufacturing Work Definition Management	11/19/2021	Approved		IS_101_3000000020
499843	The Work Definition Name A82, Version 1 for Item TX200-7 in O...	Manufacturing Work Definition Management	11/18/2021	Approved		IS_101_3000000020
499825	The Work Definition Name Main, Version 3 for Item TX200-7 in ...	Manufacturing Work Definition Management	11/17/2021	Approved		IS_101_3000000020
499823	The Work Definition Name Main, Version 2 for Item TX200-7 in ...	Manufacturing Work Definition Management	11/17/2021	Approved		IS_101_3000000020
499803	The Work Definition Name Main, Version 1 for Item TX200-7 in ...	Manufacturing Work Definition Management	11/15/2021	Approved		IS_104_3000000020
499663	The Work Definition Name A82, Version 1 for Item TX200-1 in O...	Manufacturing Work Definition Management	11/3/2021	Approved		IS_101_3000000020
499627	The Work Definition Name A83, Version 1 for Item TX200-1 in O...	Manufacturing Work Definition Management	10/29/2021	Approved		IS_102_3000000020

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.

